U.S. Army
Corps of Engineers

New England District
Concord, Massachusetts

U.S. Environmental
Protection Agency

New England Region
Boston, Massachusetts

RESPONSIVENESS SUMMARY TO PUBLIC COMMENTS ON NEW INFORMATION ECOLOGICAL RISK ASSESSMENT FOR THE GE/HOUSATONIC RIVER SITE REST OF RIVER

DCN: GE-021705-ACOQ

March 2005

Environmental Remediation Contract
GE/Housatonic River Project
Pittsfield, Massachusetts

Contract No. DACW33-00-D-0006

Task Order 0003

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WESTON SOLUTIONS

RESPONSIVENESS SUMMARY TO PUBLIC COMMENTS ON NEW INFORMATION — ECOLOGICAL RISK ASSESSMENT FOR THE GENERAL ELECTRIC (GE)/HOUSATONIC RIVER SITE, REST OF RIVER

ENVIRONMENTAL REMEDIATION CONTRACT
GENERAL ELECTRIC (GE)/HOUSATONIC RIVER PROJECT
PITTSFIELD, MASSACHUSETTS

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Prepared for

U.S. ARMY CORPS OF ENGINEERS
New England District
Concord, Massachusetts

and

U.S. ENVIRONMENTAL PROTECTION AGENCY
New England Region
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LIST OF ACRONYMS

ANOVA	analysis of variance
CAE	chemical assimilation efficiency
COPC	contaminant of potential concern
CT DEP	Connecticut Department of Environmental Protection
DELT	deformities, erosions, lesions, and tumors
EPA	U.S. Environmental Protection Agency
ERA	Ecological Risk Assessment
EROD	ethoxyresorufin-O-dethylase
FEL	Fort Environmental Laboratories, Inc.
GE	General Electric Company
GOF	goodness of fit
HEAL	Housatonic Environmental Action League, Inc.
HRI	Housatonic River Initiative
IMPG	Interim Media Protection Goal
LOAEL	lowest observed adverse effect level
µg	microgram
MATC	Maximum Acceptable Threshold Concentration
NOAEL	no observed adverse effect level
PCB	polychlorinated biphenyl
PSA	Primary Study Area
ROR	Rest of River
SSD	species sensitivity distribution
TAG	Technical Assistance Grant
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
TDI	total daily intake
TEF	toxic equivalency factor
TEQ	toxic equivalence
TMA	Trout Management Area
tPCB	total PCBs
USGS	U.S. Geological Survey

INTRODUCTION

Introduction

This document presents the response from the U.S. Environmental Protection Agency (EPA) to comments received from the public pertaining to new information included in the Ecological Risk Assessment for the GE/Housatonic River Site, Rest of River (ERA). The June 2003 ERA was revised and reissued in November 2004 in response to comments and questions posed by a Peer Review Panel. The Peer Review was conducted by seven independent experts in the field of ecological risk assessment.

Under the terms of the Consent Decree, EPA was required to conduct an ecological risk assessment of the area referred to as the "Rest of the River," defined as the area of river and adjacent floodplain downstream from the confluence of the East and West Branches of the Housatonic River in Pittsfield, MA, and to conduct an independent Peer Review of the ERA. The conclusions of the ecological risk assessment, along with the conclusions from the human health risk assessment that was also conducted by EPA and underwent Peer Review, will be taken into account by GE when developing an Interim Media Protection Goals (IMPG) Proposal that will be submitted to EPA for review.

Following the Peer Review of the July 2003 draft of the ERA, EPA chose to exercise its option to revise and reissue the document in response to Peer Review comments. The revised ERA was issued on November 15, 2004, and EPA announced a 30-day public comment period, subsequently extended to 60 days, during which members of the public were invited to submit written comments restricted to the new information contained within the document. The public comment period closed on January 18, 2005. EPA received five sets of comments on the revised ERA. This document provides EPA's response to those comments.

Approach and Organization of this Document

The full text of each of the five sets of comments received and of comments excerpted from transmittal letters are reproduced in this Responsiveness Summary. The comments are presented alphabetically by commenter or group, as follows (the abbreviation used for each commenter throughout the document is enclosed in parentheses):

- State of Connecticut, Department of Environmental Protection (CT).
- General Electric Company (GE).
- Housatonic Environmental Action League (HEAL).
- Massachusetts Audubon Society (MAS).
- Technical Assistance Grant recipient – Housatonic River Initiative/Environmental Stewardship Concepts (TAG).

EPA carefully reviewed the comments from each of the above entities and identified appropriate locations within each set of comments to insert responses. Each response is identified by the abbreviation for the commenter followed by a sequential number. For example, the first response to comments from the State of Connecticut is identified as RESPONSE CT-1; the seventh response to comments from the Housatonic Environmental Action League is identified as RESPONSE HEAL-7. Each response is intended to address the comment or related series of comments immediately preceding it. In identifying appropriate locations for comments, EPA attempted to provide more comprehensive responses to related comments, as opposed to responding to individual sentences.

References used by EPA in responding to comments immediately follow the response. Although this in some cases requires citations to be repeated, it will allow readers interested in referring to the references to quickly identify those references that support a particular response.

Relationship of the Responsiveness Summary to the Ecological Risk Assessment for Rest of River

The Peer Review Panel reviewed the July 2003 draft Ecological Risk Assessment and comments provided to the Panel on that document by members of the public. A public Peer Review meeting was held in January 2004, after which the Panel submitted their final written comments on the document. At the beginning of the Peer Review process in 2003, EPA provided the opportunity for any party to submit written comments on the draft Ecological Risk Assessment to the Peer Review Panel during a public comment period. EPA also provided the opportunity for any party to comment orally (and in writing) at the January 2004 Peer Review Panel meeting. In June 2004, EPA produced a Responsiveness Summary to the Peer Review Panel comments.

EPA chose to revise the ERA, including new information as necessary, to respond to the Peer Review Panel comments; this resulted in the November 2004 revised Ecological Risk Assessment. The November 15, 2004 notice issued by EPA soliciting public comment on the new information stated that EPA was seeking comment on “only the new information contained in the risk assessment regarding risks to animals that live in or visit the river or floodplain.” This additional opportunity for input from the public to the process was provided at this site to continue to promote public involvement in the development of documents and the decision-making process for the Rest of River.

EPA provided paper and/or electronic copies of the November 2004 revised Ecological Risk Assessment to the site information repositories and interested Citizens Coordinating Council members, and also provided a detailed list of the new information included in the revised Ecological Risk Assessment, to facilitate identification and review of the new information. In addition, both the document and the list of new information were posted on EPA’s website. At the December 1, 2004 Citizens Coordinating Council meeting, EPA provided an overview of the changes to the ERA based on the Peer Review Panel comments and answered questions from the public regarding the new information and the comment period. At the request of members of the public, EPA granted an extension of the public comment period to 60 days, closing

January 18, 2005. If a comment received during the public comment period did not pertain to the new information presented in the ERA in response to comments from the Peer Review Panel, EPA did not provide a response in this Responsiveness Summary.

Together with this Responsiveness Summary, the November 2004 revised Ecological Risk Assessment now is considered to be the final ERA for the GE/Housatonic River Rest of River site. In addition to the opportunities described above that were available for the public to provide input to the Ecological Risk Assessment, pursuant to the Consent Decree, and the Reissued RCRA Permit (Appendix G to the Decree), all parties will have an additional opportunity to comment when EPA issues the Statement of Basis proposing a response action for the Rest of River.

COMMENTS OF THE STATE OF CONNECTICUT, DEPARTMENT OF ENVIRONMENTAL PROTECTION (CT)

Comments of the State of Connecticut, Department of Environmental Protection (CT)

EPA is currently accepting public comment, through January 18, 2005, on new information that was added to the Ecological Risk Assessment for the GE-Pittsfield/Housatonic River Site (the Site). This information was added in response to written comments provided by the Peer Review Panel. EPA has provided a listing of the new material added to the risk assessment, along with the revised Ecological Risk Assessment and the Responsiveness Summary, which provides EPA's responses to the Peer Review comments received. I have reviewed these documents in addition to the written comments provided by the Peer Review Panel in order to summarize these documents with respect to their applicability to Connecticut and within context of the proposed remedial process for the Site, identify issues of concern for the State, and provide comment to EPA.

Background

Polychlorinated biphenyls (PCBs) were released into the Housatonic River from the General Electric (GE) facility located in Pittsfield Massachusetts. These PCBs were subsequently distributed throughout the river, including portions within Connecticut (CT). As a result, fish consumption advisories have been in place for the CT portion of the river since 1977. GE is currently involved in the investigation/remediation of contamination at their facility, within the City of Pittsfield and within the river as a result of releases from their facility. This very large study area has been divided into several portions. The Housatonic River within CT is included in the Rest of the River portion of the Site that extends from the confluence of the East and West Branches of the Housatonic River two miles below the GE facility in MA, to the confluence of the Housatonic River with Long Island Sound in the Stratford/Milford Area. (See map in Appendix A) Because of the presence of PCBs downstream of the Derby Dam from sources other than GE, the practical limit of the study area within CT has been set at the Derby Dam.

As part of the regulatory process, Human Health and Ecological Risk Assessments have been prepared for the Rest of River portion of the Site. These documents were previously released and underwent public comment and a peer review process. The revised Ecological Risk Assessment has recently been released for public comment. This document will contribute to future regulatory decisions regarding what activities, if any, occur within the Connecticut portion of the river. In the future, GE will propose cleanup values and analyze alternatives. EPA will draft a Cleanup Plan, expected in 2007.

Summary Ecological Risk Assessment for CT Portions of the River

The Ecological Risk Assessment (ERA) was conducted to evaluate risks to ecological populations within the Rest of River (ROR) portion of the Site. The main focus of the ERA was the Primary Study Area (PSA), a 10.7 mile subset of the ROR area that is located in Massachusetts and extends from the confluence of the East and West Branches of the Housatonic River down to Woods Pond Dam. Extensive sampling of environmental media and biological communities occurred within the PSA. Ecological risks within CT were evaluated by identifying important biological communities within the State. These included benthic invertebrates, amphibians, warmwater fish (e.g. bass, sunfish, perch), coldwater fish (trout), mink, river otter and the bald eagle. Maximum Acceptable Threshold Concentrations (MATCs) for either sediment or biota (tissue) were developed based on the results of studies conducted within the PSA. These values are set as threshold concentrations between low and moderate risks. As such, they are not conservative concentrations delineating areas of "no risk" from "risk." Low to moderate levels of risk are associated with the MATCs.

The MATCs were used within the ERA to screen sediment and fish tissue data available for CT or were compared with the results of wildlife exposure modeling conducted for the mink, otter and bald eagle. A summary of the ERA evaluation and conclusions regarding risks for each organism is provided below:

<u>Benthic Invertebrates</u>: Two MATCs were developed to assess risks to this population. A benchmark for PCB concentrations in bulk sediment of 3 mg PCB/kg sediment was developed based on chronic toxicity tests using *Chironomus* and observed effects on the benthic community in the Primary Study Area in Massachusetts. Another MATC was developed using tissue concentrations reported in the scientific literature. The MATC of 3 mg/kg wet weight in tissues of the benthic organisms represents the concentration below which adverse effects were not reported in the studies examined. Based on comparisons to PCB concentrations in the upper 6 inches of sediments collected from various points in the river, and limited benthic tissue samples, EPA concluded that PCBs within the CT portion of the river pose a low risk of harm to the benthic community.

<u>Amphibians</u>: A soil and sediment MATC of 3.27 mg/kg tPCBs (total PCBs) was derived for the PSA based on developmental malformations observed in studies conducted on amphibians. This value represents the concentration of PCBs at which some sensitive endpoints (alteration of the gender ratio within the population studied) showed a response, but was not deemed as biologically relevant as the MATC based on malformations. Above this concentration, ecologically significant responses are expected. Sediment concentrations for the Housatonic River downstream of the PSA and into CT were used to evaluate potential effects on amphibians. Additionally, estimates of floodplain tPCB concentrations were made by interpolating the river based sediment values to the limit of the 100-year floodplain. In this manner, risks within the floodplain were also assessed. Sediment PCB concentrations within CT were below the MATC so amphibian populations were not identified as being at risk.

<u>Warmwater Fish:</u> A MATC of 55 mg/kg ww tPCBs in fish tissues was established to separate low risk groups from those exposed to intermediate or high risks. This value was derived based on results of studies on Largemouth Bass, evaluating accumulation of PCBs and potential reproductive/developmental effects. Additionally, studies conducted on warmwater fish and rainbow trout to simulate the maternal transfer of PCBs to oocytes were also considered. Literature based tissue concentration thresholds were developed but not included in the MATC. The literature based value was lower than that derived from the studies conducted as part of the ERA. However, EPA determined that there was a higher level of uncertainty associated with the literature studies. Tissue concentrations in warmwater fish (bass, perch, sunfish) collected in CT were evaluated using the MATC of 55 mg/kg ww in fish tissue. Tissue concentrations in warmwater fish collected in CT were below the MATC.

<u>Coldwater Fish (Trout):</u> A MATC of 14 mg/kg ww tPCBs in fish tissues was established based on the MATC for warmwater fish species, divided by a factor of 4 to account for potential differences in sensitivities between the different species. The MATC separates low risk groups from those exposed to intermediate or high risks. In order to evaluate risks to trout, warmwater fish data, and/or trout fillet data were used to estimate whole body trout concentrations. These estimates indicate that whole body trout concentrations within CT should be below the MATC for trout. Risks to trout were not evaluated downstream of Reach 12 (Bull's Bridge). EPA did not believe that there was suitable trout habitat below Bulls Bridge Dam. However, there is the Bull's Bridge Trout Management Area, which extends from the Bull's Bridge Impoundment to the Gaylordsville Bridge (Route 7) in New Milford.

RESPONSE CT-1: In western Connecticut, CT DEP opened a new Trout Management Area (TMA) in 2002 (Bull's Bridge TMA) that is open year-round as a catch-and-release only fishery. According to CT DEP (Barry, pers. comm. 2005), in addition to trout stocked in this area, there are some wild trout that are associated with small feeder tributaries to the Housatonic River (e.g., Ten Mile River). These fish are found primarily in the stretch of the Housatonic River between Bull's Bridge Dam and Gaylordsville, CT, with very low numbers of trout found farther downstream.

