Comments of General Electric Company on the Ecological Risk Assessment for the General Electric/ Housatonic River Site, Rest of River (November 2004 Draft)

Prepared by:

BBL Sciences, Inc.
Petaluma, California

ARCADIS G&M, Inc.
Portland, Maine

Branton Environmental Consulting
Vancouver, British Columbia

LWB Environmental
Oak Ridge, Tennessee

On Behalf of:

General Electric Company
Pittsfield, Massachusetts

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1. *Introduction and Summary*

The General Electric Company (GE) is providing these Comments to the U.S. Environmental Protection Agency (EPA) on the November 2004 draft of EPA's *Ecological Risk Assessment for General Electric (GE)/Housatonic River Site, Rest of River* (ERA) (EPA 2004a). These Comments were prepared on GE's behalf by BBL Sciences, ARCADIS G&M, Inc., Branton Environmental Consulting, and LWB Environmental Services. They focus only on new information and analyses presented in the November 2004 draft that were not presented in, or have been changed from, the July 2003 draft of the ERA (EPA 2003). Moreover, these Comments address only some of the assessment endpoints and are limited to discussing only the most critical new information and analyses that affect the basic conclusions of the ERA regarding those assessment endpoints. However, GE adheres to and preserves its positions on all points set forth in GE's prior comments (BBL et al. 2003; GE 2004) on the July 2003 draft ERA, and reserves the right to raise those points in any future proceeding. In addition, lack of comment herein on other new material or interpretations in the ERA does not necessarily indicate GE's agreement with such material and interpretations; GE reserves the right to present any arguments relating to such material and interpretations in an appropriate future proceeding.

Many of the changes that EPA has made to the ERA were intended to address comments made by the peer reviewers on the prior draft ERA, as summarized in EPA's *Responsiveness Summary to the Peer Review of the Ecological Risk Assessment for General Electric (GE)/Housatonic River Site, Rest of River* (Responsiveness Summary) (EPA 2004b). In a number of respects, however, the changes made are not responsive to and/or do not appropriately reflect the peer reviewers' comments. In addition, a number of the new analyses presented in the revised ERA do not properly characterize or interpret the data. These Comments identify and describe several key instances of both of these types of flaws, and include recommendations for further changes in the final ERA.

In summary, the main points set forth in these Comments are as follows, with GE's recommendations for further revisions to the ERA highlighted in italics:

- Benthic invertebrates: The methods used to calculate the PCB effects thresholds for benthic invertebrates are not responsive to comments of the peer review panel that all non-redundant endpoints be used in the development of effects thresholds. The methods are also contrary to EPA's statement in the Responsiveness Summary that the full range of endpoints would be used in the development of the MATC. Instead, the chronic toxicity effects threshold is based on the most sensitive endpoint for the most sensitive species. *EPA should use all non-redundant endpoints in the calculation of effects thresholds, rather than only the most sensitive.* In addition, for the benthic community data, four of the five effects levels used in the calculation of the threshold are from coarse-grained stations, which showed greater effects relative to reference stations than did fine-grained locations; and only the most sensitive of three diversity indices is used to calculate the effects threshold. *Separate benthic community effects thresholds should be developed for coarse- and fine-grained sediments to account for the confounding effect of habitat, and all three diversity indices should be used. Similarly, separate maximum acceptable threshold concentrations (MATCs) should be developed for coarse- and fine-grained sediments;* otherwise, the assessment of risk in fine-grained sediments will be driven by effects observed only in coarse-grained sediments.

- Wood frogs: The sediment PCB MATC for amphibians is based on only one endpoint in EPA's wood frog study – the 20% effect level for metamorph malformations in Phase III of the study – with further, anecdotal support provided by another endpoint – the Phase III sex ratio data. If the malformation and sex ratio data are to be relied upon, then all the relevant results for those endpoints should be used in developing the MATC, as recommended by the peer review panel. *In that event, a revised MATC should be calculated based on the geometric mean of all three relevant endpoints that showed effects – the 20% effects levels for Phase I and Phase III malformations and the 50% effects level for sex ratio (given EPA's own conclusion* *that the 20% effects level for sex ratio is likely not biologically relevant).* In addition, while the revised wood frog population model addresses some of the GE and peer reviewer comments on the July 2003 draft, it still fails to account for density-dependence within the base model or to provide a realistic description of wood frog population dynamics, both with or without the influence of PCBs. *GE recommends that compensatory density-dependence be included in the base scenarios rather than only in the sensitivity analysis.*

- Wood ducks: EPA's new modeling analysis for wood ducks, which predicts high risks, is not borne out by either field collections or dose-based hazard quotients. That modeling uses both effects metrics and exposure assumptions that overestimate risks. *GE recommends that: (1) for the lower end of the effects metric range for total PCBs, EPA should use a study of reproductive effects of PCBs on mallards (which is more closely related species to wood ducks than the chickens now used); (2) due to the many uncertainties associated with modeling maternal transfer of TEQs and estimating egg-based effects metrics for TEQs, TEQ risks should be evaluated based on dose, rather than egg concentration; (3) if an egg-based TEQ approach is retained, EPA should revise its method of estimating maternal transfer from hen to egg and should include metabolism of PCBs in the model; and (4) the model should be revised to account for the substantially different proportions of invertebrates in the hen's diet between the pre-laying and laying periods.*

- Tree swallows: The most substantial change made to the discussion of the tree swallow field study is the change from "no" to "yes" for the evidence of harm assigned to the study. However, the text that precedes the risk characterization for tree swallows continues to show that the study does not in fact provide evidence of harm. *EPA should reverse the change in the evidence-of-harm designation in order to ensure that the risk findings are fully supported by the underlying study.*

- Mink: The revised ERA uses a new probit analysis (not suggested by the peer reviewers) to develop a new PCB MATC for mink from the kit survival data in the mink feeding study. This new MATC does not appropriately reflect the spread in the data and is inconsistent with the site-specific NOAEL and LOAEL values reported by the investigators. Moreover, EPA's claim that the revised MATC is supported by studies from other sites is incorrect. *Accordingly, EPA should not base the MATC for mink on the new probit analysis results.*

- <u>Shrews</u>: The primary change in the discussion of effects on shrews is the development of a PCB MATC, based on a new hockey stick regression analysis of the site-specific short-tailed shrew demography study. In addition, the language describing the results of EPA's supplemental analysis of the short-tailed shrew data has been changed to de-emphasize the weakness of the statistical results, and the evidence-of-harm conclusion has been changed from "undetermined" to "yes," despite the lack of any new data. These changes fail to reflect: (a) the substantial uncertainty in the new MATC, as demonstrated by the fact that the regression can only be fit to the data based on one of the two exposure scenarios (arithmetic mean soil PCB concentrations, but not spatially weighted average PCB concentrations); and (b) the uncertainty and weakness of the results of EPA's statistical analysis, as noted by several peer reviewers and acknowledged by EPA in the Responsiveness Summary. *Given these uncertainties, the final ERA should: (1) explicitly recognize the uncertainty associated with basing the MATC on an analysis that can be fit to the data only under one of two exposure scenarios; (2) re-insert a discussion of the uncertainty and weakness in the exposure-response relationship found in EPA's statistical analysis; and (3) change the conclusion in the weight of evidence back to "undetermined."*

2. *Community Structure, Survival, Growth, and Reproduction of Benthic Invertebrates*

A number of changes were made in the benthic invertebrate assessment in the November 2004 ERA based on input from the peer review panel. The key changes made in this assessment were the separation of chronic and acute toxicity thresholds, the development of separate thresholds for coarse- and fine-grained sediment in the benthic community analysis, and the use of the threshold from the benthic community analysis in development of the sediment MATC. Despite the substantial changes in methodology, however, the MATC of 3 mg/kg for total PCBs (tPCBs) remains unchanged from the July 2003 ERA (see EPA 2004a, Vol. 1, p. 3-59; Vol. 4, p. D-118).

The majority of the changes made in the benthic invertebrate assessment are responsive to the peer review panel's comments, and their application is straightforward. However, the current analysis does not incorporate the peer reviewers' recommendation that all species, rather than the just the most sensitive, and all available data be used in the development of toxicity thresholds (e.g., EPA 2004b, pp. 116 & 154, 131, and 142, reflecting comments of peer reviewers Thompson, Forbes, and Sample, respectively, and not disputed by any other reviewers). Instead, the ERA bases the chronic effects threshold from the toxicity tests solely on the most sensitive species and endpoint (*Chironomus tentans* ash free dry weight), rather than all non-redundant endpoints. Similarly, in developing the effects thresholds for the benthic community assessment, the ERA does not use all relevant data. Rather, four of the five effects levels used in the calculation are for benthic community metrics in coarse-grained stations, which appear to be more sensitive to PCBs than those in fine-grained locations. In addition, only the most sensitive of three diversity indices (Shannon-Wiener function) is used to calculate the effects threshold.

An additional problem with the revised benthic invertebrate assessment is that only one MATC is developed for coarse- and fine-grained sediment. The benthic community assessment appropriately separates coarse- and fine-grained locations when developing effects thresholds (e.g., EC20, EC50). This separation should be carried through to the development of the MATC; otherwise, the assessment of risk in fine-grained sediments will be driven by effects observed only in coarse-grained sediments.

Specific concerns related to the development of the chronic effects threshold from the toxicity tests, the benthic community assessment threshold, and the derivation of the MATC are discussed below.

2.1 Chronic Effects Threshold from Toxicity Tests

The chronic effects threshold is based on only one of six available endpoints for only one of two species evaluated (i.e., IC20 for *C. tentans* 20-d ash free dry weight) (EPA 2004a, Vol. 1, p. 3-41; Vol. 4, p. D-61). The rationale provided for this approach is that, because only two possible species were available for the development of a chronic toxicity threshold, a species sensitivity distribution (SSD) could not be developed and, therefore, the most sensitive endpoint from the most sensitive species was used to derive the effects threshold (EPA 2004a, Vol. 1, p. 3-41; Vol. 4, p. D-61).

This approach clearly contradicts the intent of several of the peer review comments, which recommended use of all available test species (e.g., EPA 2004a, pp. 131, 142, 154). This approach is also contrary to EPA's statement in the Responsiveness Summary that the full range of endpoints would be used in the development of the MATC. Regarding the *Hyallela azteca* laboratory tests, the Responsiveness Summary stated that "EPA believes that the chronic tests with endpoints for survival (42-day), growth (28-day), and reproduction (28-42 day) are equally important and provide relatively independent measures of contaminant stress and should all be considered in the MATC derivation" (EPA 2004b, Response 3.1-TT-8, pp. 118-119). EPA responded similarly for the endpoints of survival and growth in the *C. tentans* test, stating that "…a concentration-response relationship exists and therefore the data are appropriate for use in the MATC calculation" (EPA 2004b, Response 3.1-TT-8, p. 119). EPA also stated that, "[a]lthough multiple endpoints are included for both laboratory species (mortality and sublethal responses), this is appropriate given that the sublethal responses (growth and reproduction) are ecologically relevant endpoints" (EPA 2004b, Response 3.1-VF-

18, p. 150). Even though these multiple endpoints were deemed appropriate for consideration in developing the MATC, only one of them, the IC20 for *C. tentans* ash free dry weight, is used in the developing the MATC in the revised ERA. It is inappropriate for the other endpoints to be used only as anecdotal support for the threshold developed from the most sensitive endpoint for the most sensitive species, as is currently done in the ERA (EPA 2004a, Vol. 4, p. D-62).

As previously discussed in GE's comments on the July 2003 ERA (BBL et al. 2003, p. 5-6), GE does not agree with the use of 20% effect levels in calculating a threshold.[1] However, EPA claims that these results are "ecologically relevant" and uses them as the basis for the chronic toxicity effects threshold (EPA 2004a, Vol. 4, p. D-48). If EPA continues to use the 20% effect levels for the development of the chronic toxicity effects threshold, we believe that the threshold should be calculated as follows: The chronic toxicity effects threshold should be set equal to the geometric mean of all the LC20/IC20s for all six non-redundant endpoints evaluated in the laboratory studies (see Table 2.1 below). Where endpoints were measured multiple times in the same study, the endpoint from the longest exposure period should be used. Further, where two similar endpoints were measured in the same study (i.e., total young and total young per female), the more sensitive of the two endpoints should be used in the threshold. This practice would be consistent with the methods used to develop the acute toxicity threshold (EPA 2004a, Vol. 1, p. 3-42; Vol. 4, p. D-62).

When the geometric mean of the LC20/IC20s of the non-redundant endpoints is calculated, the chronic toxicity intermediate risk threshold is 7.0 mg/kg tPCB (Table 2.1), rather than 2.0 mg/kg tPCB, as is currently presented. Similarly, using the above

[1] The reason is that the use of 20% effect levels may overestimate effects if they cannot be statistically distinguished from the reference response. For the LC20 and IC20 values to be statistically distinguishable from the reference, and thus valid, the minimum significant difference (MSD) between them must be less than or equal to 20%. High variability in response in the toxicity tests yielded MSDs that usually exceeded 20% and were often greater than 50% (EPA 2004a, Vol. 4, p. D-48; Table D.3-2).

approach, the chronic toxicity high risk threshold based on the LC50/IC50s is 13.7 mg/kg tPCB (Table 2.1), rather than 4.7 mg/kg tPCB, as is currently presented.

Table 2.1. Summary of Endpoints Calculated for Chronic Toxicity Tests: Calculations Made Using "Most Synoptic" Exposure Data Set Only and Non-redundant Endpoints

	Results (mg/kg PCB)	
Endpoint	**LC20/IC20 by Probit[a]**	**LC50/IC50 by Probit[a]**
C. tentans		
20-d ash-free dry weight	2.0	4.7
20-d survival	<8.7[b]	<8.7[b]
43-d emergence	<8.7[b]	<8.7[b]
Geometric mean for *C. tentans*	**5.3**	**7.1**
H. azteca		
42-d dry weight	66.3 (NC)	>72[b]
42-survival	3.1	22.8
42-d total young	3.9	11.1
Geometric mean for *H. azteca*	**9.3**	**26.3**
Overall geometric mean based on geometric means for each species	**7.0**	**13.7**

Summary of data provided in EPA (2004a), Tables D.3-7 and D.3-8.

[a]Mean of comparison to references A1 and A3.

[b]When value is ">"or "<", the value itself is used in the calculation of the threshold consistent with the method used to derive a threshold from the six lowest endpoints in the July 2003 ERA.

NA=not applicable, NC=not calculated

2.2 Effects Thresholds from Benthic Community Assessment

A critical problem with the derivation of the threshold concentration from the benthic community endpoints is that a single threshold is calculated for both coarse- and fine-grained locations. Multiple metrics are used to evaluate the benthic community data in coarse- and fine-grained locations; however, the effects threshold for the benthic community is based on the geometric mean of only one metric from the fine-grained locations (SSD) and four from coarse-grained locations (SSD, abundance, richness and the Shannon-Wiener function) (EPA 2004a, Vol. 1, p. 3-57; Vol. 4, p. D-96). This approach is inconsistent with the analyses that EPA conducted on the benthic community in the ERA, which were applied separately for coarse- and fine-grained locations to minimize the impact of habitat (i.e., grain size, which substantially influences benthic community metrics) as a confounding factor (EPA 2004a, Vol. 4, p. D-93). Moreover, EPA's approach puts considerably greater weight on the results from the coarse-grained stations, which showed more adverse effects relative to reference stations than did the fine-grained stations. Thus, that approach results in the assessment of risks in fine-grained stations being based mainly on effects observed in coarse-grained stations. For these reasons, the effects thresholds for the benthic community study should be developed separately for coarse- and fine-grained sediments.