The establishment of the Bull's Bridge TMA does not affect the fish risk characterization provided in the November 2004 ERA, for the following reasons:

<u>(1) Suitability of Spawning Habitat</u> - The Bull's Bridge TMA was sampled a number of times prior to stocking of brown trout. Wild brown trout are present in the area, but are present only at a "low level" (Humphreys, pers. comm. 2005). Important limiting factors for trout habitat downstream of the Bull's Bridge Dam are thermal stress (i.e., periodic increases in water temperature) and alterations in flow regime related to regulation of the river by the Bull's Bridge and Falls Village hydropower stations. A few young-of-year (i.e., non-stocked) trout have been observed, but the level of reproduction in this reach is not adequate for sustaining a significant natural fishery (Humphreys, pers. comm. 2005). EPA acknowledges that the term "lack of suitable habitat" used in ERA Section F.4.6.2 requires clarification. A more precise statement is that trout spawning activity downstream of Reach 12 occurs only at a low level relative to upstream coldwater habitats in the Housatonic River in northern Connecticut and is insufficient to sustain a natural fishery.

<u>(2) Relevance of MATC to Stocked Fish</u> – The PCB MATC for trout is intended to be protective of reproduction, because reproductive endpoints were shown to be more sensitive than survival or growth in older fish (in both literature-based and site-specific effects assessments). The life stage of greatest biological sensitivity to PCBs is fry development (swim-up and post swim-up fry). The trout in the Housatonic River TMAs are stocked at an age and size (9 to 12 inches) that is well beyond the sensitive life stages, which were the basis for the development of the MATC.

(3) Tissue concentrations of PCBs in Reach 13 fish (and farther downstream) are lower than those observed in Reach 12. Because the measured/estimated whole body concentrations in Reach 12 fish were demonstrated to be below the MATC, estimates of Reach 13 fish tissue concentrations would therefore also not exceed the MATC, even for the few wild trout present. Therefore, the overall risk conclusion for downstream reaches of the Housatonic River remains as stated in the November 2004 version of the ERA.

The fillet tPCB concentrations in brown trout and rainbow trout samples collected from Reach 13 were 2.0 mg/kg ww and 2.4 mg/kg ww, respectively (BBL and QEA 2003). Fillet tPCB concentrations in all other species collected in Reach 13 since 1990 (n=91 individual measurements including smallmouth bass, yellow perch, and centrarchid sunfish) were nearly all below 2 mg/kg ww, and the maximum individual tPCB fillet concentration measured was only 3.8 mg/kg ww. Even following extrapolations from fillet to whole-body measurements and interspecies extrapolations (as described in the ERA), these concentrations would not exceed the MATC for trout of 14 mg/kg ww. Therefore, the risk characterization for the few reproducing wild trout in Reach 13 remains as "low risk."

References:

Barry, T. 2005. Personal communication. Telephone conversation between Tim Barry (Connecticut Department of Environmental Protection, Bureau of Natural Resources, Fisheries Division, Western Connecticut) and Gary Lawrence (EVS Environment Consultants, North Vancouver, BC) regarding wild trout habitat within the Bull's Bridge Trout Management Areas (TMA) on the Housatonic River. February 8, 2005.

BBL (Blasland, Bouck & Lee, Inc.) and QEA (Quantitative Environmental Analysis, LLC). 2003. *Housatonic River – Rest of River RCRA Facility Investigation Report*. Prepared for General Electric Company, Pittsfield, MA. September 2003.

Humphreys, M. 2005. Personal communication. Telephone conversation between Michael Humphreys (Fisheries Biologist, Connecticut Department of Environmental Protection, Inland Waters Division) and Gary Lawrence (EVS Environment Consultants, North Vancouver, BC) regarding trout habitat downstream of Bull's Bridge and evidence of lesions on Connecticut portions of the Housatonic River. February 9, 2005.

Mink and River Otter: A MATC of 0.984 mg/kg tPCBs in fish was developed based on the mink kit survival from 0 - 6 weeks in a single, long-term feeding study on captive mink exposed to fish collected from the Primary Study Area in Massachusetts. Dietary exposures to mink and river otter were based on the proportion of contaminated prey items (fish and crayfish) likely contained in their diets. Since data for tPCB concentrations in crayfish tissue was not available for the rest of river study area, crayfish concentrations were assumed to be equal to fish tissue concentrations. Based on these assumptions, it was assumed that 59% of the diet of mink and

100% of the diet of river otter were composed of fish/crayfish. Mink and river otter were identified as potentially at risk from the CT/Massachusetts border down to the Stevenson Dam on Lake Zoar.

Bald Eagle: Risks to bald eagles were evaluated based on toxicity estimates from a surrogate species as well as modeled concentrations to estimate accumulation of PCBs in eggs. The MATC of 30.41 mg/kg tPCBs in fish was developed based on a determination of the threshold at which the total daily intake of PCBs for an eagle would exceed the toxicity threshold for tPCBs in eggs. The diet of eagles was assumed to consist of 83.4% fish and 16.1% waterfowl. EPA assumed that the waterfowl consumed during the winter were likely to have migrated to the Housatonic Area from northern locations, and therefore, were unlikely to contain PCBs. However, it is the experience of CT DEP Wildlife staff that waterfowl residing in CT during the winter are likely to remain in the area for extended periods of time, allowing for potential uptake of contaminants such as PCBs.

RESPONSE CT-2: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Additionally, there are no data available to substantiate the assumption that waterfowl caught within CT do not possess a body burden of PCBs. CT DEP has data from only one duck collected within the Housatonic Basin, and tissue concentrations of PCBs were elevated.

RESPONSE CT-3: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Finally, it must be noted that there are bald eagles that reside within the basin for the entire year. Assumptions made regarding contaminant concentrations in the diet of overwintering eagles may not apply to those eagles that reside throughout the entire year.

RESPONSE CT-4: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

An additional evaluation of risks to bald eagles breeding within the study area was conducted within the ERA. The study focused on a breeding pair of bald eagles located south of Interstate 84. It was assumed that this pair would forage in the southern reach of Lake Lillinoah and within Lake Zoar. Low, moderate and high tPCB intake rates were evaluated and compared with the MATC. Risks to bald eagles within CT were determined to be low.

Note: In Appendix K - Survival, Growth and Reproduction of Threatened and Endangered Species, reference is made to a personal communication of Ms. Julie Victoria, CTDEP, with Woodlot Alternatives Inc. on December 12, 2002. Ms. Victoria's name is misspelled throughout the Appendix as "Bictoria".

Revised ERA - Outstanding Issues

Under the current comment period EPA has established that only issues raised during the peer review process or modified within the risk assessment in response to comments are available for further discussion.

> **RESPONSE CT-5:** To clarify the purpose of this comment period paraphrased in the comment above, as stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information included in the November 2004 revised Ecological Risk Assessment in response to Peer Review comments, and is responding only to comments that pertain to the new information.

There are two issues that were raised during the peer review process that pertain to Connecticut: 1) the characterization of the river within the rest of river segment which includes CT; and 2) the derivation of Maximum Acceptable Threshold Concentrations. These issues will be discussed below.

1: Characterization of the Housatonic River within Connecticut

Peer Review Comments:

Several members of the Peer Review requested justification for the reduced sampling within CT or recommended that the river within CT be better characterized. Several reviewers specifically identified sediments behind the dams as areas that could accumulate higher concentrations of PCBs in sediments.

EPA Response:

EPA disagreed and asserted that adequate characterization of the physical, ecological and cultural aspects of the river were provided. EPA also sited the inclusion of historical data as well as additional samples collected as part of the ERA.

Summary of CT DEP Response:

The characterization of PCBs within abiotic and biotic media in CT is limited and prevents a complete evaluation of risk to ecological receptors at this time. The limitations of the characterization arise from the difficulty in precisely characterizing such a large area as the Housatonic River within the State. The data contained within the current draft of the ERA is sufficient to provide a limited assessment of risks within CT. However, the inadequacies in the dataset, both regarding the number and type of samples collected, prevent reaching a definitive conclusion regarding risks within all reaches of the river in CT at this time. Additionally, potential future risks from mobilization or migration of deeper bedded sediments were not included in the risk assessment.

Discussion:

The current revisions to the Ecological Risk Assessment do not adequately address concerns regarding the environmental characterization within Connecticut. This is of particular importance given that future activities within the river to address PCBs are based, at least in part, on the conclusions of the human and ecological risk assessments.

The Ecological Risk Assessment reflects the following summary provided in the Executive Summary (pages ES-1 to ES-2) in several places throughout the report:

> "The purpose of this ecological risk assessment (ERA) is to **characterize and quantify the current and potential risks to biota** exposed to contaminants of potential concern (COPCs) in the Housatonic River below the confluence of the East and West Branches (known as the "Rest of River"), **focusing on polychlorinated biphenyls (PCBs) and other hazardous substances** originating from the General Electric Company (GE) facility in Pittsfield, MA." (Emphasis added)

Additionally, Section 1.3 (Regulatory Background) of the revised report states:

> "The ecological risk assessment, together with the human health risk assessment and the model of PCB fate, transport, and bioaccumulation, **will inform EPA's decision on what additional remedial actions, if any, may be required** in the river and floodplain downstream of the confluence." (Emphasis added)

The adequacy of the characterization of the Rest of River area is germane both to the ERA as well as to potential future activities/requirements for the Connecticut portion of the river. In response to comments expressing concern about the limited amount of data collected within CT, EPA stated that the characterization was adequate. However, given the stated purpose of the risk assessment, the characterization of current and potential risks, and the potential implications of its conclusions, a further evaluation of the adequacy of the characterization within CT is warranted.

Consider a practical illustration of this matter - a new project, possibly a new road project, maintenance of a dam, installation of a fish ladder or a fishing pier, is proposed within the Housatonic River somewhere in Connecticut. Is there sufficient information available within the ERA to quantify the PCB concentrations within the proposed project area? Is there sufficient information available within the ERA to determine that PCBs do not pose an environmental risk within the project area? The answer to both questions is "no." The level of detail present within the ERA is insufficient to adequately characterize the levels of PCBs with a high level of detail. Any future activities within the river cannot rely on the environmental characterization of the PCB levels in the river as present within the risk assessment to define the scope of the PCBs within the project area. Similarly, this lack of specificity creates uncertainty regarding potential risks to environmental receptors due to exposures to PCBs, currently and in the future.

The study area within the CT portion of the river encompasses approximately 72 river miles. This is a very large area to definitively characterize. It would take a huge effort, much time and great expense to explicitly identify and quantify PCBs within an area this large. So, while a large number of samples may contribute to the existing risk assessment, it is not sufficient to definitively quantify the nature and extent of contamination within CT. There is not sufficient information available to **specifically** identify PCB concentrations within various portions of the river. There is sufficient information to **generally** identify PCB concentrations within surficial sediments in the river. It is this general, surficial data that serves as the basis for the ERA.

There are several problems with this approach that must be considered as the river restoration process moves forward. First, by restricting the evaluation of risk to the consideration of surficial sediments, EPA is assuming that the river is static; that in the future there are no opportunities for deeper sediments to become mobilized and influence the concentrations of PCBs available within biologically active sediment horizons. Consideration of surficial sediments may address **current** risks, but will not necessarily address **potential** risks, as identified within the purpose for the risk assessment. There is limited data available for deeper sediments, mostly from samples collected in association with the dams on the river. However, this limited data set does identify higher concentrations of PCBs at depth within some areas. Some of these concentrations exceed the MATC values used by EPA, indicating that risk to various populations may occur if the deeper sediments were made available.

Secondly, there is the practical aspect that the risk assessment cannot assure that there are not significant areas with elevated PCB levels within the river. It was not possible to sample all major depositional areas within CT, for example. And so, the conclusions presented within the ERA must be viewed with the understanding that they pertain to the current dataset but cannot be taken as a definitive characterization for all portions of the river within CT.

The characterization within CT is also incomplete due in part to the omission of contaminants of concerns evaluated within the PSA in addition to PCBs. For example, within the PSA, risks to the benthic invertebrate community were evaluated relative to exposures to dioxins/furans, metals, dibenzofuran and PAHs in addition to total PCBs. Exposure to these additional constituents potentially increases risks to exposed populations. The lack of inclusion of these substances within the CT portion of the study is inconsistent with the goals of the ERA, to characterize and quantify the current and potential risks to biota focusing on polychlorinated biphenyls (PCBs) and other hazardous substances originating from the General Electric Company (GE) facility in Pittsfield, MA. The omission is understandable due to the practical consideration that the historical datasets that comprise a substantial part of the ERA data did not include these substances. However, the lack of inclusion of these substances in the rest of river evaluations and the lack of consideration, even indirectly, of these substances to contribute to risk within CT is a data gap and contributes uncertainty to the conclusions reached in the ERA and may underestimate risks to ecological populations within CT.

Additionally, adequate descriptions of the sampling locations within CT are not provided within the report. It is not possible to determine if the sediment samples were obtained from depositional areas, or were from areas less likely to accumulate PCBs, for example. The details of the sampling locations and sediment type are important factors for characterizing the sediments within CT and interpreting the available data.

Finally, there was limited sampling of biological communities within CT. I do not believe that it is necessary to conduct additional toxicity studies within CT as were conducted within the PSA. However, additional sampling of biological tissues within CT may be needed. There are limited data for fish and benthic invertebrates. However, there is no data available for waterfowl. Waterfowl have accumulated PCBs within Massachusetts. Additionally, CT DEP has data from one duck collected within the Housatonic River basin that had elevated PCB levels.

Recommendations - Characterization of CT

These criticisms underscore the difficult nature of the task undertaken to evaluate ecological risks within the Housatonic River in CT. To summarize, the ERA provides an overview of the general risks experienced by ecological populations within CT exposed to surficial sediments under current conditions. However, the report does not present sufficient data to definitively assess ecological risks within CT. Additionally, the report did not adequately assess potential risks that could occur if bedded sediments with higher concentrations of PCBs were mobilized. Therefore, revisions to the ERA to address these issues are recommended.

> **RESPONSE CT-6:** EPA provided a response to the issue of sampling and risk characterization in Connecticut in the Responsiveness Summary to the Peer Review (see response to General Issue No. 5). The Ecological Risk Assessment was not revised on this matter subsequent to the Peer Review meeting; therefore, this comment is outside the scope of this public comment period and Responsiveness Summary.