An additional problem with the selection of metrics used in the derivation of the effects threshold for the benthic community is that only one of three available diversity indices is used. Three diversity indices were calculated, including the Shannon-Wiener function, Simpson's Index, and Simpson's modified Index. However, the ERA used only the results of the most sensitive of these, the Shannon-Wiener function (for coarse-grained sediments only), in the calculation of the benthic community effects threshold (EPA 2004a, Vol. 1, p. 3-57; Vol. 4, p. D-96). This is inappropriate for two reasons. First, several peer reviewers indicated there are problems with the Shannon-Wiener function and recommended using the Simpson's Index (EPA 2004b, pp. 121, 134, and 135, reflecting comments of reviewers Thompson, Forbes, and LaPoint). Second, the use of only the Shannon-Wiener function for coarse-grained sediments as a representative of diversity in the calculation of the benthic community toxicity threshold is contrary to peer review comments that all endpoints, not just the most sensitive, be used to calculate thresholds (e.g., EPA 2004b, pp. 131, 142, 154, reflecting comments of reviewers Forbes, Sample, and Thompson). It would be more appropriate to take the geometric mean of the three diversity indices to represent diversity in the development of the effects threshold.

Effects concentrations (i.e., EC20/HC20, EC50/HC50) for all available metrics (abundance, taxa richness, diversity and SSD) should be used to develop the effects thresholds for the coarse- and fine-grained benthic community locations. These metrics for the coarse-grained locations are provided in the ERA with the exception of the EC50 for diversity (EPA 2004a, Vol. 1, p. 3-57; Vol. 4, p. D-96). All EC50s for diversity, for both coarse- and fine-grained sediments, were above the range of PCB concentrations tested. For the fine-grained locations, the highest tPCB sediment concentration tested (14.1 mg/kg sediment tPCB) should be used as the no effect level for taxa richness and total abundance, given that no adverse effects on abundance or ecologically relevant effects on taxa richness, relative to reference locations, were observed at those concentrations. Using these no effect levels as surrogates for the 20% effects levels results in a very conservative threshold. As discussed previously, diversity should be represented by the geometric mean of the three diversity indices that were measured. For the SSD, a 20% effects level is calculated in the ERA for fine-grained sediments (6.4 mg/kg tPCB) (EPA 2004a, Vol. 1, p. 3-57; Vol. 4, p. D-91, D-96; Vol. 4, Att. D.7, p. 13). This can be considered a very conservative estimate of effects based on the gradual slope of the SSD regression (EPA 2004a, Vol. 1, Figure 3.3-17; Vol. 4, Att. D.7, Figure 1). That regression indicates that the highest measured concentration, which is more than twice the estimated 20% effects PCB threshold (14.1 mg/kg tPCB and 6.4 mg/kg tPCB), is associated with only slightly more than a 20% effects level.

If the effects threshold is calculated separately for coarse- and fine-grained locations and the values described in the previous paragraph are used in the threshold derivation, the intermediate risk threshold, represented by the 20% effects level, would be 7.7 mg/kg tPCB for coarse-grained sediment and 17.4 mg/kg tPCB in fine-grained sediment (Table 2.2 below). These values should replace the current value reported in the ERA of 5.6 mg/kg tPCB for both coarse- and fine-grained sediment (EPA 2004a, Vol. 1, p. 3-57; Vol. 4, p. D-96). The high-risk threshold of 27.9 mg/kg tPCB presented in the November 2004 ERA is based on only three endpoints for coarse-grained sediments (SSD, taxa richness and total abundance) (EPA 2004a, Vol. 1, p. 3-57; Vol. 4, p. D-96). As indicated in Table 2.2 below, for a majority of endpoints measured, no effects were seen at the 50% effects level. As a result, the high-risk threshold for coarse-grained sediment presented in the ERA should be considered very conservative.

Table 2.2. Benthic Community Metrics for Coarse- and Fine-grained Sediment

Metric	Coarse-grained sediment EC20/HC20	Coarse-grained sediment EC50/HC50	Fine-grained sediment EC20/HC20	Fine-grained sediment EC50/HC50
Species sensitivity distribution	2.3	4.1	6.4	[e]
Taxa richness	13.4	141 to 195[a]	>14.1[c]	[c]
Total abundance	5.8	37.3 to 40.4[a]	>14.1[d]	[d]
Diversity indices				
Shannon Wiener H'	4.7	[b]	58.7	[b]
Simpson's Index	70.3	[b]	275	[b]
Modified Simpson's Index	23.5	[b]	22.8	[b]
Geometric mean of diversity indices	**19.8**		**71.7**	
Geometric mean using geometric mean of diversity indices	**7.7**		**17.4**	

Summary of abundance and richness data provided in EPA (2004a), Vol. 4, pp. D-80 - 81; SSD data provided in Att. 7, diversity data provided in Attachment D.8, Table 3.
[a]Range of concentrations based on DL substitution method.
[b]All calculated EC50 values were outside the range of PCB concentrations measured.
[c] No ecologically significant effect.
[d] Not significantly different from reference at highest tPCB concentration.
[e]Effects at this magnitude were not seen at the sediment tPCB concentrations evaluated.

2.3 Calculation of MATC

The MATC for benthic invertebrates (coarse- and fine-grained sediment) in the November 2004 ERA is based upon the geometric mean of the intermediate risk thresholds from the toxicity study and the benthic community study (EPA 2004a, Vol. 1, p. 3-59; Vol. 4, p. D-118). As discussed previously, separate MATCs should be developed for coarse- and fine-grained sediment to minimize grain size as a confounding factor. Using the geometric mean of the effects thresholds calculated in these Comments (see Tables 2.1 and 2.2), the MATC for coarse-grained sediment should be 7.4 mg/kg tPCB and the MATC for fine-grained sediment should be 11 mg/kg tPCB (Table 2.3 below). These values should replace the MATC of 3 mg/kg tPCB that is presented in the November 2004 ERA.

Table 2.3. MATC for Coarse- and Fine-Grained Sediment

	Intermediate Risk Threshold mg/kg tPCB	
Endpoint	**Coarse-grained Sediment**	**Fine-grained Sediment**
Toxicity Study		
Overall geometric mean based on geometric means of all endpoints for each species	7.0	7.0
Benthic Community Study		
Geometric mean of all metrics using geometric mean of diversity indices	7.7	17.4
MATC based on geometric mean of species/diversity indices	**7.4**	**11.0**

3. *Community Condition, Survival, Reproduction, Development and Maturation of Amphibians*

In the most recent draft of the ERA (EPA 2004a), the sediment MATC for PCBs in vernal pools has been raised from 3 mg/kg to 3.27 mg/kg and is presented as based on an "integrated" threshold for malformations and sex ratio. In fact, that MATC does not take account of all relevant endpoints. In addition, a sensitivity analysis has been provided for the population model; however, the model still does not properly account for density-dependence and the models' predictions of extinction within 20 years (even without the presence of PCBs) are contradicted by the presence of an amphibian population in the Housatonic River floodplain. These problems with the sediment MATC and the population model are discussed below.

3.1 Basis for the Sediment MATC for Amphibians

The MATC is described in the November 2004 ERA as being based on an "integrated" threshold for two sensitive endpoints – metamorph malformations and sex ratio (EPA 2004a, Vol. 1, p. 4-67; Vol. 5, p. E-142). However, as explained elsewhere in the ERA, the MATC is actually based on the EC20 for Phase III malformations, with further support provided by the sex ratio data, although EPA notes that the EC20 for sex ratio is of uncertain biological relevance (EPA 2004a, Vol. 1, p. 4-53; Vol. 5, p. E-144). As discussed in GE's prior comments (BBL et al. 2003, pp. 6-7 - 6-10, 6-12 - 6-14, Att. G), the development of an effects threshold based on malformations is extremely conservative, since it does not consider data on survival, growth, or metamorphosis, which showed no effects of PCBs; and the sex ratio data do not provide reliable evidence of adverse PCB effects and thus should not be used to develop site-specific effects thresholds. However, if EPA continues to rely on the malformation and sex ratio data, then ***all*** results for those endpoints (excluding the endpoints that EPA agrees are of questionable biological relevance) should be used in developing an integrated MATC.