2: Maximum Acceptable Threshold Concentrations

Peer Review Comments:

The Peer Review Panel made several comments regarding the derivation of the MATC values. The comments focused on the method by which the values were derived, such as separating acute and chronic endpoints, eliminating redundancy, defining the most appropriate data to use, etc. The Reviewers had differing opinions regarding the conservatism of the MATC values.

EPA Response:

EPA agreed with most of the recommendations and made changes within the documents. These changes, however, did not change the conclusions from the first draft ERA to the revision.

Summary of CT DEP Response:

The MATC values developed within the risk assessment provide a means to evaluate risks to ecological communities and are sufficient for the purposes of the ERA. However, these values may not reflect acceptable thresholds from a environmental management perspective for ambient

PCBs within the environment. Such discussions are most appropriate during the evaluation of cleanup goals for the river.

Discussion:

The MATC values for the various endpoints were established to separate populations experiencing lower levels of risk from those exposed to intermediate/high risk levels. The different MATC values have differing levels of conservatism, depending upon the strength of the data used and the interpretation of the data. Within the context of the ERA, the MATC values serve a useful purpose, allowing the qualitative evaluation of risks within Connecticut. These concentrations, however, have been established within a risk assessment, and, in accordance with EPA Guidance, separate from the risk management process but considering general management goals. These values are not numeric interpretations of acceptable environmental concentrations established in accordance with State policy statements, such as the Connecticut Water Quality Standards. In accepting the qualitative assessment of risks within CT, CT DEP does not imply that the MATC values are numeric interpretations of our policy nor do we agree, at this time, that these values are acceptable ambient concentrations of PCBs, beyond which there are no risks, or acceptable risks, to the ecosystem within our State. It is beyond the scope of the risk assessment to discuss the way these MATC values may be used, if at all, in future risk management decisions. Acceptable ambient values based on State policy must be addressed as the remedial process for the river moves forward.

Recommendations – MATC

CT DEP accepts the use of the MATC within the context of the ERA for delineating exposures to PCB concentrations with lower risks from those associated with moderate/high risks. As such, they are not conservative concentrations delineating areas of "no risk" from "risk.” Low to moderate levels of risk are associated with the MATCs.

However, it is noted that the level of risk associated with these values (intermediate risk to exposed populations) is not necessarily consistent with management goals for the river. I recommend that the CT portions of the Housatonic River be considered during the future phases of remedial investigation and implementation, especially during the development of remediation goals. I am not recommending changes to the ERA regard MATC values.

> **RESPONSE CT-7:** The commenter does not request a change to the Ecological Risk Assessment with this comment. This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Summary

I support the screening level approach to evaluating risks to ecological communities in CT used within the ERA. However, due to the weakness associated with the characterization of the ambient PCB concentrations within the river and within associated biological communities, a definitive characterization of risks within all areas of the river in CT is precluded.

RESPONSE CT-8: Please refer to Response CT-6.

Additionally, future risks from potential releases of bedded sediments that contain higher levels of PCBs were not evaluated.

RESPONSE CT-9: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

I recommend that these deficiencies be addressed within revisions to the ERA. Additionally, remedial goals established consistent with management objectives for the river must be established as part of the remedial process.

RESPONSE CT-10: The process set forth in the Consent Decree, and in Appendix G to the Consent Decree, requires that GE propose Interim Media Protection Goals (IMPGs), preliminary goals that are shown to be protective of human health and the environment and that will serve as points of departure in evaluating potential corrective measures. This comment does not address new information included in the November 2004 revised Ecological Risk Assessment.

COMMENTS OF THE GENERAL ELECTRIC COMPANY (GE)

Comments of the General Electric Company (GE)

The following comment was excerpted from the cover letter accompanying GE's comments on the November 2004 draft of the Ecological Risk Assessment:

GE appreciates the opportunity to submit comments on the new information and analyses in the revised ERA. We note for the record, however, that this opportunity is only part of the process that should be followed with respect to such new information and analyses. The Consent Decree requires, in Paragraph 22.d, that EPA's ERA be subject to peer review by a panel of independent risk assessment experts. That requirement contemplates that all significant analyses and conclusions in the ERA be subject to such peer review. In this case, EPA has added new analyses and conclusions to the ERA that were not included in the July 2003 draft and thus have not been subject to peer review. These include a new analysis for a receptor (wood ducks) that was not included in the July 2003 draft at all and new or changed statistical analyses of the data on benthic invertebrates, mink, and shrews.

> **RESPONSE GE-1**: The process undertaken by EPA is consistent with the relevant provisions of the Consent Decree. As described above in the Introduction to this Responsiveness Summary, the July 2003 version of the Ecological Risk Assessment did undergo Peer Review, including a 4-day public Peer Review meeting in January 2004. In the Peer Review process, the panelists recommended particular areas for follow-up by EPA. Pursuant to that direction, EPA gathered additional information and has solicited an additional round of public comment on such information. The fact that EPA followed up on specific recommendations of panelists and solicited public comment on new information does not mean that EPA is required to convene another peer review process at this point. Also, as noted above, all parties will be provided an additional opportunity to comment when EPA issues the Statement of Basis proposing a response action for the Rest of River.

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:

- <u>Benthic invertebrates</u>: 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.

    RESPONSE GE-2: The EPA response to the summary GE comments concerning the benthic invertebrate assessment endpoint is provided below in the detailed response to comments.

- <u>Wood frogs</u>: 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.*

RESPONSE GE-3: The EPA response to the summary GE comments concerning the amphibian assessment endpoint is provided below in the detailed response to comments.

- 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.*

RESPONSE GE-4: The EPA response to the summary GE comments concerning wood duck as a representative species in the insectivorous bird assessment endpoint is provided below in the detailed response to comments.

- 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.*

RESPONSE GE-5: The EPA response to the summary GE comments concerning tree swallows as a representative species in the insectivorous bird assessment endpoint is provided below in the detailed response to comments.

- 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.*

RESPONSE GE-6: The EPA response to the summary GE comments concerning the piscivorous mammal assessment endpoint is provided below in the detailed response to comments.

- Shrews: 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."*

RESPONSE GE-7: The EPA response to the summary GE comments concerning the omnivorous and carnivorous mammal assessment endpoint is provided below in the detailed response to comments.

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.

RESPONSE GE-8: The EPA response to these comments is provided below for each of the three points raised by GE, respectively.

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 (28day), 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. 56), 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 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.

[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).

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

RESPONSE GE-9: EPA disagrees that the approach to developing a chronic threshold applied in the revised ERA contradicts the intent of the Peer Review comments, and also disagrees that the approach is contrary to EPA's statements in the Responsiveness Summary. Both the Peer Review Panel and the Responsiveness Summary indicated that the full range of toxicity endpoints should be considered in the MATC derivation, and this was done in November 2004 ERA. The response to General Issue 6.F in the Responsiveness Summary stated:

> *EPA agrees that the toxicity thresholds for multiple endpoints should be considered. However, the analysis must also take into consideration the sensitivity of the test endpoints, in terms of exposure type/duration, the tolerance of the test organisms, and the relevance of the measurement endpoint to the Assessment Endpoint. It should also be recognized that investigators commonly include collection of data for a variety of metrics that may not necessarily reflect the impact of a stressor on the test organism, and may therefore not be appropriate for development of a toxicity threshold. In the revised ERA, EPA will develop MATCs based on*

consideration of all species and endpoints relevant to the Assessment Endpoint, but with the recognition that the conclusions and actions based on the risk assessment must be protective.

EPA did in fact evaluate the full range of endpoints in the *Hyalella* and *Chironomus* tests in the derivation of the chronic toxicity threshold. However, consideration of the full range of endpoints is not synonymous with simple application of an arithmetic mean, geometric mean, or other measure of central tendency of the threshold concentrations of all endpoints. Neither the Peer Review comments nor the Responsiveness Summary indicate that EPA should calculate a simple measure of central tendency.

There was not consensus among Peer Review Panel members regarding the details of the calculation method for deriving toxicity thresholds. However, the Panel indicated a preference for evaluation of the range of endpoint sensitivities, preferably using a distributional approach (such as the species sensitivity distribution [SSD]; see Response 3.1-TL-4). Unfortunately, the number of species and endpoints available for chronic MATC derivation were only six and two, respectively, because the Panel also indicated a preference for the separation of endpoints into acute versus chronic and for the elimination of "redundant endpoints." While six endpoints is inadequate for application of a quantitative SSD, a semi-quantitative integration of the six endpoints was conducted by EPA that considered the following factors: endpoint sensitivity; effect size; statistical power; consistency of responses across treatments (e.g., 28-d, 35-d, and 42-d reproduction); and biological relevance.

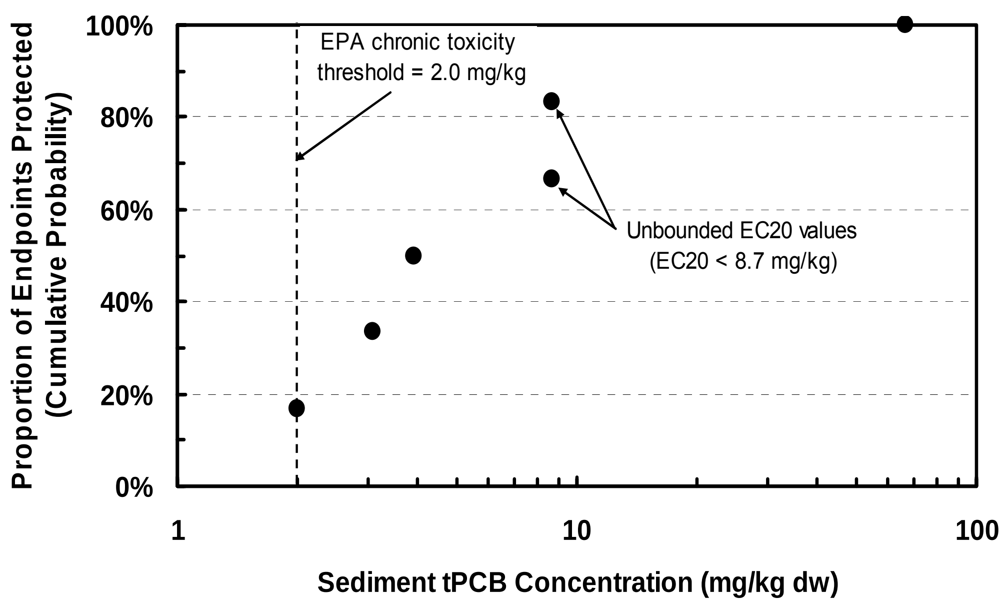
Use of a geometric mean, or any other averaging procedure, was not specified by the Peer Review Panel. Use of such a procedure effectively dilutes the results of sensitive endpoints with results of insensitive endpoints, such that the derived threshold value is not protective of a large proportion of the endpoints. In fact, one Peer Reviewer (see Response 3.1-VF-6) indicated that use of the most sensitive endpoint for each species was an acceptable approach once the data were separated into acute and chronic endpoints.

EPA believes that GE's proposed chronic toxicity threshold is not adequately protective because it fails to protect against effects for the majority of test endpoints. The lack of protectiveness of GE's proposed threshold is illustrated in Table 2.1 in the GE comments. Use of an overall geometric mean (LC_{20}/IC_{20}) in the derivation resulted in a threshold (7.0 mg/kg tPCB) that is clearly not protective of *Chironomus* growth, *Hyalella* survival, or *Hyalella* reproduction. In addition, the 7.0 mg/kg tPCB threshold may not be protective of *Chironomus* survival or *Chironomus* emergence, given that the thresholds used in the calculation were unbounded (i.e., <8.7 mg/kg) and were very close to the calculated value of 7.0 mg/kg tPCB. Therefore, only one of the six chronic endpoints is adequately protected using the calculation method proposed by GE.

The GE calculations of MATCs are strongly influenced by the absence of a sensitive *Hyalella* growth response, which led to high threshold values for that individual endpoint. Because the exact mechanism for PCB toxicity in aquatic invertebrates is unknown, lack of a growth response should not substantially weaken the evidence from other biologically-relevant endpoints, particularly mortality. If a threshold does not protect against mortality to an organism, it is illogical to assert that a higher threshold can be justified simply by averaging with less sensitive sublethal endpoints.

EPA, in considering the full range of chronic toxicity endpoints, sought to derive an MATC that would be protective of survival, growth and reproduction endpoints for the aquatic invertebrates found in the field. Consistent with the SSD approach used in ERA Attachment D.7, the transition from low to intermediate risk was defined using the approximate 20^{th} percentile of the distribution (see Figure GE-9-1). In establishing water quality criteria, the 5^{th} percentile is often chosen as the value considered protective for most species in a community (Posthuma et al. 2002). However, EPA selected a 20^{th} percentile to be consistent with risk definitions applied elsewhere in the ERA, and considering the sensitivity of the laboratory test species.

Figure GE-9-1. Distribution of LC_{20}/IC_{20} Values from Chronic Toxicity Endpoints (Survival, Growth, Reproduction) for *Hyalella* and *Chironomus*



The approach presented in Figure GE-9-1 is consistent with the requests of the Peer Reviewers that EPA consider all the available endpoints, and that consideration be given to distribution-based methods for evaluating sensitivity. A formal species sensitivity distribution (SSD) could not be applied because there were only two species with chronic toxicity endpoints (*Hyalella* and *Chironomus*).

However, both chronic test species indicated either mortality or ecologically relevant sublethal effects at concentrations close to the 2.0 mg/kg threshold. *Hyalella* exhibited 20% responses to both the survival and reproduction endpoints at 3.1 and 3.9 mg/kg, respectively, whereas *Chironomus* exhibited 20% responses to the survival and reproduction endpoints at 2.0 and <8.7 mg/kg, respectively (i.e., unbounded effect concentration).

Even if the toxicity thresholds (i.e., thresholds at which 20% effects to survival, growth, or reproduction occur) for the two species were averaged, the resulting chronic toxicity threshold would be 2.5 mg/kg, which is only slightly higher than the 2.0 mg/kg threshold that coincides with the most sensitive individual endpoint. This demonstrates that the two chronic tests were in strong agreement and that the chronic toxicity threshold was not driven by an anomalous individual endpoint result.

Part of GE's criticism of the EPA's threshold derivation stems from the use of 20% effect levels in calculating thresholds. The selection of effect sizes representing low, intermediate, and high risk did not change between the July 2003 and November 2004 ERA versions; therefore, this comment does not apply to the new information contained in the November 2004 revised Ecological Risk Assessment. As stated previously, in this Responsiveness Summary, EPA is responding only to comments made on new information added to the November 2004 revised Ecological Risk Assessment.