Three endpoints showed significant of effects of PCBs in EPA's three-phase wood frog study: larval malformations and metamorph abnormalities in Phases I and III and skewed sex ratios in Phase III. Detailed statistical analyses were conducted on all three of these endpoints. However, the Phase I malformation data are excluded from the integrated threshold. Based on peer review comments that all relevant endpoints, not just the most sensitive, should be used in the development of thresholds (EPA 2004b, pp. 131, 142, 154), the Phase I malformation data should be used in the integrated threshold for amphibians. In addition, if EPA continues to use the skewed sex ratio endpoint, then the EC50 for sex ratio should be used in the development of the effects threshold, as the ERA itself indicates that a 20% effects level for sex ratio is likely not biologically relevant (EPA 2004a, Vol. 1, p. 4-53; Vol. 5, pp. E-116, E-144).

Using this approach, an integrated effects threshold for amphibians should be based on the geometric mean of the EC20 for Phase I and Phase III abnormalities and malformations and the EC50 for Phase III sex ratio. Given the uncertainties associated with the ecological relevance of both the malformations and sex ratio for the population, this approach provides a conservative assessment of risk. If the threshold is calculated in this way, the integrated MATC for low risk would be 12.5 mg/kg tPCB in sediment (Table 3.1). Similarly, the high-risk threshold should be based on the EC50s for all endpoints, rather than just the most sensitive endpoint – sex ratio – as is currently done (EPA 2004a, Vol. 5, p. E-145). If the threshold is calculated in this way, the integrated high-risk threshold would be 28.4 mg/kg tPCB in sediment (Table 3.1).

Table 3.1. MATC based on Geometric Mean of Phase I and Phase III Malformations and Phase III Sex Ratio

Endpoint	Low Risk mg/kg tPCB*	High Risk mg/kg tPCB*
Phase I Malformations[a]	LC20 >62	LC50 >62
Phase III Malformations[b]	LC20 3.27	LC50 38.6
Phase III Sex Ratio[b]	LC50 9.54	LC50 9.54
MATC based on geometric mean of above endpoints	**12.5**	**28.4**

[a] vernal pool sediment tPCB concentration
[b] spatially weighted mean sediment tPCB concentrations

3.2 Wood Frog Population Model

The revised wood frog population model documented in Attachment E-4 of the November 2004 ERA addresses some of the GE and peer reviewer comments on the July 2003 draft, but it still fails to account for density-dependence within the model or to provide a realistic description of wood frog population dynamics, both with or without the influence of PCBs.

The summary results presented in Table 20 of Attachment E-4 (EPA 2004a) show that the revised model predicts even more rapid extinction of the wood frog population in the PSA than did the original model (EPA 2003, Vol. 5, Att. E.3). In the revised model, even under the most optimistic assumptions (non-declining population, no PCB impacts), the median time to extinction of the PSA wood frog population is only 20 years, compared to 32 years in the original model. Median time to extinctions for populations exposed to PCBs range from 4.5 to 11 years. As noted in GE's previous comments on the model (BBL et al. 2003, pp. 6-10 - 6-11, G-9 - G-12), if EPA's model were accurate, the wood frog population on the floodplain should already be extinct, and it is not.

The ERA claims that the base model incorporates density-dependence by establishing a ceiling beyond which frog populations were not allowed to grow (EPA 2004a, Vol. 5, Att. E-4, p. 21). Such an approach, however, does not adequately take account of density-dependence because it does not permit the population growth rate to increase at low abundance levels. By contrast, the ERA also includes a sensitivity analysis that takes account of density-dependence incorporating compensation (increase in survival or fecundity as density decreases) (EPA 2004a, Vol. 5, pp. E-137 - E139 and Att. E-4, pp. 54-56). The inclusion of such compensatory density-dependence substantially decreases the risk of extinction for all model projections. Figure 16 (EPA 2004a, Vol. 5, Att. E-4, p. 57) shows the influence of alternative assumptions concerning density-dependence on the risk that the abundance of wood frogs will be at or below a given level after 10 years. In the non-declining base model (Panel B), there is greater than a 30% risk that the population will decline from the starting value (~75,000 frogs) to only 10,000 frogs after 10 years, even with no PCB impacts. With compensatory density-dependence included (Panel A), the risk that the population will decline to 10,000 frogs is far less than 10% for even the most severely PCB-impacted model projections. In the declining base model (Panel D), there is approximately a 90% risk that the population will decline to less than 10,000 frogs even with no PCB impacts. With compensatory density-dependence included (Panel C), the risk of a decline to less than 10,000 frogs is less than 40% for even the most severely PCB-impacted model projections.

EPA's claim that the models are "robust in projecting the increased risk of population decline and extinction due to tPCB contamination" (EPA 2004a, Vol. 5, p. E-139) is based on the differences in estimated extinction risks for unimpacted and impacted populations. With respect to the absolute extinction risk, however, it is clear that the model still substantially overpredicts extinction both with and without PCB exposure. Based on the sensitivity analysis, extinction risks for both unimpacted and impacted populations are far lower when compensatory density-dependence is included in the model projections. Since that approach better takes account of density-dependence, GE recommends that compensatory density-dependence be included in the base scenarios rather than only in the sensitivity analysis. This is particularly important if the wood frog population model may be used in remedial action planning to balance the benefits of PCB exposure reduction against the increased risk of population extinction resulting from habitat disturbance during remediation.

4. *Survival, Growth, and Reproduction of Insectivorous Birds*

The primary changes to the assessment of survival, growth, and reproduction of insectivorous birds are the addition of wood ducks as a receptor and the change in the conclusion regarding evidence of harm provided by the tree swallow study. The addition of the wood duck appears to be in response to one peer reviewer's repeated comment on the matter (Ottinger 2004, pp. 5, 6, 13, 14, 15; EPA 2004b, pp. 227, 233, 247). Because this entire measurement endpoint is new, GE is providing comments and recommendations on EPA's overall wood duck analysis. The change in the evidence of harm attributed to the tree swallow field study appears to be in response to two peer reviewers' comments (see EPA 2004b, pp. 235, 243, addressing comments of reviewers LaPoint and Sample). However, because neither the underlying study (Custer 2002) nor the analysis of that study changed since the July 2003 version of the ERA, there is now an inconsistency between the analyses and the risk characterization for tree swallows.

4.1 Measured Exposure and Effects for Wood Ducks

The November 2004 ERA includes a new measurement endpoint for insectivorous birds based on modeled exposure and effects (or hazard quotients, HQs) in wood ducks. The approach employed with wood ducks is similar to that used for other avian HQs, with a few exceptions. As with most other avian receptors, risks posed by PCBs were evaluated by estimating the dietary intake (i.e., dose) of PCBs in laying hens and comparing that dose to effects metrics developed from published toxicological studies on the avian receptors that EPA regards as most sensitive (i.e., white leghorn chickens, studied by Lillie et al. 1974) and most tolerant (i.e., American kestrels, studied by Fernie et al. 2001) (EPA 2004a, Vol. 2, p. 7-40; Vol. 5, p. G-82). The approach taken to evaluate risks posed by TEQs differs somewhat from that used for other avian receptors. As described in the ERA (EPA 2004a, Vol. 2, p. 7-11; Vol. 5, pp. G-51, G-52), the concentration of TEQ (ng/kg) in female breeding wood ducks over the 14-day pre-laying period was estimated by multiplying the total daily intake (TDI) (in ng/kg bw/d) by the chemical assimilation efficiency (CAE) (unitless) and summing the results for 14 days. The concentration of TEQ in hens was then multiplied by a literature-derived egg:adult concentration ratio to determine the concentration of TEQ (ng/kg ww) in the egg. Finally, the modeled egg concentration was compared to a literature-derived egg-based effect metric specific to wood ducks and TEQ, based on a study by White and Seginak (1994), in order to determine risk.

GE has several major concerns about EPA's new analysis:

- The model's predictions are not borne out by incidental field observations and collections.
- The effects metrics used by EPA for PCBs are not based on the most appropriate species or studies, and the effects metric used for TEQs appears to overestimate risks to Housatonic River wood ducks.
- EPA's exposure modeling employs several assumptions that tend to overestimate exposure.

Each of these points is discussed further below.

4.1.1 Inconsistency with Field Observations

The ERA predicts high risks posed to wood ducks from both PCBs and TEQs (EPA 2004a, Vol. 2, pp. 7-60, 7-65, 7-70; Vol. 5, pp. G-88 - G-91). This conclusion is based on high HQ values. For example, EPA's analysis predicts concentrations of TEQs in eggs ranging from 40.9 ng/kg to 7,907 ng/kg, with mean values in the range of 595 ng/kg to 2,943, depending upon location and egg order (EPA 2004a, Vol. 5, Table G.2-40). TEQ concentrations in five eggs that were collected from the Site and analyzed generally support the model's predictions, although the sample size was low (n=5, mean = 1,336 ng/kg ww, range = 703 to 2,077 ng/kg ww) (EPA 2004a, Vol. 2, p. 7-61; Vol. 5, p. G-55). For comparison, effects metrics in the range of >20 ng/kg to 50 ng/kg were derived by White and Seginak (1994) in a field study of wood ducks exposed to a mixture of dioxins and furans in Bayou Meto, Arkansas (see EPA 2004a, Vol. 1, p. 7-40). At concentrations above that range, White and Seginak (1994) observed large proportions of nonviable eggs, deformities of the lower bill, and subcutaneous edema of the head and neck. Thus, egg TEQ concentrations in the Housatonic River wood ducks may be up to 400 times higher than those that produced overt adverse effects in Bayou Meto. Nevertheless, no malformations or edemas have been reported in the four years of field work and two years of wood duck collections conducted in support of the ERA. Although a controlled quantitative study of reproductive success and teratogenicity in wood ducks has not been conducted on the Housatonic River, wood ducks are fairly common in the area and biologists' time in the field has been extensive. Thus, such overt effects should be apparent through incidental observations if they are indeed occurring, given that HQs are as high as 400. No such observations have been made and none of the adult wood ducks or wood duck embryos collected to date have been deformed. It stands to reason, then, that ERA's predictions must be overestimating risks to wood ducks at the Housatonic River site.

The following sections discuss parameters that are most likely contributing to this overestimate and that, in GE's view, should be changed.

4.1.2 Effects Metrics

Effects Metrics for tPCBs

The most important limitation of the wood duck PCB HQs is the use of a range of PCB effects metrics based on white leghorn chickens (Lillie et al. 1974) as reportedly representing the most sensitive avian species, and American kestrels (Fernie et al. 2001) as reportedly the most tolerant species.

For the lower bound of the range, it is inappropriate to use the dated Lillie et al. (1974) study on white leghorn chickens, which are domesticated and are substantially more sensitive than wild species to PCBs (Bosveld and Van den Berg 1994), when a suitable study on another duck species (mallards) is available (Custer and Heinz 1980). As recognized in EPA's (1995) *Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria*: "many traditional laboratory species…are bred from a fairly homogeneous gene-pool. Use of a [test dose] derived from a 'wildlife' species is thought to provide a more realistic representation of the dose-response relationship which may occur in the natural environment" (EPA 1995, p. 11). The same is true for domesticated chickens. Thus, effects metrics based on domesticated species should be used only in the absence of any suitable studies on wild species. In this case, a study by Custer and Heinz (1980) on mallards, which was not included in the ERA, provides a suitable study on a closely related wild species. That study yielded a NOAEL of 1.4 mg/kg bw/d tPCBs, which should be used for the lower bound of the range.

For the upper bound of the range, EPA's site-specific field study of tree swallows (Custer 2002) shows that species to be more tolerant than American kestrels. Hence, a site-specific and stressor-specific dose-based metric should be generated from that study and used for the upper bound of the range.

Effects Metrics for TEQs

As noted above, EPA has used the wood duck study by White and Seginak (1994) in Bayou Meto as the basis for the TEQ effects metrics. Although this study does not require interspecies extrapolation, there are important differences in field conditions at Bayou Meto and the Housatonic River that limit extrapolation of the effects metrics. Differences in the TEF schemes used (I-TEFs vs. WHO TEFs) are acknowledged in the ERA (see EPA 2004a, Vol. 2, p. 7-41; Vol. 5, Att. G.2). That difference alone, however, does not appear to be sufficient to account for the absence of overt abnormalities in Housatonic wood ducks despite concentrations of TEQs in eggs that are hundreds of times greater than White and Seginak's (1994) effects metrics. The mixtures of dioxins, furans, and PCBs differ substantially between Bayou Meto and the Housatonic River, and those different mixtures may have very different toxicities (even apart from the differences due to the TEF schemes). For example, Bayou Meto is primarily impacted with dioxins, while PCBs are predominant in the Housatonic River. Moreover, there may be secondary stressors in the Arkansas population that were not considered. Differences in competition, food sources, bioenergetics, co-contaminants, or other factors may also be relevant. Although the cause of the over-prediction of risks based on White and Seginak's (1994) effects metrics cannot be determined based on the information provided by White and Seginak (1994), the absence of any evidence of malformations or edema in the Housatonic River wood duck and egg collections suggests that the study does indeed overestimate TEQ risks to Housatonic River wood ducks.

In an effort to ground-truth the ERA's egg-based HQ findings, GE calculated risks posed by TEQs under the more conventional dose-based approach. Using the equation for TDI that is provided in the ERA (EPA 2004a, Vol. 1, pp. 6-8, 7-10; Vol. 5, p. G-14), as well as the ERA's reported median concentrations of TEQ in aquatic invertebrates and litter invertebrates at location 13 (EPA 2004a, Vol. 5, Table G.2-38), and the ERA's assumptions regarding foraging time, food ingestion rate, and the proportion of diet derived from aquatic invertebrates and litter invertebrates (EPA 2004a, Vol. 5, Table G.2-34), the median TEQ dose to breeding wood ducks is 99 ng/kg bw/day. That value may be compared to the same dose-based effects metrics for TEQ that are applied to all other avian receptors, which range from 44 ng/kg bw/day to 25,000 ng/kg bw/day (EPA 2004a, Vol. 2, p. 7-40; Vol. 5, p. G-83). Resultant HQs range from 0.004 to 2.3, consistent with a finding of low or borderline risks. Under most circumstances, low or borderline risks would not be expected to cause overt malformations and edema that could be observed incidentally. Hence, a dose-based approach to evaluating TEQ risks to wood ducks would appear to yield results that are more consistent with field observations and collections. This dose-based TEQ risk calculation supports GE's contention that the White and Seginak (1994) study overestimates risks to Housatonic River wood ducks, in part due to the TEF scheme applied, but likely also due to differences in contaminant mixtures, secondary stressors, ecological factors, and/or confounding factors.

4.1.3 Specific Exposure Assumptions

In addition to the effects metrics used, three exposure assumptions used in EPA's modeling tend to result in over-predictions and should be revised – namely, (1) the assumed composition of the diets of pre-laying and laying hens, (2) the application of the maternal transfer data reported by Bargar et al. (2001), and (3) the assumption that PCBs are not metabolized.