References:

Posthuma, L., T.P. Traas, and G.W. Suter II. 2002. General introduction to species sensitivity distributions. Chapter 1 in L. Posthuma, G.W. Suter II, and T.P. Traas. *Species Sensitivity Distributions in Ecotoxicology*. Boca Raton, Lewis Publishers. pp. 3-10.

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.

RESPONSE GE-10a: EPA did not derive separate community-based threshold PCB concentrations for coarse- vs. fine-grained sediment due to larger uncertainties in the dose-response relationships for fine-grained sediments. These uncertainties included:

- Sample size – For fine-grained sediments, there was only one reference location (R4; total of 12 replicates) available for comparison against the fine-grained contaminated sediment in the PSA. This is in contrast to the coarse-grained stations, for which three separate reference stations (A1, A2, A3; total of 36 replicates) were collected.
- Proximity and relevance to exposed PSA habitat – Because no suitable fine-grained reference habitat could be located within the Housatonic River, the R4 reference location was 13 miles south of the PSA, at Threemile Pond. Although the particle size distributions of the reference sediment were similar to the contaminated stations, uncertainty remains with respect to whether this single station located outside the main channel of the Housatonic River is truly representative of the downstream areas of the PSA.
- Variability in assemblages – The fine-grained PSA habitats exhibited a large degree of inter-station variability in the invertebrate abundance and biomass. As shown in Figure D.3-23 of the November 2004 ERA, the fine-grained locations exhibited qualitative differences in benthic communities among stations, possibly related to variations in surrounding riparian habitat (wet meadow, shrub swamp, shallow emergent marsh). These natural variations complicated the assessment of contaminant dose-response to some extent.
- Exposure concentration range – The sediment tPCB exposure concentrations measured in fine-grained benthic community grab samples tended to be lower than PCB concentrations measured in adjacent sampling conducted in fine-grained PSA reaches. For example, three of four contaminated stations had mean and median tPCB concentrations below 5 mg/kg tPCB. Combined with large PCB heterogeneity at the micro-scale, this made discrimination of significant dose-response relationships difficult, because the ratio of variability to concentration gradient was large.

In light of these uncertainties, a single community-based threshold was developed for the PSA. The threshold is intended to provide protection for not only the substrate types evaluated in the community study (which were standardized among stations during sampling, to the extent possible), but also for other substrates that are intermediate between (or slightly different from) the tested substrates. It was not practical to evaluate all substrate types found in the

PSA; therefore, extrapolation of findings to different substrate types was necessary. Although EPA agrees that the evidence of community impairment in fine-grained sediment is not as compelling as in coarse-grained sediments, it is unclear to what extent this degree of observed impairment results from the uncertainties described above, as compared to systematic differences in environmental responses across habitats. Consequently, the benthic community threshold places greater weight on the effects observed in coarse-grained sediment.

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.

RESPONSE GE-10b: Calculations of both Shannon-Wiener and Simpson's Index were provided in response to the request of the Peer Reviewers that the Shannon-Wiener results not be discarded (see Responsiveness Summary Specific Response 3.1-TT-12; response to General Issue 11.A). The criticisms of Shannon-Wiener H' in the Peer Review comments were based mainly on the presumed insensitivity of the index for communities that exhibit low species richness. As indicated in the Responsiveness Summary (see Response 3.1-TL-3), one reviewer claimed that Shannon-Wiener "is an insensitive measure of the relative frequency of species" (May 1975) and does not consider "differences in species taxonomy among sites." The Housatonic River results indicate that Shannon-Wiener H' was actually more sensitive to differences in coarse-grained sediment, exhibiting the highest regression r^2 and lowest p-value of all three diversity measures. The other criticisms of the Shannon-Wiener Index raised by the Peer Reviewers can also be made with regard to all simple diversity indices, and therefore cannot be used as a rationale for favoring one diversity index over another.

All diversity indices have limitations, both theoretical and practical in nature, and a number of reviews have been conducted to evaluate the various merits and limitations of simple diversity indices (Washington, 1984; Hill 1973; May 1975). For example, Washington (1984) has criticized application of Shannon-Weiner H' due to “lack of exploration of biological relevance,” whereas Hill (1973) has criticized the Simpson index as being a measure of "dominance concentration" because it is sensitive to the abundance of only the more plentiful species. There are also conflicting opinions regarding the relative sensitivity of various diversity indices. In contrast to the opinion offered during Peer Review (see Response 3.1-TL-3), in some cases Shannon’s index has exhibited lower variation and more sensitivity to impairment than Simpson’s index (Rabeni et al. 1997).

Based on the available information, there is no reason to consistently adopt one diversity metric over another. However, the benthic community data suggest that there is a rationale for selecting the most sensitive diversity metric in effect threshold derivation. This is due to the observed heterogeneity in responses of individual taxa to PCBs, an aspect of the benthic community analysis that was requested by the Peer Review Panel before and during the ERA Document Overview meeting. When individual taxa were evaluated (e.g., at genus and species level), it was observed that several taxonomic groups were relatively tolerant of PCB contamination, whereas others were highly sensitive. When the benthic communities are viewed using broad metrics (e.g., abundance, richness, diversity), significant perturbations to the benthic community were often present but could not be discriminated using simple diversity indices alone. This suggests that the more sensitive diversity-based thresholds are more likely to represent the actual environmental concentrations at which ecological responses occur in the Housatonic River. This theory was supported by results of the species sensitivity distribution (SSD) analysis (Attachment D.7 of November 2004 ERA), which yielded effects thresholds similar to the lower bound of the diversity-based thresholds.

EPA disagrees that the results of the diversity-based thresholds should be derived using a geometric mean or other measure of central tendency. That approach would yield thresholds that are not sufficiently protective, for the same reasons described above.

References:

Hill, M.O. 1973. Diversity and evenness: a unifying notation and its consequences. *Ecology* 54: 427-432.

May, R.M. 1975. Patterns of species abundance and diversity. In M.L. Cody and J.M. Diamond (Eds.). *Patterns of Species Abundance and Diversity*. Harvard University Press, MA. pp. 81-120.

Rabeni, C.F., R.J. Sarver, N. Wang, G.S. Wallace, M. Weiland, and J.T. Peterson. 1997. *Biological Criteria for Streams of Missouri: A Final Report to the Missouri Department of Natural Resources from the Missouri Cooperative Fish and Wildlife Research Unit*. November 1997. Cooperative Fish and Wildlife Research Unit, University of Missouri, Columbia, Missouri.

Washington, H.G. 1984. Diversity, biotic and similarity indices. A review with special relevance to aquatic ecosystems. *Water Research* 18:653-694.

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	`	[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.

RESPONSE GE-10c: EPA disagrees that the MATC should be calculated using simple arithmetic averaging (geometric mean) of all endpoints as presented in GE Table 2.2. There are three specific problems with the approach proposed by GE for benthic community MATC derivation:

(1) Over-Reliance on Broad Metrics – GE proposes to average the thresholds derived from abundance, taxa richness, diversity, and the SSD. This leads to a bias of the threshold toward the three broad benthic community metrics (abundance, richness, diversity) that were demonstrated to be less sensitive (i.e., less capable of discriminating alterations in benthic communities that affect individual taxa) relative to the analysis of individual taxa. EPA believes that the species sensitivity approach should be afforded more weight, in part because the broad metrics are somewhat redundant (i.e., richness and diversity are highly correlated). It is for this reason that two of the five endpoints selected by EPA for the effects threshold calculation represent SSD thresholds.

(2) No Consideration of Endpoint Relevance – GE proposes to assign equal weight to each endpoint. Such an approach ignores important differences among endpoints with respect to sensitivity, uncertainty, and relevance to the assessment endpoint. Just as some measurement endpoints are assigned

greater weight in the formal weight-of-evidence evaluation of harm, it is not necessary to assign equal weighting to all endpoints for which sediment tPCB thresholds can be calculated. Although EPA acknowledges that professional judgment is required in the selection of endpoints considered relevant for MATC derivation, the derivation method applied is appropriate and technically defensible. For example, results of the M-HBI measurement endpoint (which would yield unbounded effects thresholds) were excluded from the calculation due to undesirable and non-site-specific attributes of this endpoint (e.g., specificity for organic pollution; Washington 1984). Using the calculation rationale provided by GE, additional no-effect endpoints that have poor relevance to the assessment endpoint (such as M-HBI) could be added to the calculation, thereby diluting the sensitive responses observed in endpoints that have a higher level of ecological relevance.

(3) Use of Geometric Mean of Diversity Indices – The use of a geometric mean results in an overestimate of the concentration at which community impacts are observed, as discussed in Response GE-10b.

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**

RESPONSE GE-11: The calculations provided by GE in Table 2.3 are based on data-processing assumptions that, in EPA's opinion, do not provide a sufficient level of protection to the benthic community. EPA's concerns with the proposed toxicity-based threshold of 7.0 mg/kg dw are summarized in Response GE-9. EPA's concerns with the proposed community-based thresholds of 7.7 to 17.4 mg/kg dw are summarized in Response GE-10(a-c).

Overall, GE's suggested modifications to EPA's threshold derivation reflect a difference of opinion with respect to the appropriate degree of conservatism required in the face of uncertainty. The calculation formulas proposed by GE advocate the use of geometric means of intermediate-level effects concentrations. Using the geometric mean approach, large responses to sensitive taxa or endpoints can be diluted by a few endpoints that are insensitive to PCB contamination. This approach is advocated by GE in spite of the numerous endpoints that indicate pronounced responses (e.g., greater than 80% mortality in *Chironomus* survival; greater than 50% reduction in multiple individual taxa) at PCB concentrations below the suggested thresholds. EPA believes that the steep dose-response curves for some endpoints, and the concordance of other lines of evidence not considered in the MATC calculation (e.g., acute in-situ toxicity results, rank analyses, and multidimensional scaling of community data), justify and require a higher level of conservatism than has been incorporated in GE's analysis.

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.

RESPONSE GE-12: The EPA responses to the specific comments summarized here are provided below for each of the two points raised by GE.

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 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

RESPONSE GE-13: ERA Section E.4.9.1 describes the decision criteria EPA applied to the derivation of the MATC. A total of 11 endpoints were evaluated in the wood frog study to assess the potential impact of PCBs on different amphibian life stages, including reproduction, growth, and maturation based on known or expected toxicological effects of PCBs on amphibians. Some of these endpoints were insensitive, or effects data were incomplete or inconclusive. Later developmental stages were observed to be more sensitive indicators of toxic effects than earlier life stages for the wood frog, and demonstrated a dose-response relationship.

The MATC for amphibians was based on the integration of the two sensitive and biologically relevant endpoints (metamorph malformation and sex ratio). The rationale for integrating the point estimates of the two endpoints was that it is difficult to determine which endpoint is more sensitive with respect to population-level impacts. Furthermore, the two endpoints may act in concert to limit the viability of local wood frog populations. For example, of the Phase III wood frog metamorphs that were malformed, a higher proportion of the total number of malformed animals were female (the proportion of malformed males ranged from 0 to 42% at the four pools with the highest sediment tPCBs; the proportion of malformed females ranged from 33 to 67%).

Characteristic malformations observed in Phase III metamorphs included abnormal development of the lens of the eye, liver necrosis, gonadal necrosis, gonadal translocation, abnormal skin maturation, cardiac and cardio-vascular mal-development, and visceral and abdominal edema (FEL 2002). As described in Section E.4.9.2, Dr. Fort stated that, based on the degree of malformation observed in the gonads of the female wood frog metamorphs, most individuals (approximately 70 to 100%) would likely be sterile. The likely rate of sterility predicted by Dr. Fort was one line of evidence considered during the derivation of the MATC for both tissue and sediment.

Skewed sex ratio was another line of evidence that was considered in the derivation of the MATCs. Most amphibians, unlike higher trophic-level predators, have a reproductive strategy wherein large numbers of young are produced, minimal parental care of the young is typical, and higher juvenile output *and* mortality are typical of amphibians relative to animals located higher in the food web. There is a compensation mechanism in many amphibian species (including those resident in the PSA), such that an effect size of 5% to 10% may be of **less biological relevance** (emphasis added to clarify that EPA did not state that this endpoint is **not** relevant, but rather is **less** biologically relevant) to the local population. (Such an effect size could be a significant for a higher-order predator that has more limited reproductive resources).

One of the MATC decision criteria was to use endpoints with dose-response relationships. The incidence of malformations in Phase I and III metamorphs and skewed sex ratios in Phase III metamorphs all showed dose-response relationships. Phase I metamorph malformation dose-response relationship data, however, were incomplete because only external malformations were recorded. This underestimated the likely true overall rate of malformations, and resulted in EC_{20}s and EC_{50}s that were uncertain. Because of this, EPA does not agree with the derivation of the MATC as proposed by GE.

There are a number of possible methods for calculating MATCs using the dose-response data presented in the ERA. For example, a numerically integrated sediment MATC of 1.41 mg/kg tPCB could be derived from the geometric mean of EC_{20} Phase III metamorph malformation (3.27 mg/kg tPCB) and EC_{20} Phase III metamorph sex ratio (0.67 mg/kg tPCB) data; however, as discussed above in Response GE-9, simply calculating a measure of central tendency of a number of effects thresholds does not necessarily produce the most scientifically defensible MATC. Instead, the sediment MATC of 3.27 mg/kg tPCB was derived in the manner that it was because a 20% incidence of malformation was considered more biologically relevant than a 20% effect size for sex skewness (as described in Section E.4.3.3). In addition, an MATC of 3.27 mg/kg is believed to provide adequate protection for other amphibian species, which is also an objective of this Assessment Endpoint. Therefore, given the likelihood of adverse population effects associated with the skewed sex ratios and malformed gonads and other malformations observed in the wood frog metamorphs, as well as the uncertainty regarding the relative sensitivity of other species such as leopard frogs or salamanders, EPA does not believe that raising the MATC above 3.27 mg/kg tPCBs is sufficiently protective of amphibians.

References:

FEL (Fort Environmental Laboratories, Inc.). 2002. *Final Report – Frog Reproduction and Development Study. 2000 Rana sylvatica Vernal Pool Study*. Study protocol no.: WESR01–RSTS03–1. Prepared by Fort Environmental Laboratories Inc., Stillwater, OK.

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.