Diet Composition

EPA's modeling assumes that the percentage of aquatic and terrestrial invertebrates (combined) in the diets of breeding wood duck hens is 76% (EPA 2004a, Vol. 2, p. 7-19; Vol. 5, p. G-49). That percentage represents the wood duck hens' diet during the laying period, as reported by Drobney and Fredrickson (1979). Those authors report that, during the 14-day pre-laying period, invertebrates comprise a substantially lower proportion (i.e., 53%) of the wood duck hen diet. Because EPA's calculation of wood duck total daily intake (TDI) spans both the pre-laying and laying period, uncertainty in the model result would reduced by applying Drobney and Fredrickson's (1979) pre-laying proportions to the pre-laying part of the breeding cycle and then applying their laying proportions to the laying part of the cycle.

Maternal Transfer

To determine the concentration of TEQ in wood duck eggs, the estimated TEQ concentration in hens was multiplied by an egg:hen concentration ratio derived from a study by Bargar et al. (2001) (see EPA 2004a, Vol. 2, p. 7-19; Vol. 5, p. G-52). The manner in which the Bargar et al. (2001) study is used to estimate maternal transfer appears to result in unnecessary uncertainty and overestimation of exposure. Bargar et al. (2001) injected three different PCB congeners (PCBs 105, 156, and 189) individually and as a mixture subcutaneously into white leghorn chicken hens every four days during a 21-day period. They quantified maternal transfer to eggs on both a mass basis and a concentration ratio basis. On a mass basis, 0.42% to 0.61% of the injected PCBs (in μg) were excreted into eggs. On a concentration ratio basis, the egg:hen concentration ratio averaged 0.22 (for wet weight measurements).

As noted by Bargar et al. (2001), egg size relative to body size is a possible reason for interspecies excretion variability. GE also notes that interspecies differences in lipid fractions in hens and eggs likely contribute to interspecies excretion variability. One would only expect egg:hen concentration ratios to be similar across species if the relative masses of the egg and the hen, as well as the lipid fractions in eggs and hens, were also similar across species. Although Bargar et al. (2001) present no data on the lipid fractions of their study animals, they report that each egg laid by white leghorn chickens accounts for approximately 3% of the hen's body weight. By contrast, data in the literature indicate that each wood duck egg accounts for 6% to 6.5% of the hen's weight.[2] Due to this considerable difference in the relative masses of hens and eggs between these species, Bargar et al.'s (2001) egg:hen concentration ratios yield estimates of maternal transfer that are higher than those generated from mass-based measures of maternal transfer. As noted above, GE recommends using a dose-based approach to quantify TEQ risks for wood ducks. However, if an egg-based approach is retained, maternal transfer should be estimated based on transfer of 0.42% to 0.61% of the PCB mass ingested by wood duck hens, instead of the egg:hen concentration ratios reported by Bargar et al. (2001), because of the substantial difference in the relative masses of eggs and hens in chickens and wood ducks.

In addition, Bargar et al.'s (2001) method of administering the dose (subcutaneous injection) and timing of doing so may not accurately represent maternal transfer that occurs at steady-state through dietary exposure. In particular, the absorbed doses of PCBs in the chickens treated by Bargar et al. were not likely at steady-state before egg-laying was initiated. Excretion rates are expected to differ under steady-state and non-steady-state conditions, particularly when multiple dosings are administered discontinuously. If egg-based HQs are retained in the ERA, this uncertainty should be acknowledged.

Assumption of No PCB Metabolism

The ERA assumes that no metabolism of PCBs occurs in the hens (EPA 2004a, Vol. 5, p. G-51). However, as subsequently noted in the ERA (EPA 2004a, Vol. 6, p. K-28), Dahlgren et al. (1971) estimated metabolism of 2.4% of the PCB dose over a 28 day

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[2] Hepp and Belrose (1995) report that a wood duck's clutch accounts for 78% of the hen's weight. The same authors report an average clutch size of 12, while Grice and Rogers (1965) report an average clutch size of 13. Dividing 0.78 by 12 and 13 yields the range of 6% to 6.5% presented above.

period. Given the available data, metabolism of PCBs warrants quantitative inclusion in the ERA model for wood ducks, in order to reduce the model's uncertainty and overestimation of exposure.

4.2 *Change in Designated Evidence of Harm to Tree Swallows*

As in the July 2003 draft of the ERA, the November 2004 ERA uses two lines of evidence to evaluate potential risks to tree swallows – a field study conducted by Custer (2002) and measured exposure and effects (i.e., HQ). The most important change made to the tree swallow assessment endpoint is the change from "no" to "yes" for the evidence of harm assigned to the tree swallow field study. Based on the EPA Responsiveness Summary (EPA 2004b, pp. 46, 48, 235, 238, 243), it appears that this change was made in response to comments by two peer reviewers (reviewers LaPoint and Sample), even though the majority of the peer reviewers did not disagree with the July 2003 ERA's characterization of this study (see EPA 2004b, pp. 235-236, 238, 247-248).

Because the underlying study itself was not changed since the July 2003 version of the ERA, the change in evidence of harm (from "no" to "yes") must be based on a change in the interpretation of that study. However, the text that precedes the risk characterization for tree swallows continues to indicate that the study does not in fact provide evidence of harm. For example, the ERA states that "the tree swallow reproduction study (Custer 2002) indicated that tree swallows did not experience serious adverse effects, despite high tissue concentrations of tPCBs and TEQ in nestlings in the PSA locations. The fecundity of tree swallows in the PSA was not significantly different from that of tree swallows generally in central Massachusetts as reported by Chapman (1955)" (EPA 2004a, Vol. 2, p. 7-60). Elsewhere, the ERA states that "fecundity of tree swallows in the PSA seemed to be unaffected by contaminants" (EPA 2004a, Vol. 5, p. G-67). Similarly, after acknowledging that the robin field study provides no evidence of adverse effects, the ERA reports that "the tree swallow field study similarly suggests this species does not experience serious adverse effects" (EPA 2004a, Vol. 5, p. G-112).

Given these statements, the ERA's change in conclusion must be based on giving greater importance to the two findings in the tree swallow study that the ERA indicates may suggest effects. Those findings, however, do not demonstrate evidence of harm. First, the ERA notes that there was a "significant negative relationship between tPCBs in eggs and hatching success in 1999" (EPA 2004a, Volume 5, p. G-66). Despite a p-value less than 0.05, however, this finding should not be considered statistically significant result because it relies on flawed application of logistic regression. Custer (2002, p. 14) defined a good fit of the model to the data as a Goodness of Fit (GOF) with $p > 0.05$. Because a GOF at that level was not attained ($p = 0.028$, Custer 2002, p. 21), the logistic regression should not have been used to draw conclusions regarding the effects of exposure to PCBs on hatching success. Although Custer (2002) and the ERA did state that the quality of the fit was poor, neither report adequately discounted the relationship between PCB exposure and hatching success given that poor fit. Furthermore, based on an R^2 value of 0.06, the relationship between tPCBs in eggs and hatching success was extremely weak; that is, differences in PCB concentrations accounted for only 6% of the variability observed in hatching success.

Second, one might infer evidence of harm from the observation that clutches with dead embryos had geometric mean concentrations that "exceeded the field-based threshold of 62.2 mg/kg ww tPCBs in eggs established from the studies by McCarthy and Secord (1999a, 1999b)" (EPA 2004a, Vol. 5, p. G-68). Such an inference is flawed because it compares concentrations across different age classes. Contrary to the above quote, McCarty and Secord's (1999a) threshold of 62.2 mg/kg is based on mean <u>14-day nestling</u> concentrations in 1994, rather than egg concentrations: "[c]oncentrations in nestlings ranged from 3,710 ng/g at Saratoga to 39,800 ng/g at Special Area 13 and 62,200 ng/g at the Remnant site (all PCB concentrations from Secord et al., unpublished data)" (McCarty and Secord 1999a, p. 1433), and "[t]ree swallow nestlings were collected for chemical analysis from the same nests…on day 14 (1994) or day 15 (1995) posthatch (Secord et al. 1999, p. 2520).