RESPONSE GE-14: The wood frog stochastic population model was developed to determine whether the adverse effects of PCB exposure on wood frogs, including increased incidences of internal and external malformations on individual frogs and skewed sex ratios within the population, influence the dynamics of the wood frog population within the Housatonic River Primary Study Area (PSA). To model density-dependence in a stochastic population projection, relationships between density, the timing of metamorphosis, survival, and reproductive success must be specified. The data necessary to specify such relationships are not fully available for the PSA. The model, however, was designed from the outset to examine the sensitivity of the population-level projections to tPCB impacts on wood frogs using site-specific data (both field studies and laboratory toxicity studies) to the maximum extent possible. In this manner it did provide a realistic description of wood frog population dynamics, both with and without the influence of tPCBs. To evaluate the potential importance of density-dependence on the results of the wood frog population modeling, a sensitivity analysis was performed by increasing and decreasing vital rates by 5 and 10%, and by evaluating changes in environmental correlation assumptions and dispersal rates. This analysis was included in the November 2004 revised ERA.

As with most population modeling exercises, certain vital rate information was not available for the PSA. Literature values, therefore, were used, which resulted in some uncertainty in model outputs. Additionally, it was assumed that there was no immigration or emigration of frogs into or out of the PSA during the modeling, when in fact there is likely some movement of frogs in and out of the PSA. This is particularly true in places where there are adjacent vernal pools that are outside the 10-year floodplain, where the vast majority of tPCBs occur in the soil and sediment. This spatial arrangement of contaminated and uncontaminated vernal pools provides a mechanism for repopulating impacted vernal pools, which is one possible explanation for why the wood frog is not extinct in the PSA.

While it is true that wood frogs are observed in the PSA, the population modeling study, including the sensitivity analysis, showed that even with strong density-dependence, the impact of tPCBs on the probability of population decline and extinction is significant. There was increased risk due to tPCB exposure relative to the uncontaminated base model in every sensitivity analysis. Lastly, the population model as constructed for the ERA was not intended to be used to develop specific media protection goals. It was demonstrated that there is increased risk to amphibians from exposure to PCBs; the degree to which impacts to the local subpopulation are compensated for by density-dependence is not a consideration in determining risk. Population modeling was conducted to propagate the effects from PCBs to local amphibian populations to determine whether there is a likelihood of long-term negative effects; the modeling indicated that such effects are in fact likely.

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.

RESPONSE GE-15: The EPA responses addressing each of these comment areas are provided below.

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. G55). 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.

RESPONSE GE-16: Two waterfowl sampling efforts were conducted by EPA in the PSA, one in 1998 and one in 2004. In the first sampling event, waterfowl were both trapped and collected using an airboat in backwaters near Woods Pond during August and September 1998 to provide tissue samples to support the human health and ecological risk assessments. During the 1998 sampling, 20 wood ducks from the PSA were examined and dissected, and tissue was subsequently analyzed for PCBs, dioxins, furans, and other Appendix IX contaminants. In the second event, on May 10, 2004, five wood duck eggs were collected from nest boxes located along the edges of the backwaters upstream of Woods Pond. The contents of these eggs were prepared for chemical analysis and subsequently analyzed for PCBs, dioxins, furans, and other Appendix IX contaminants.

There were no additional field survey efforts or field studies conducted to investigate the effects of tPCBs on wood ducks in the PSA. The wood ducks collected in August and September of 1998 for tissue analysis were all individuals that had hatched and survived to near-adulthood. Individuals that may have succumbed to the effects of tPCBs, other contaminants, or predation, were obviously not available for collection. No young birds were examined in this field event. It is possible that wood ducks with deformed bills, edema, or other documented effects from exposure to TEQ congeners would not have survived to adulthood. Deformities affecting the feeding ability of a juvenile wood duck have the potential to make that individual less fit, and more susceptible to starvation. Similarly, ducklings suffering from other toxic effects of a contaminant are likely to be less fit.

Four of the five wood duck eggs collected in 2004 contained fresh embryos less than 4 to 5 days old, and one egg contained an embryo approximately 2.5 to 3 weeks old. No embryo deformities were observed in that latter egg sample. No bill or other deformities could have been observed in the other four egg samples because of their age and lack of development, i.e., they consisted of an egg yolk and albumin.

EPA strongly disagrees with the assertion that edema or deformities could have been observed during the course of other field investigations. While there were multiple sightings of wood ducks during field activities, they were characteristically of wood ducks fleeing. Ducklings are trained to seek cover whenever a potential predator appears. When this occurs, there is little to no opportunity to observe a deformity. Edema, or palpable swelling of skin or subcutaneous tissue, is extremely difficult to observe in the field, particularly if birds are not in the hand. Most of a wood duck's body is covered in feathers, and the feet are usually in the water or tucked close to the body of a flying individual, making field observations of edema extremely difficult. The fact that none of the birds processed for tissue analysis showed signs of edema is not indicative of the lack of toxic effects, because the sampling effort was biased towards the collection of surviving individuals near adulthood.

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.

RESPONSE GE-17: Effects data can be characterized and summarized in a variety of ways, ranging from benchmarks designed to be protective of most or all species to dose-response curves for the representative species of interest. In this ERA, effects characterization preferentially relied on concentration or dose-response curves, but defaulted to benchmarks or other estimates of effect when insufficient data were available to derive the dose-response curve. Figure 6.6-1 in the ERA illustrates the decision criteria used to characterize effects for each representative wildlife species throughout the ERA and does not represent new information. In their review of the July 2003 draft of the Ecological Risk Assessment, Peer Review Panel members commented favorably on the decision criteria used to select effects metrics for wildlife.

Because laboratory and field studies were not available to characterize effects of tPCBs to wood duck, a threshold range was derived, in accordance with the decision criteria. A threshold range is intended to provide a range of doses that would be protective of the most sensitive bird species (the lower end of the range) and the most tolerant bird species (the upper end of the range). The assumption is that species that have not been tested with regard to their sensitivity to tPCBs (e.g., wood duck) have a sensitivity intermediate between the most sensitive and most tolerant species studied. This approach is intended to be unbiased (i.e., no safety factors used to derive the threshold range) and to account for the uncertainty regarding sensitivity of wood ducks to tPCBs. The threshold range for the reproductive success of wood ducks exposed to tPCBs selected for this assessment is 0.12 to 7.0 mg/kg bw/d based on reproductive studies conducted on white leghorn chickens (Lillie et al. 1974) and American kestrels (Fernie et al. 2001), respectively.

The use of a threshold range, when other data were not available for the representative species, was accepted by the Peer Reviewers. The threshold range used for wood ducks exposed to tPCBs is the same as that used for other bird species lacking species-specific toxicity information for tPCBs (i.e., American robin, belted kingfisher, osprey). No Peer Reviewer expressed concerns regarding use of the threshold range for the latter species.

As presented in Section G.3.1.1.2 of the November 2004 ERA, Custer and Heinz (1980) observed no significant effects on reproductive success of 9-month-old mallard ducks fed a diet containing 25 mg/kg ww Aroclor 1254. A previous study by Heath et al. (1972) had similar results. Neither study converted the dietary concentration of 25 mg/kg ww Aroclor 1254 to a dose. Therefore, it is unclear how the "NOAEL of 1.4 mg/kg bw/d tPCBs" cited in the comments prepared on behalf of GE was derived.

Further, neither study included other Aroclor 1254 treatments. Thus, a dose-response relationship has not been demonstrated for mallards exposed to tPCBs in these or other studies (i.e., control and 25 mg/kg treatments both showed no effect). As discussed in the response to General Issue 6 of the Responsiveness Summary document, three Peer Reviewers suggested that MATC derivation should consider only test endpoints that demonstrate dose-response relationships. EPA accepted this recommendation. The recommendation logically extends to the selection of effects metrics for representative wildlife species. Thus, the results of the mallard studies were not used as the basis for developing the tPCB effects metric for wood duck.

In addition to the above issues, Heath et al. (1972) reported that mallard and bobwhite quail were insensitive to dietary exposure of Aroclor 1254. Custer and Heinz (1980) also reported that mallards are less susceptible to Aroclor 1254 than are many other avian species. Wood ducks are known to be sensitive to dioxin and furan contamination and have been recommended as a bioindicator species for monitoring biological impacts from these contaminants (White and Seginak 1994; White and Hoffman 1995). This determination of sensitivity was based on the results of a field-based study where relative risk of toxicity of dioxins and furans was determined using a toxic equivalence (TEQ) approach (White and Seginak 1994). Therefore, it was assumed that wood ducks would be more sensitive than mallards to PCB congeners, as was demonstrated for dioxin and furan congeners.

EPA concurs with the GE comment that an effects metric derived from a wildlife species is preferred over an effects metric based on a domesticated species, but only if a dose-response relationship can be demonstrated for the wildlife species. Otherwise, effects metrics from domesticated species may be used, as was the case in the wood duck assessment.

References:

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Custer, T.W. and G.H. Heinz. 1980. Reproductive success and nest attentiveness of mallard ducks fed Aroclor 1254. *Environmental Pollution* (Series A) 21:313-318.

Fernie, K.J., J.E. Smits, G.R. Bortolotti, and D.M. Bird. 2001. Reproductive success of American kestrels exposed to dietary polychlorinated biphenyls. *Environmental Toxicology and Chemistry* 20:776-781.

Heath, R.G., J.W. Spann, E.F. Hill, and J.F. Kreitzer. 1972. Comparative Dietary Toxicities of Pesticides to Birds. U.S. Fish and Wildlife Service Special Scientific Report on Wildlife 152. 57 pp.

Lillie, R.J., H.C. Cecil, J. Bitman, and G.F. Fries. 1974. Differences in response of caged white leghorn layers to various polychlorinated biphenyls (PCBs) in the diet. *Poultry Science* 53:726-732.

White, D.H. and Seginak, J.T. 1994. Dioxins and furans linked to reproductive impairment in wood ducks. *J. Wildlife Management* 58(1):100-106.

White, D.H and D.J. Hoffman. 1995. Effects of Polychlorinated Dibenzo-p-dioxins and Dibenzofurans on Nesting Wood Ducks (*Aix sponsa*) at Bayou Meto, Arkansas. *Environmental Health Perspectives* 103(4):37-39.

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.

RESPONSE GE-18: No field studies were conducted to determine if overt abnormalities are present in wood ducks residing in the Primary Study Area of the Housatonic River (see Response GE-16). Without this information, there is no basis for suggesting that the dose-based approach for assessing risk of TEQ to wood ducks is more appropriate than the egg concentration modeling approach used in the November 2004 ERA. The latter approach was used in this case because species-specific toxicity data were available for TEQ in wood duck eggs (White and Seginak 1994). A similar approach was used for bald eagles, which the Peer Review Panel found preferable to the parallel dose-based approach when effects data for eggs are available. No species-specific toxicity data were available for wood ducks (or eagles) expressed as a dose-based metric.

The study by White and Seginak (1994) examined the link between TEQ and reproductive impairment in wood ducks in Bayou Meto, Arkansas. In the TEQ approach, toxicity equivalence factors (TEFs) are assigned to coplanar PCB, PCDF, and PCDD congeners that share a similar mode of action. This approach is based on the in vivo and in vitro toxicity of each planar chlorinated hydrocarbon congener in relation to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) (Van den Berg et al. 1998). TEQ is calculated by summing the congener-specific TEQ (TEF x concentration) for all coplanar PCB, PCDF, and PCDD congeners. The TEQ approach was developed to estimate and compare effects as 2,3,7,8-TCDD equivalence at different sites even if the composition of the congener mixtures at the sites differs substantially.

The GE comment suggests that differences in competition, food sources, bioenergetics, or other factors may have contributed to the calculated toxicity threshold range (>20 to 50 ng/kg TEQ in egg ww) in the White and Seginak (1994) study. However, White and Seginak observed high wood duck productivity in the site farthest downstream from the source (i.e., with the lowest TEQ in eggs) relative to the two more contaminated locations that were located closer to the source. Productivity at the site farthest downstream from the source was similar to the productivity observed at a nearby reference site. Thus, it appears that stressors other than those associated with the TEQ exposure are not causing impacts on wood duck productivity. Because Bayou Meto flows through agricultural land, wood duck egg samples were analyzed for persistent organochlorine pesticides (e.g., DDT) to determine if they could have contributed to observed effects on wood duck productivity. Very low concentrations of organochlorine residues were detected in these samples. Therefore, the presence of co-contaminants in Bayou Meto is not anticipated to be an important secondary stressor in the Arkansas wood ducks.

References:

Van den Berg, M., L. Birnbaum, A.T.C. Bosveld, B. Brunstrom, P. Cook, M. Freely, J.P. Giesy, A. Hanberg, R. Hasegawa, S.W. Kennedy, T. Kubiak, J.C. Larsen, F.X. Rolan van Leeuwen, A.K. Djien Liem, C. Nolt, R.E. Peterson, L. Poellinger, S. Safe, D. Schrenk, D. Tillitt, M. Tysklind, M. Younes, F. Waern, and T. Zacharewski. 1998. Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. *Environmental Health Perspectives* 106(12):775-792.

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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.

RESPONSE GE-19: The egg concentration model for wood ducks spans a period of 13 days prior to egg laying (Day 1 to Day 13) and 14 days during egg laying (Day 14 to Day 27), as discussed in the November 2004 ERA. Drobney and Fredrickson (1979) reported that the mean proportion of invertebrates in the diet of pre-laying and laying female wood ducks was 54% and 76%, respectively. These results were from a study conducted in southeastern Missouri.

The rate of change for the proportion of invertebrates in the wood duck diet is unknown, but likely depends on the availability of invertebrates in the local ecosystem, given that wood ducks are opportunistic feeders (Grice and Rogers 1965).

The Housatonic River PSA has an extensive forested floodplain, backwater areas, and other habitat that supports aquatic and terrestrial invertebrate populations. Therefore, female wood ducks have the opportunity for high invertebrate consumption rates, which may not be the case in other areas. Thus, for the egg TEQ concentration modeling reported in the November 2004 ERA, it was assumed that 76% of the diet of pre-laying and laying wood duck females was composed of invertebrates. This assumption was considered reasonable given the results reported by Drobney and Fredrickson (1979). This dietary assumption is further supported by the similarity between predicted egg TEQ concentration from the modeling effort and measured concentrations in wood duck eggs sampled (n=5) from the PSA.

References:

Drobney, R.D. and L.H. Fredrickson. 1979. Food selection by wood ducks in relation to breeding status. *J. Wildlife Manage*. 43:109-120.

Grice, D. and J. P. Rogers. 1965. *The Wood Duck in Massachusetts*. Final Report. Massachusetts Division of Fisheries and Game. Final Report. Federal Aid in Wildlife Restoration Project No. W-19-R.

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 21day 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

[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.

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.

RESPONSE GE-20: As noted in the GE comment, there is uncertainty associated with extrapolating the TEQ egg:adult concentration ratio for white leghorn chicken to calculate TEQ in wood duck eggs. This uncertainty was acknowledged and discussed in the November 2004 ERA (Section G.4.6, page G-124). EPA concurs with the comment that each wood duck egg likely accounts for a greater proportion of hen body weight than is the case with white leghorn chickens. That is not, however, sufficient justification for using a mass-based approach to estimate PCBs in wood duck eggs, and even if a mass-based approach were used, it would be inappropriate to simply apply the relationship derived from white leghorn chickens – the difference in egg:adult mass ratio between the two species must be taken into consideration.

It is also important to recognize that the mass of PCBs transferred from adult to egg is also partially controlled by other factors. Barger et al. (2001) and Nosek et al. (1992) reviewed the literature on maternal transfer of PCBs and TCDD, respectively, and found that the mass transferred to eggs is highly variable and species specific. This point argues against the approach suggested by GE. Nosek et al. (1992) conclude that:

> *"The total percentage of female TCDD body burden eliminated by egg laying is probably influenced by differences in adult body size, amount of maternal body fat reserves, number of eggs laid per clutch, and degree to which maternal body fat is mobilized during egg laying."*

Use of a concentration ratio for egg to adult is likely to be less variable between species because factors such as differences in adult and egg weights, and clutch size have less influence on a concentration ratio (i.e., terms cancel out) than on the absolute mass of PCBs transferred from the hen to the eggs. Bargar et al. (2001), in fact, make this argument, where they note that egg:adult concentration ratios are similar between white leghorn chicken and Adelie penguins (Tanabe et al. 1986).

Based on this information, EPA chose to extrapolate the concentration ratio for egg:adult for white leghorn chicken to calculate TEQ in wood duck eggs in the November 2004 ERA, rather than use the absolute mass approach suggested by GE. EPA believes that this approach results in less overall uncertainty, even though egg:adult TEQ concentration ratios are likely to vary somewhat between species because of, for example, species differences in maternal and egg lipid reserves, and degree to which maternal body fat is mobilized during egg laying. These factors apply also to the mass-based approach.

As noted above, even if the mass-based approach is used, it would not be appropriate to apply the transfer ratio from the Bargar et al. study on chickens (i.e., approximately 0.5% of adult contaminant mass per egg) to wood duck due to the difference in egg size relative to the adult. When the difference in relative egg mass between ducks and chickens (approximately 6% vs. approximately 3%, respectively) is accounted for, the mass-based approach produces final transfer ratios for wood duck (an egg:hen concentration ratio of approximately 0.17) similar to that reached using the concentration-based approach. In addition, modeled egg TEQ results for wood duck were close to measured values in the PSA, although the sample size for the latter is small (n=5). Therefore, despite the uncertainty regarding maternal transfer of PCBs in wood duck, the egg concentration model appears to perform well.

EPA concurs with the GE comment that the method and timing of PCB injection used in the Barger et al. (2001) study is not likely representative of wood duck exposure patterns in the PSA. EPA acknowledges that this source of uncertainty exists, in addition to the other uncertainties discussed in the November 2004 ERA.

References:

Bargar, T.A., G.I. Scott and G.P. Cobb. 2001. Maternal transfer of contaminants: Case study of the excretion of three polychlorinated biphenyl congeners and technical grade endosulfan into eggs by white leghorn chickens (*Gallus domesticus*). *Environmental Toxicology and Chemistry* 20:61-67.

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Tanabe, S., A. Subramanian, H. Hidaka and R. Tatsukawa. 1986. Transfer rates and pattern of PCB isomers and congeners and pp-DDE from mother to egg in Adelie penguin (*Pygoscelis adeliae*). *Chemosphere* 15:343-351.

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 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.

RESPONSE GE-21: Inclusion of metabolism in the exposure model for wood duck would have little impact on estimated TEQ in wood duck eggs. Dahlgren et al. (1971) estimated metabolism of Aroclor 1254 in pheasants at 2.4% of oral dose mass over a 28-day period. The authors also reported that the mass of PCBs excreted into the four eggs laid over that 28-day period was substantially higher than the mass of PCBs metabolized (8.4% of PCBs vs. 2.4%). Further, Nichols et al. (1995) reported that there is little or no metabolism of highly chlorinated congeners by avian species.

Wood duck and pheasant clutches are similar in size, ranging from 6 to 15 eggs (Grice and Rogers 1965; Ehrlich et al. 1988). Therefore, PCB excretion into the eggs is an important mechanism of PCB mass reduction in adult female wood ducks, as is the case with pheasant. Further, the ratio of total egg mass (number of eggs times mass of each egg) to body mass is higher for wood ducks than for pheasants. DARDNI (2005) reported an average pheasant egg mass of 33 g; the mean wood duck egg mass was 41 g in Housatonic River PSA (n=5). The average mass of a female pheasant is 953 g (Martin and Nelson 1952), whereas the mass of the female wood duck is 564 g (Landers et al. 1977). Therefore, assuming 13 eggs in a clutch for each species, the ratio of total egg mass to body mass for pheasant is 0.45, whereas the same ratio for wood duck is 0.99.

Therefore, excretion to eggs would be a more important route of PCB elimination in wood ducks than is the case with pheasants, and metabolism of PCBs, relative to transfer into eggs, would be a relatively minor route of PCB elimination. Because only 2.4% of PCBs were metabolized in pheasants over the 28-day study, inclusion of an even lower rate of metabolism in the wood duck egg concentration model would produce negligible improvement in its predictive capability.

Therefore, EPA believes that no change to the egg concentration model is required because:

- No data on wood duck-specific PCB metabolism are available.
- Metabolism is a minor elimination route for PCBs in pheasants and other bird species.
- Female wood ducks transfer far more PCB burden into eggs than would be removed by metabolism.
- Measured TEQ concentrations in wood duck eggs collected from the PSA (n=5) were close to the predictions of the egg concentration model (Section G.2.1.10.3 of the November 2004 ERA), further confirming that metabolism is a minor PCB removal mechanism.

References:

Dahlgren, R.B., Y.A. Greichus, R.L. Linder. 1971. Storage and excretion of polychlorinated biphenyls in the pheasant. *Journal of Wildlife Management*. 35(4):823-828.

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Nichols, J.W., C.P. Larsen, M.E. McDonald, G.J. Niemi, and G.T. Ankley. 1995. Bioenergetics-based model for accumulation of polychlorinated biphenyls by nesting tree swallows, *Tachycineta bicolor. Environmental Science and Technology* 29:604-612.

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 14-day nestling 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.

RESPONSE GE-22: The comment above and the many quotes from the November 2004 ERA cited therein can be responded to in a single summary statement: EPA believes that the results of the tree swallow field study (Custer 2002) provide evidence of harm, but that the magnitude of harm is expected to be low. As discussed in ERA Section G.4.2.2, the primary evidence for this conclusion comes from the following results:

- There was a significant relationship between tPCB concentrations in eggs and hatching success in 1999 ($p=0.044$), though the relationship was not strong. No significant relationship was observed in 2000.
- In 1998 and 1999, clutches that contained dead embryos had significantly higher concentrations of tPCBs than those that hatched normally ($p<0.001$).
- EROD activity was significantly induced at locations along the main stem of the Housatonic River compared to Threemile Pond. This result is not an indicator of harm, but rather provides supporting evidence that PCBs and other dioxin-like chemicals are contributing to the observed, albeit minor, effects on hatching success.

As noted in the GE comment, two Peer Reviewers (Sample and LaPoint) suggested that the results of the tree swallow field study did provide evidence of harm, even if the harm was not severe. EPA found these comments to be persuasive, and because of these comments, and also the Panel comments to review the entire weight-of-evidence to ensure consistency, revised the November 2004 ERA accordingly. The remaining reviewers did not comment on whether they agreed or disagreed with the July 2003 ERA conclusion that the tree swallow field study did not provide evidence of harm. The remaining reviewers, as well as Sample, however, generally agreed with the conclusion of low risk for tree swallows that was presented in the July 2003 ERA. That conclusion was not changed in the November 2004 ERA.

The GE comment notes that the logistic regression conducted by Custer (2002) for hatching success versus tPCB concentrations in eggs did not pass the goodness-of-fit test. This is not unexpected given the wide scatter in the data and the weak relationship between tPCB concentration in eggs and hatching success. The results of goodness-of-fit tests should be used with caution (Aldenberg et al. 2002) and should not be the sole criterion for selecting a regression model or fitted distribution (EPA 1999). Equally, or more important is to graphically evaluate the fit of a model to the data (EPA 1999). Examination of Figure 4 in Custer (2002) indicates that the logistic model fits the data reasonably well. Further, the data do not systematically depart from the model for any given concentration range. Given these considerations, EPA believes that the results of the logistic model shown in Figure 4 of Custer (2002) may be used in the ERA for tree swallows.

EPA acknowledges that the comparison of egg concentrations for tree swallows in the PSA to the effect metric from McCarty and Secord (1999) involves a comparison across different life stages. This comparison was considered ancillary evidence in the November 2004 ERA, and was not used in the weight-of-evidence determination of risk.

References:

Aldenberg, T., J.S. Jaworska and T.P. Traas. 2002. Normal species sensitivity distributions and probabilistic ecological risk assessment. In: *Species Sensitivity Distributions in Ecotoxicology*. Posthuma, L., G.W. Suter and T.P. Traas, eds. Lewis Publishers, Boca Raton, FL. pp. 49-102.

Custer, C.M. 2002. *Exposure and Effects of Chemical Contaminants on Tree Swallows Nesting Along the Housatonic River, Berkshire Co., Massachusetts, 1998-2000*. Final report to U.S. Environmental Protection Agency. USGS, Upper Midwest Environmental Sciences Center, La Crosse, WI.

EPA (U.S. Environmental Protection Agency). 1999. *Risk Assessment Guidance for Superfund: Volume 3 – Part A, Process for Conducting Probabilistic Risk Assessment*. Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C.

McCarty, J.P. and A.L. Secord. 1999. Reproductive ecology of tree swallows (*Tachycineta bicolor*) with high levels of polychlorinated biphenyl contamination. *Environmental Toxicology and Chemistry* 18:1433-1439.

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.

RESPONSE GE-23: EPA's responses to the issues summarized in the paragraph above are provided following the more detailed technical comments below.

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).

RESPONSE GE-24: Those Peer Reviewers who commented directly on the statistical analysis used in the July 2003 ERA for the mink feeding study expressed a range of comments, including:

- Sample stated that "it is unfortunate that the dose range used in the study did not extend to one or possibly two higher doses. These higher doses would have likely produced more severe effects and would have strengthened the overall dose-response relationships." (ERA Responsiveness Summary, p. 271).
- Thompson stated that "with the caveat of needing to look again at GE's comments on dose/response – this is a very well done study …" (p. 285).
- Stahl stated that "there is no definitive dose-response relationship between kit survival and tPCB content of the fish …" (p. 291).

No other Peer Reviewers commented directly on the statistical analysis (ANOVA) used in the July 2003 ERA to analyze the mink feeding study results. Reviewers commented in general that other statistical methods should be considered in the revision of the ERA, and EPA agreed to do so in the Responsiveness Summary (see response to General Issue 1.C). Further, in written comments to the Peer Review Panel (Attachment N, Comments of General Electric Company on the Ecological Risk Assessment for the General Electric/Housatonic River Site, Rest of River [July 2003 Draft]) and in their presentation at the Peer Review Public

Meeting, GE's consultants were highly critical of the ANOVA conducted on the mink feeding study results and expressed the opinion that they did not believe that there was evidence of a dose-response relationship.

In response to the comments from the Peer Reviewers, including those to address GE's expressed concerns, EPA committed in the ERA Responsiveness Summary (response to General Issue 15.B, p. 49) to conduct a regression analysis. A regression analysis more directly tests whether there is a dose-response relationship than does an ANOVA, and, as described in the ERA Responsiveness Summary, "The regression analysis will allow for a better discussion of the relationship between the dose-response from the mink feeding study and the dose-response presented in the ERA from published Aroclor 1254 feeding studies, as these analyses would then be more directly comparable. This will provide for better use of the mink feeding study data in the risk characterization, as was noted by one Reviewer." (Responsiveness Summary, p. 49).

A probit analysis assuming an underlying binomial error distribution is the standard regression technique for analyzing toxicity test results for quantal endpoints (e.g., mortality of kits) (Bailer and Oris 1997), and was the technique employed to further explore the comments regarding the dose-response relationship.