The pipper and nestling tissue measurements presented in the ERA clearly demonstrate differences in concentrations of PCBs between hatching and nestling development (EPA 2004a, Vol. 2, pp. 7-32, 7-33; Vol. 5, Tables G.2-6, G.2-19, G.2-20, G.2-21, G.2-22, G.2-23). Thus, the ERA's comparison of measured concentrations of PCBs in eggs to a literature-based benchmark for nestling concentrations does not provide defensible evidence of risk. Regardless of the finding, such comparisons are only relevant to the HQ line of evidence and should not be used in the interpretation of a field study.

For these reasons, the tree swallow field study does not provide any reliable evidence of harm to tree swallows. GE believes that EPA should reverse the change in the evidence-of-harm designation in order to ensure that the risk findings are fully supported by the underlying study. In addition, EPA should eliminate or correct the language comparing egg concentrations in the field study to the McCarty and Secord (1999a,b) effect metric for nestlings.

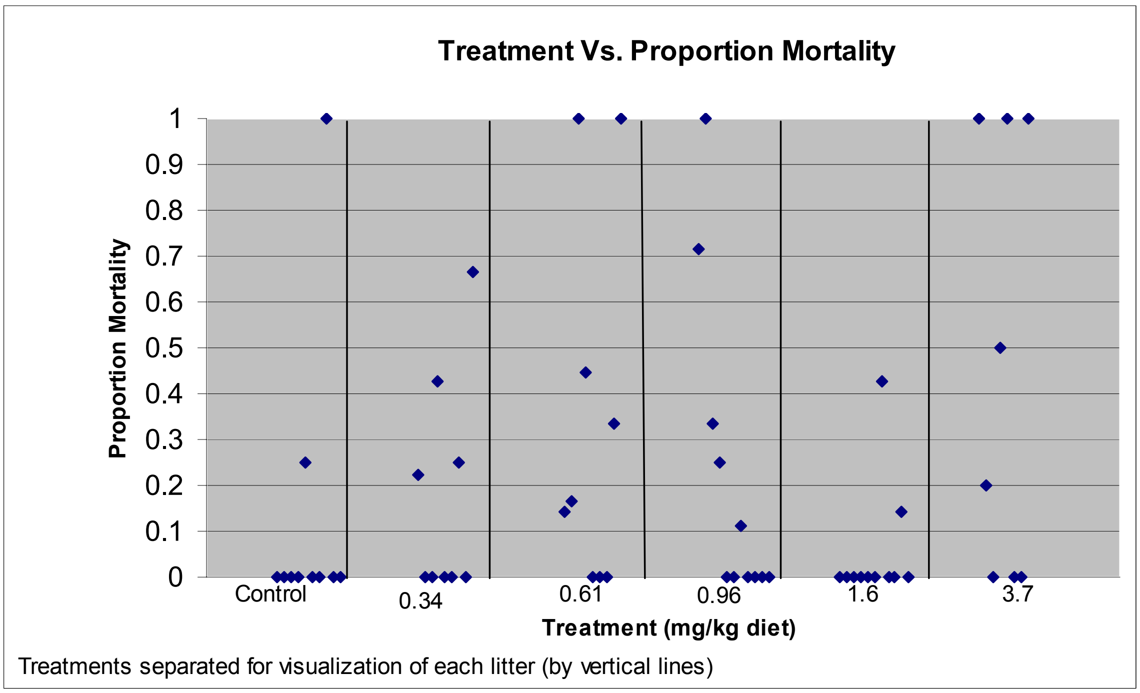
5. *Survival, Growth and Reproduction of Piscivorous Mammals*

The primary change to the assessment of survival, growth, and reproduction of piscivorous mammals in the November 2004 ERA consists of the addition of a new probit analysis to assess the dose-response curve for 6-week kit survival from EPA's mink feeding study (EPA 2004a, Vol. 6, p. I-52). This analysis is in addition to the statistical analysis, using analysis of variance (ANOVA), performed by the study investigators (Bursian et al. 2003) and reported in the July 2003 draft ERA. This analysis has resulted in the development of a new PCB MATC of 0.98 mg/kg (EPA 2004a, Vol. 6, p. I-106), to replace the MATC of. 2.65 mg/kg in the July 2003 draft (which was the geometric mean of the LOAEL and NOAEL reported by Bursian et al. (2003)). As discussed below, this new MATC does not adequately reflect the spread of the kit survival results across treatments, which show no evident dose-response relationship, and is inconsistent with the site-specific NOAEL from the study. Moreover, the ERA's use of literature data from other sites to support this new MATC is inappropriate due primarily to differences in toxicity between the PCB test mixtures used in the selected literature studies and the PCB mixture present in the Housatonic River area.

At the outset, it should be noted that the new probit analysis presented in the November 2004 ERA was not recommended by the peer reviewers. One peer reviewer (Thompson) noted that EPA should address GE's comment that no dose-response relationship was demonstrated in the mink feeding study (EPA 2004b, p. 277), and another reviewer (Stahl) indicated that there was no definitive dose-response relationship between kit survival and PCB concentrations in fish (EPA, 2004b, p. 291). These reviewers, however, did not suggest the type of analysis that EPA has now conducted. Further, the majority of the peer reviewers agreed that the July 2003 ERA's presentation and analysis of the mink feeding study were appropriate (EPA 2004b, pp. 282-285). While GE had commented that the identified LOAEL from the study (3.7 mg/kg in diet) should in fact be a NOAEL (BBL et al. 2003, pp. 10-3 - 10-4 & Attachment N), the peer reviewers were satisfied with the NOAEL and MATC derived in the July 2003 ERA (EPA 2003, Vol. 2, p. 9-78; Vol. 6, p. I-83). Moreover, in the Responsiveness Summary, EPA asserted that the statistical analysis (ANOVA) used by Bursian et al. (2003) and presented in the July 2003 draft ERA "is a reasonable methodology given the design of the study (EPA 2004b, p. 49). Nevertheless, EPA has conducted a new probit analysis of the 6-week kit survival data that has resulted in estimated values of LC10 (0.231 mg/kg in diet) and LC20 (0.984 mg/kg in diet) that are well below EPA's statistically determined NOAEL from the study (1.6 mg/kg in diet). The EPA has used the LC20 value of 0.984 mg/kg in fish as the new MATC for PCBs (EPA 2004a, Vol. 2, p. 9-51; Vol. 6, p. I-106).

While the probit analysis conducted by EPA for the 6-week survival results from the mink feeding study was found to be significant (based on a p value of 0.0021), it is apparent, based on Figure I.3-4 of the ERA, that the probit curve and in particular the confidence intervals do not adequately reflect the data given the spread in results across all treatment groups. As shown in Figure 5.1 below, the mink data are highly variable, and no dose-response is evident, especially given that the second highest treatment group had the highest survivability for the 6-week kit survivability endpoint. Moreover, the NOAEL determined by ANOVA provides a measured threshold dose while the probit analysis provides a modeled or estimated dose. Given the inconsistency between the probit curve and the underlying data, and the fact that the probit analysis results are not consistent with previously conducted statistical analysis for the data, it is inappropriate to use this analysis to estimate an LC20 and/or a MATC value for mink.

Figure 5.1. Summary of Six Week Kit Mortality by Treatment



In addition to the probit analysis, to support the new MATC, the ERA argues that that MATC should not be considered conservative because it is above similar metrics from other mink feeding studies (EPA 2004a, Vol. 6, p. I-106). This statement is based on a comparison of the MATC to one observed LOAEL from the literature (Heaton et al. 1995) and to the literature-based TRV developed in the ERA for comparison to modeled food chain exposure. This TRV in turn was based on an LC20 that EPA derived from the literature using a dose-response analysis of combined doses from studies reported in two other papers (Aulerich and Ringer 1977, Aulerich et al. 1985).[3] As discussed below, the

[3] Use of these two papers to develop the literature-based dose-response curve for mink represents a change from the July 2003 draft ERA, which stated that the two acceptable studies

ERA's comparison is completely inappropriate and lends no additional credibility to the new MATC value.

The Heaton et al. (1995) study involved mink that were fed Saginaw Bay fish, which contain a PCB mixture different from that in Housatonic River fish as well as other contaminants (e.g., dioxin). The other two papers used for TRV development (Aulerich and Ringer 1977, Aulerich et al 1985) included studies conducted with a variety of individual PCB congeners and mixtures. The Aulerich and Ringer (1977) paper summarized multiple studies which utilized Great Lakes or marine fish containing PCBs and other contaminants, non-weathered Aroclor 1254, combinations of Aroclor 1254 and pesticides, and other non-weathered Aroclors (1016, 1221, and 1242). The Aulerich et al (1985) study evaluated the effects of non-weathered Aroclor 1254 as well as three individual PCB congeners (136, 153 and 169). While the EPA was not explicit about which specific treatments from the two Aulerich papers were included in the development of the dose-response curve used to determine the LC20, none of the data sets included in these papers represents a weathered mixture similar to the Housatonic River fish. Due to these differences, these studies are not suitable for comparison to the feeding study using Housatonic River fish.

The ERA itself acknowledges that "most of the difference in results between the Saginaw Bay . . . and Housatonic River mink feeding studies is due to the reduced absorption and toxicity of the congener mixture in the Housatonic River fish" (EPA 2004a, Vol. 6, p. I-62). EPA also acknowledged in the Responsiveness Summary that "the contaminant mixture present in the PSA appears to be less toxic than observed at other sites" (EPA 2004b, Response 3.6-BS-5, p. 271), demonstrating further the limited utility of literature-

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for developing such a curve were Bleavins et al. (1980) and Aulerich et al. (1985) (EPA 2003, Vol. 6, p. I-53). In the November 2004 ERA, Bleavins et al. (1980) is apparently no longer considered acceptable, while Aulerich and Ringer (1977) is now considered acceptable (EPA 2004a, Vol. 6, p. I-67). As a result, a new dose-response curve has been fit, and slightly revised (lower) tPCB TRVs have been derived (EPA 2004a, Vol. 6, p. I-67). No explanation is given for this change and none of the peer reviewers commented on this.

derived toxicity thresholds and the importance of site-specific studies for the mink evaluation.

For the above reasons EPA should not base the MATC for mink on the new probit analysis. Instead, while GE preserves its prior position that the mink feeding study did not show effects even at the highest dose, GE believes that basing the MATC on the geometric mean of the NOAEL and LOAEL values reported by Bursian et al. (2003) is more supportable and consistent with the underlying data than is the new MATC.

6. *Survival, Growth and Reproduction of Omnivorous and Carnivorous Mammals*

The primary change to the assessment of survival, growth, and reproduction of omnivorous and carnivorous mammals is the development of a PCB MATC based on a new regression analysis of the data from the site-specific short-tailed shrew demography study. In addition, the language describing the results of EPA's supplemental statistical analysis of the short-tailed shrew data has been changed to de-emphasize the weakness of the statistical results; and the conclusion in the weight of evidence has also changed from "undetermined" to "yes." As discussed below, these changes fail to appropriately recognize the substantial uncertainty of the new MATC and of EPA's statistical results and the weakness of any apparent relationship between PCB exposure and effects on shrew survival.

No MATC was provided in the July 2003 ERA. In the November 2004 ERA, a MATC is derived based on a hockey stick regression between the arithmetic mean of tPCB concentrations in soil and shrew survival (EPA 2004a, Vol. 1, p. 10-43; Vol. 6, p. J-82, J-91, Figure J.4-9). In fact, this hockey stick regression can only be used with the arithmetic mean soil tPCB concentrations. If the spatially weighted average tPCB concentrations are used, the highest sediment tPCB concentration does not have the highest mortality (i.e., no evidence of an exposure-response relationship between tPCBs and mortality), and therefore the shape of the curve would not support a hockey stick regression (see EPA 2004a, Vol. 6, Figures J.3-8 and Figures J.3-9). The fact that the hockey stick regression can only be fit to the data based on one of the two exposure scenarios illustrates the weakness of any apparent PCB-related response. As a result, the MATC resulting from this analysis should be considered uncertain. In these circumstances, the ERA should be revised to explicitly acknowledge that the regression only works with one of the two exposure scenarios and to recognize the consequent weakness of any exposure-response relationship and the uncertainties associated with using this analysis as the basis for the MATC.

In addition, the language used in the November 2004 ERA to describe the results of the EPA reanalysis of data from the shrew demography study has been changed. The July 2003 ERA acknowledged that, although EPA's supplemental analysis found a significant relationship between concentrations of tPCBs in soil and survival of shrews from summer to autumn for males, females, and males and females together, the relationship was not strong (EPA 2003, Vol. 1, p. 10-54; Vol. 6, J-57, J-58). The text also indicated that because the slope of the regression model is not steep (EPA 2003, Vol. 6, Figures J.3-8 and J.3-9), survival was "only slightly reduced at the 'high' contaminated grids compared to the 'low' contaminated grids" (EPA 2003, Vol. 6, p. J-58). By contrast, the current text simply indicates that there was a significant relationship and that, based on the regression model, survival was reduced in the "high" contaminated grids compared to the "low" contaminated grids (ERA 2004a, Vol. 2, p. 10-32; Vol. 6, p. J-55).

This change in language substantially affects how the strength of EPA's reanalysis of the shrew survival data is communicated in the ERA. This revision is contrary to the spirit of the comments made by several of the peer reviewers, who indicated that the results of the shrew reanalysis were uncertain. For example, one peer reviewer (Forbes) stated that, "[g]iven the dependence of the statistical significance on subtle differences between two (seemingly) appropriate statistical methods, the most robust conclusion that can be made from this study is that the response is borderline" (EPA 2004b, p. 294). Other peer reviewers (Sample and Thompson) commented that while the Boonstra and EPA statistical analyses are different, both should be presented (EPA 2004b, pp. 297, 298), with reviewer Thompson noting that “[b]ottom line is that response is not strong” (EPA 2004b, p. 298). The change in language is also inconsistent with the statement made in the Responsiveness Summary that EPA “concurs with the comment that the conclusion from this study is that the dose-response relationships were not strong” (EPA 2004b, p. 52).

Although the differences between the statistical analyses are discussed (EPA 2004a, Vol. 6, p. J-66), the uncertainties associated with the statistical analyses – and not just the uncertainties associated with the study itself (EPA 2004a, Vol. 6, p. J-90) – should be addressed. Further, consistent with the peer reviewers’ comments and given that, as noted above, EPA’s hockey stick regression analysis can be fit to the data only using arithmetic means and not spatial average concentrations, the ERA should be revised to re-insert the language indicating that, even accepting EPA’s reanalysis, the relationship between PCB concentrations and shrew survival from summer to autumn is not strong.

In the weight-of-evidence analysis, the finding for evidence of harm has changed from “undetermined” (EPA 2003, Vol. 1, p. 10-58) to “yes” (EPA 2004a, Vol. 1, p. 10-36) despite the lack of any new data. There is no basis for this change. Considering the uncertainties associated with the contradictory findings of the Boonstra and EPA statistical analyses and the dependence of EPA’s hockey stick regression on one of the two exposure estimates (i.e., arithmetic means vs. spatially weighted averages), the finding for evidence of harm should remain “undetermined.”

7. *References*

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