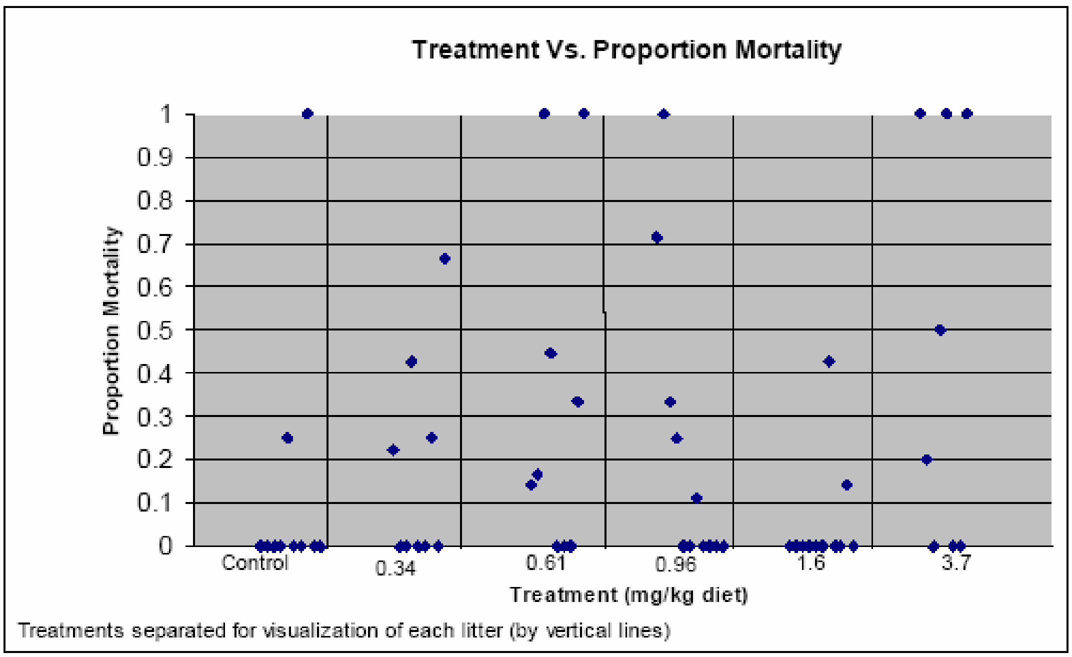
In addition, in the Responsiveness Summary (response to General Issue 6.D, p. 21), EPA agreed with Peer Reviewer comments that MATCs be derived only from study results that demonstrated a dose-response relationship. Consistent with this commitment, it was logical to use the results of the probit analysis conducted for kit survival from 0 to 6 weeks in the mink feeding study, which did show a statistically significant dose-response relationship, to develop the MATC for piscivorous mammals. MATCs are generally used as an estimate of the threshold concentration above which effects are expected to occur. For the piscivorous mammals MATC, EPA set the MATC equal to the LC_{20} from the probit analysis (no safety factors were used to adjust this value). A concentration that results in 20% lethality (a component of the definition of the threshold break between low and intermediate risk used in the ERA for multiple endpoints) exceeds what would typically be considered by EPA as a maximum acceptable threshold value for effects for a species such as mink.

Reference:

Bailer, A.J. and J.T. Oris. 1997. Estimating inhibition concentrations for different response scales using generalized linear models. *Environmental Toxicology and Chemistry* 16:1554-1559.

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



RESPONSE GE-25: As is often the case in toxicity tests such as the mink feeding study where the replication within treatment involves proportion mortality (or survival) among a limited number of individuals (median = 5 live-born kits), there is much intra-treatment variability for survival of mink kits from 0 to 6 weeks of age. However, if the sample size is high (n [treatments x replicates] = 58 for mink feeding study) and there is a relationship between the response and independent variables, regression analysis will detect a significant dose-response relationship in spite of the high intra-treatment variability. This was the case with kit survival from 0 to 6 weeks in the mink feeding study. Figure I.3-4 in the November 2004 ERA shows the fitted probit model as well as the scatter of the data.

The GE comment regarding confidence limits reflects a common misunderstanding about what confidence limits represent. They do **not** represent the bounds within which 95% of data points are expected to fall, as implied in the GE comment. The confidence limits shown in Figure I.3-4 represent, as they do for any regression analysis, the 95% confidence limits about the estimated mean. A 95% confidence interval around an arithmetic mean implies that 95% of the intervals calculated from repeated sampling of a population will include the unknown (true) arithmetic mean (Warren-Hicks and Moore 1998). Thus, if sample size is high and model fit is reasonable, confidence intervals can be narrow even with much data scatter.

The comment that the ANOVA results are preferred over the results of the regression analysis for expressing the results from toxicity testing is counter to the recent scientific literature on the topic. A synopsis of this topic follows.

The use of NOAELs or LOAELs as the basis for estimating "no effects" levels has been criticized (Stephan and Rogers 1985; Bruce and Versteeg 1992; Hoeckstra and Van Ewijk 1993; Pack 1993; Suter 1996; Chapman et al. 1996; Moore and Caux 1997) for a variety of reasons including:

- Hypothesis testing procedures clearly state the α value (Type I error) but generally leave the β value (Type II error) unconstrained meaning that the typical test will err on the side of stating that there is no toxicity present even when it is (Type II error) (Peterman and M'Gonigle 1992).
- The NOAEL and LOAEL are always test levels and do not necessarily correspond to biologically relevant thresholds or specified effects levels.
- Poor experimental design (e.g., small sample size, improper spacing of treatment doses, large intra-treatment variance) can mistakenly indicate that the substance is less toxic than it really is (Stephan and Rogers 1985; Suter et al. 1987; Barnthouse et al. 1987).
- Most of the information in the dose-response curve (e.g., the slope, confidence limits) is lost and thus the investigator has no means of evaluating the test results, and cannot, for example, use the results to estimate risks of differing severity.

An alternative for estimating low toxic effects is the regression-based approach. This approach involves fitting a regression model equation (e.g., probit, logistic) to toxicity test results to estimate the dose-response function and then interpolating or extrapolating to the effect level of interest (e.g., LC_{20}). The analysis may be done by means of a non-linear regression or a weighted linear regression on transformed data (Nyholm et al. 1992). Some of the major advantages of the approach over hypothesis testing for estimating low toxic effects include:

- It is a well-defined procedure for interpolation of effects to untested concentrations.
- Test statistics can determine whether model fit is adequate and whether the assumptions of the analysis have been met, thus precluding the use of poor quality information or inappropriate models.

- All of the information in the dose-response curve is used in the analysis (Stephan and Rogers 1985; Bruce and Versteeg 1992; Pack 1993).

For the above reasons (also see Response GE-24), EPA believes that the LC_{20} from the probit analysis is responsive to the Peer Review Panel comments, is scientifically valid, and preferable to the NOAEL and LOAEL derived from the ANOVA conducted on kit survival from 0 to 6 weeks.

References:

Barnthouse, L.W., G.W. Suter, A.E. Rosen and J.J. Beauchamp. 1987. Estimating responses of fish populations to toxic contaminants. *Environmental Toxicology and Chemistry* 6:811-824.

Bruce, R.D. and D.J. Versteeg. 1992. A statistical procedure for modeling continuous toxicity data. *Environmental Toxicology and Chemistry* 11:1485-1494.

Chapman, P.M., R.S. Caldwell and P.F. Chapman. 1996. A warning: NOECs are inappropriate for regulatory use. *Environmental Toxicology and Chemistry* 15:77-79.

Hoeckstra, J.A. and P.H. Van Ewijk. 1993. Alternatives for the no-observed-effect level. *Environmental Toxicology and Chemistry* 12:187-194.

Nyholm, N., P.S. Sorensen and K.O. Kusk. 1992. Statistical treatment of data from microbial toxicity tests. *Environmental Toxicology and Chemistry* 11:157-167.

Moore, D.R.J. and P.-Y. Caux. 1997. Estimating low toxic effects. *Environmental Toxicology and Chemistry* 16:794-801.

Pack, S. 1993. A review of statistical data analysis and experimental design in OECD aquatic toxicology test guidelines. Unpublished report, Shell Research Ltd., Sittingbourne Research Centre, Sittingborne, Kent, U.K. 42 p.

Peterman, R.M. and M. M'Gonigle. 1992. Statistical power analysis and the precautionary principle. *Marine Pollution Bulletin* 24:231-234.

Stephan, C.E. and J.W. Rogers. 1985. Advantages of using regression analysis to calculate results of chronic toxicity tests. In R.C. Bahner and D.J. Hansen, eds., *Aquatic Toxicology and Hazard Assessment*. STP 891. American Society for Testing and Materials, Philadelphia. pp. 328-338.

Suter, G.W. 1996. Abuse of hypothesis testing statistics in ecological risk assessment. *Human and Ecological Risk Assessment* 2:331-347.

Suter, G.W., A.E. Rosen, E. Linder and D.F. Parkhurst. 1987. Endpoints for responses of fish to chronic toxic exposures. *Environmental Toxicology and Chemistry* 6:793-809.

Warren-Hicks, W.J. and D.R.J. Moore (eds). 1998. *Uncertainty Analysis in Ecological Risk Assessment*. SETAC Press, Pensacola, FL.

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 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),

[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 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.

demonstrating further the limited utility of literature derived toxicity thresholds and the importance of site-specific studies for the mink evaluation.

RESPONSE GE-26: EPA acknowledges that the congener mixture at any other site will differ from that present in the Housatonic River. Those differences were acknowledged and discussed in detail in the November 2004 ERA (Section I.3.2.5, p. I-60 to I-62), comparing the results of the mink feeding studies conducted for the Housatonic River to those conducted for Saginaw Bay.

The comment from GE incorrectly asserts that, "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 LC_{20}." In Section I.3.3.2, p. I-67, of the November 2004 ERA, EPA stated that, "the derivation of a dose-response relationship for fecundity was further refined to include only those studies that had PCB mixtures with at least 54% chlorine content …" In addition, the first sentence of ERA Section I.3.3.2 indicates that development of a dose-response curve for tPCBs would focus on studies conducted with "mink exposed to Aroclor 1254." The PCB treatments used in the dose-response modeling for mink contained only Aroclor 1254. These treatments and the control treatments used in the dose-response modeling can be found in Tables 7, 9, and 10 of Aulerich and Ringer (1977) and Table 5 of Aulerich et al. (1985).

As is the case with the Saginaw Bay congener mixture, the congener composition of Aroclor 1254 will differ from the weathered mixture of Aroclor 1260 and 1254 found in fish from the Housatonic River PSA. There is also, however, considerable overlap in congener composition. It is for this reason that MATCs at other PCB-contaminated sites (e.g., Calcasieu Estuary in Louisiana) have typically relied on the published results from feeding studies using commercial Aroclors. Thus, it is reasonable to compare the results of the Saginaw Bay, Aroclor 1254, and Housatonic River mink feeding studies, as long as the differences between the studies are acknowledged and considered. As noted above, this was done in the ERA.

The comparison of the results of the Saginaw Bay, Aroclor 1254, and Housatonic River mink feeding studies indicate that the LC_{20} for tPCBs from the Housatonic River study (0.984 mg/kg tPCBs) was higher than the LOAEL from the Saginaw Bay study (0.72 mg/kg tPCBs) and the LC_{20} from the Aroclor 1254 studies (0.248 mg/kg tPCBs). In light of the discussion in Section I.3.2.5 of the November 2004 ERA, this result is not surprising, and further indicates that the MATC derived for the Housatonic River is not overly conservative. First, the MATC is equivalent to the concentration that would be expected to cause 20% reduced survival of mink kits from 0 to 6 weeks. In addition, no safety factors were used to adjust the LC_{20} to a concentration expected to cause no effect, as is traditionally done in nearly all ecological risk assessments. Finally, the Housatonic River MATC is higher than corresponding results from other mink feeding studies, as the data indicate and as noted by GE in the comment above.

References:

Aulerich, R.J. and R.K. Ringer. 1977. Current status of PCB toxicity to mink, and effect on their reproduction. *Archives of Environmental Contamination and Toxicology* 6:279-292.

Aulerich, R.J., S.J. Bursian, W.J. Breslin, B.A. Olson and R.K. Ringer. 1985. Toxicological manifestations of 2,4,5-, 2',4',5'-, 2,3,6,2',3',6'-, and 3,4,5,3',4',5'-hexachlorobiphenyl and Aroclor 1254 in mink. *Journal of Toxicology and Environmental Health* 15:63-79.

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.

RESPONSE GE-27: Based on the rationale provided in the Responsiveness Summary to the Peer Review, the November 2004 revised ERA, and the responses to GE's comments above, EPA believes that the MATC for mink is fully supported by the data, consistent with sound scientific practice, and responsive to the comments of the Peer Review Panel.

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.

> **RESPONSE GE-28:** The hockey stick regression model for shrew mortality can be fit to spatially weighted average tPCB concentrations in soil. The fit of the model (p=0.051), however, is weaker than was the case for the model that used measured average tPCB concentration in soil (p=0.0012). Probit analyses presented by EPA in the July 2003 (Section J.4.3.4.6) ERA and November 2004 (Section J.3.3.4.6) ERA "indicated a significant relationship between the spatially weighted mean concentration of tPCBs in soil and survival of shrews" for males, females, and males and females combined. Similar results were obtained using mean measured concentrations of tPCBs in soil. The preponderance of evidence thus indicates that there is a relationship between tPCB concentration in soil and shrew survival. Even so, there is an acknowledgement in Section J.3.3.4.6 that the results of the regression analyses may have been influenced "by habitat differences among the grids, small sample sizes, the effects of flooding, the analytical methods used to measure tPCBs, and the relatively small number of treatments." Because the hockey stick regression model using measured average tPCB concentration produced a better model fit than did the model using spatially weighted average tPCB concentration, the former was used in MATC development.

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).

RESPONSE GE-29: As noted in Response GE-28, there is acknowledgement in ERA Section J.3.3.4.6 that the results of the EPA regression analyses may have been influenced "by habitat differences among the grids, small sample sizes, the effects of flooding, the analytical methods used to measure tPCBs, and the relatively small number of treatments." Further, as recommended by the majority of Peer Reviewers, both the Boonstra and EPA statistical analyses were presented in the November 2004 ERA (see Section J.3.3.4), and both analyses were compared and discussed in detail in Section J.4.3. For the reasons outlined in ERA Section J.4.3, EPA believes that the supplemental analyses conducted are correct and make better use of the data than did the Boonstra analyses. This opinion was supported by two Panel members (Section 3.7(b) of Responsiveness Summary). Presentation of both sets of analyses in the ERA provides readers with the ability to compare and evaluate the EPA and Boonstra analyses.

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 reinsert the language indicating that, even accepting EPA's reanalysis, the relationship between PCB concentrations and shrew survival from summer to autumn is not strong.

RESPONSE GE-30: Please refer to Responses GE-28 and GE-29.

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."

RESPONSE GE-31: As noted in Responses GE-28 and GE-29, EPA believes that a preponderance of evidence indicates a negative relationship between the survival of shrews in the PSA and tPCB concentration in soil. Further, the hockey stick regression analysis was strongly significant ($p=0.0012$) using measured mean concentration of soil concentration and borderline significant ($p=0.051$) using spatially weighted soil concentration. Based on these analyses, EPA believes that the shrew demography study does provide evidence of harm. Section J.4.4 of the November ERA provides further support for this position.

COMMENTS OF THE HOUSATONIC ENVIRONMENTAL ACTION LEAGUE, INC. (HEAL)

Comments of the Housatonic Environmental Action League, Inc. (HEAL)

The Housatonic Environmental Action League, Inc. (HEAL) is a 501(c)(3) non-profit, non-partisan, broad-based, grassroots environmental advocacy coalition that includes individuals and organizations from the tri-state area (CT, MA, NY) who are dedicated to the protection of the Housatonic River and its watershed. Our organization has been actively involved with the Environmental Protection Agency's (EPA) Housatonic River Project particularly as it relates to General Electric's (GE) polychlorinated biphenyl (PCB) contamination of the river system.

Please enter HEAL's comments for the revised EcoRA into consideration.

1. HEAL fully supports and endorses the comments submitted by Dr. Peter L. deFur and his associates at Environmental Stewardship Concepts. Dr. deFur was contracted by the Housatonic River Initiative (HRI) who is the single recipient of the EPA's Technical Assistance Grant (TAG). HEAL appreciates the opportunity afforded our organization to provide input to Dr. deFur during his expert review of the revised EcoRA.

2. In EPA's November 15th press release, Robert Varney, EPA's Regional Administrator states: *"In the spirit of full and open participation at this unique site, EPA is providing an opportunity for interested individuals to review and comment on the new information in this important document."*

HEAL appreciates this additional opportunity to provide comments on one of the most critically important documents associated with this site. HEAL requested an extension to the comment period due to the absence of the document in at least one of the official repositories. The Cornwall [CT] repository was provided only CDs of the revised EcoRA; not even a hardcopy of the Executive Summary accompanied the CDs. In order to compare the original and revised EcoRA, one would either need two computers or the complete hardcopy(ies). It is difficult to ascertain what the revisions are in the new document in the absence of the ability to cross-reference. We understand the need for the document to be highly technical with scientific language. An additional non-technical Executive Summary written for the lay public would go far to satisfy Mr. Varney's desire for "full and open participation".

RESPONSE HEAL-1: As discussed above, EPA has made considerable efforts to encourage and solicit input from the public at this site in general and for this Ecological Risk Assessment in particular. As noted, EPA provided a detailed list of the new information in the revised Ecological Risk Assessment to make the review more accessible. EPA believes that the current Executive Summary provides a reasonable level of detail for all readers, with a more detailed summary of the entire risk assessment provided in Volume 1 for the more technical audience. In addition, to enhance public participation, EPA has provided a Technical Assistance Grant (TAG) to allow for the retention of qualified technical representatives on technical issues.

3. (ES-2; line 9) *Site-specific toxicity tests.* This entry is more accurate by including "*(limited testing conducted in Connecticut)*".

    RESPONSE HEAL-2: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

4. (ES-2; line 17) …*where farming was the main occupation from colonial settlement through the late 1800s.* Life in the Housatonic River basin did not begin with European introduction. Please consider a characterization that includes pre-colonial occupation.

    RESPONSE HEAL-3: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

5. (ES-4; line 1)*The GE facility in Pittsfield is the only known source of PCBs found in the Housatonic River sediment and floodplain soil in Massachusetts.* To expand on the accuracy of this statement, please consider adding "*and in Connecticut as far south as the Derby Dam*".

    RESPONSE HEAL-4: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

6. (ES-4; line 9) *The Rest of River is the portion of the river from the confluence of the East and West Branches of the Housatonic River (the confluence) to the Massachusetts border with Connecticut, a distance of approximately 54 miles (87 km), and beyond into Connecticut to Long Island Sound.* The Consent Decree characterizes Rest of River (ROR) from the confluence in Massachusetts to Derby Dam in CT. This statement needs to be revised. A second entry can then be inserted to define the PSA and the CT section of the river. If you include the mileage of the MA section of ROR, it is only logical to include the mileage of the CT section of ROR.

    RESPONSE HEAL-5: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

7. (ES-4; line 14) *The lateral extent of the area under investigation includes the floodplain extending to the 1-ppm tPCB isopleth, which is approximately equivalent to the 10-year*

floodplain. The floodplain in the CT section of the river has not been adequately tested or characterized. This statement needs to qualify that EPA is referring to the PSA in MA.

> **RESPONSE HEAL-6:** This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

8. (ES-4; line 22) *The ERA also includes an evaluation of the river and floodplain downstream of the PSA to the Derby Dam in Connecticut, approximately 14 miles upstream from Long Island Sound.* We request that you include the word "abbreviated" (or one similar) before the word evaluation. Why do you include the mileage backward from Long Island Sound yet you never include the miles from the CT/MA border to Derby Dam?

> **RESPONSE HEAL-7:** This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

9. (ES-4; line 25) *Next to the initial 0.5-mile (0.8-km) reach bordering the GE facility, Reach 5 has the highest concentrations and highest frequency of detections of PCBs in sediment.* Please consider adding "in sampling and testing to date".

> **RESPONSE HEAL-8:** This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

10. (ES-6;line 26) ***Reach 17*** *– From downstream of the Derby Dam to Long Island Sound (tidal, and not part of GE/Housatonic River site due to other sources of PCBs) (13.7 miles).* On line 22, EPA indicates the miles from Long Island Sound to Derby Dam is 14; which is correct. Additionally, the river downstream from Derby Dam is not included in the Consent Decree as a result of closed-door negotiations between General Electric and EPA. Claiming "other sources of PCBs" is a misrepresentation of facts.

> **RESPONSE HEAL-9:** This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

11. (ES-6; line 28)*The land uses of the floodplain properties in Massachusetts include residential, commercial/industrial, agricultural, recreational (such as canoeing, fishing, and*

hunting), wildlife management, and parks and a golf course. The Housatonic River floodplain is an attractive area for recreation, including fishing and waterfowl hunting.

These two sentences are redundant, disregard the floodplain uses in CT and assume that the listed land uses are the only ones taking place. Why are land uses by humans being included in the revised EcoRA?

> **RESPONSE HEAL-10:** This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

12. (ES-16; line 24)*Therefore, the overall risk conclusion for fish is low/intermediate risk.* We would like to reinforce our concerns regarding the data that indicates apparent reproducing populations of certain species in the riverine system. The current EPA risk assessment protocol that relies solely on evidence of reproducing populations as an indicator of the "health" of a species is inadequate and, we believe, incorrect in the presence of polychlorinated biphenyls and other toxins introduced/dumped into the Housatonic River watershed by General Electric. We have found this to be most dramatically demonstrated in the fish population in the Connecticut section of the river. Multiple HEAL members and other stakeholders continue to observe fish with gross external abnormalities in various species (e.g. various body lesions, sores and anatomical anomalies). Toxins that do not overtly lead to the immediate demise of a contaminated organism and allows continued, yet impaired, reproduction, do not fit within the EPA's ecological risk assessment framework. Additional attention in the data to individuals within a population is indicated. To repeat HEAL's oral testimony presented to the Peer Review panel: ***IF THE PISCIVOROUS MINK AND OTTER POPULATIONS ARE EXPERIENCING SEVERE HEALTH EFFECTS AND CONSIDERED AT HIGH RISK IN A SYSTEM, HOW CAN FISH IN THAT SAME SYSTEM BE CONSIDERED AT LITTLE TO NO OR LOW RISK??***

> **RESPONSE HEAL-11:** The incorporation of the USGS histopathology analyses, combined with the DELT (deformities, erosions, lesions, tumors) information collected during tissue sampling, expanded upon the effects assessment provided in the July 2003 ERA, in response to comments from the Peer Review Panel. The fish weight-of-evidence assessment also included evaluation of both site-specific and literature-based fish reproductive and developmental toxicity studies. Therefore, the November 2004 ERA did not rely "solely on evidence of reproducing populations as an indicator of the 'health' of a species," but rather considered multiple lines of evidence, and appropriately included an expanded discussion of adult fish abnormalities as requested by the Peer Reviewers. The weighting factors and evidence of harm designations applied to population endpoints (e.g., GE largemouth bass reproduction study) were refined in the November 2004 ERA, but these changes were made in a manner consistent with Peer Reviewer comments.

The comment from HEAL implies that EPA did not consider biological endpoints that "do not overtly lead to the immediate demise" of fish. Both the revisions incorporated in the November 2004 ERA (summarized above) and the material included in the July 2003 ERA directly address sublethal endpoints. Endpoints that are linked to "impaired reproduction" are included in the ERA, and where individual-level responses were discussed in the November 2004 ERA, their potential implications for reproduction and community health were considered.

The comment repeats references to anecdotal observations of gross external abnormalities in various species (e.g., various body lesions, sores, and anatomical anomalies). In the November 2004 ERA, EPA considered all of the available information on fish abnormalities in the PSA, including information from the extensive fish sampling conducted by EPA as part of the Rest of River study, and concluded that, with the exception of some incidence of tumor-like lesions on koi (goldfish) and incidence of glob-eye in yellow perch, individual fish examined in the PSA appeared normal and healthy. References to observations of fish by the public were not included in the ERA because no summaries of these observations (e.g., survey results) or means of evaluating the accuracy/reliability of the observations were available. Therefore, it was not possible to validate or discuss these anecdotal observations in an objective or defensible manner.

EPA has recently contacted three government agencies to gain additional insight to the issue of visual observations of abnormalities:

- According to the U.S. Fish and Wildlife Service (McKeon, pers. comm. 2005), based on the extensive sampling that was performed of the river and associated impoundments, visible fish abnormalities (i.e., lesions, tumors) were observed only on goldfish and a few bullheads, whereas other species appeared normal.
- Massachusetts Division of Fisheries and Wildlife (MassWildlife) (Madden, pers. comm. 2005) conducts surveys in the Housatonic River to provide data on species composition and length frequency for purposes of fisheries management. According to MassWildlife, some fish with abnormalities are observed during their sampling, but formal records of these abnormalities are not maintained and they have no basis on which to compare the frequency of such abnormalities relative to other river systems.
- The Connecticut Department of Environmental Protection (CT DEP) (Barry, pers. comm. 2005; Humphreys, pers. comm. 2005) conducts sampling and inspection of CT portions of the Housatonic River, particularly in trout management areas. CT DEP has not observed gross external lesions warranting investigation by the DEP fish pathologist.

Overall, the information obtained from these regulatory agencies is consistent with EPA's observations and indicates that the effects observed in individuals were properly characterized in the November 2004 ERA.

References:

Barry, T. 2005. Personal communication. Telephone conversation between Tim Barry (Connecticut Department of Environmental Protection, Bureau of Natural Resources, Fisheries Division, Western Connecticut) and Gary Lawrence (EVS Environment Consultants, North Vancouver, BC) regarding wild trout habitat within the Bull's Bridge Trout Management Areas (TMA) on the Housatonic River. February 8, 2005.

Humphreys, M. 2005. Personal communication. Telephone conversation between Michael Humphreys (Fisheries Biologist, Connecticut Department of Environmental Protection, Inland Waters Division) and Gary Lawrence (EVS Environment Consultants, North Vancouver, BC) regarding trout habitat downstream of Bull's Bridge and evidence of lesions on Connecticut portions of the Housatonic River. February 9, 2005.

McKeon, J. 2005. Personal communication. Electronic mail from Joseph F. McKeon (Central New England Anadromous Fish Coordinator, U.S. Fish and Wildlife Service, Central New England Fishery Resources Complex, Nashua, New Hampshire) to Gary Lawrence (EVS Environment Consultants, North Vancouver, BC) regarding evidence of external lesions on Housatonic River fish observed during electrofishing sampling. February 9, 2005.

Madden, A. 2005. Personal communication. Electronic mail from Andrew Madden, Western District Aquatic Biologist, Massachusetts Division of Fisheries and Wildlife) to Gary Lawrence (EVS Environment Consultants, North Vancouver, BC) regarding evidence of external lesions on Housatonic River fish observed during electrofishing sampling of Massachusetts below Woods Pond Dam. February 16, 2005.

13. (ES-18; line 3) *The effect of this impairment on local fish population size, recruitment, and/or resilience to natural or anthropogenic stressors is not known.* In light of this statement, Table ES-3 (ES-17), F-Field Study Endpoints, Evidence of Harm should be changed from "No" to "Undetermined".

RESPONSE HEAL-12: EPA revised the risk characterization for the field study measurement endpoints from "Undetermined" to "No" in the November 2004 ERA. This change was in response to comments from some Peer Reviewers that fish field studies demonstrate a lack of large-scale population effect (see response to General Issue 13). However, the ERA also documented the uncertainty in these measurement endpoints and qualified the "No" assignments by indicating that the "No" designation applies only to moderate to large population-level responses. The "undetermined" designation would be applicable only for evaluation of subtle population-level responses. There was not consensus among the Peer Reviewers on this issue:

- Three Reviewers commented that the risk characterization was generally appropriate (Responses 3.3-RS-2 and 3.3-BS-3; Mary Ann Ottinger, p. 206, line 12).
- One Reviewer (Responses 3.3-TT-11 and 3.3-TT-12) disagreed with the "undetermined" assignment for field survey endpoints, commenting that the field studies provided useful information, but also agreed that field studies cannot predict lesser impacts.
- One Reviewer (Response 3.3-VF-7) commented that the risk characterization depends on the interpretation of the assessment endpoint for fish.
- Two Reviewers (Responses 3.3-TL-1 and 3.3-JO-13) commented that the "self-sustaining" nature of the population was inadequate for assessing whether harm has occurred.

Given the diversity of viewpoints provided by the Panel, and given that the issue is partly of a semantic nature, EPA believes that the November 2004 ERA revisions were consistent with the Peer Review comments and with the Responsiveness Summary.

14. (ES-33; line 19) *In general, potential risks to benthic invertebrates occur in limited areas downstream of Woods Pond to Rising Pond. These areas are depositional and tend to have higher concentrations of tPCBs. Below Rising Pond, sediment does not contain concentrations of tPCBs that represent a potential risk to benthic invertebrates. The latter conclusion is supported by comparison of field-collected invertebrate tissue residue data (West Cornwall, CT) to literature-derived PCB tissue thresholds.* The West Cornwall area of the river is rocky with less deposition of sediment as compared to the areas behind dams. Inadequate sediment sampling/testing was completed behind all of CT's dams.

RESPONSE HEAL-13: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

15. (ES-48; line 27) *The detailed ecological characterization performed at this site has greatly reduced the uncertainties associated with problem formulation.* Although the PSA benefited from a detailed ecological characterization, CT continues to be inadequately sampled, tested and characterized.

RESPONSE HEAL-14: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

16. (ES-49; line 11) *There are several sources of uncertainty in the assessment of effects, including extrapolation errors and a limited number of toxicity studies conducted with the representative species.* We would like to see added at the end of this sentence: "particularly in Connecticut".

RESPONSE HEAL-15: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

17. (ES-49; line 21) *The greatest potential source of uncertainty for the fish and wildlife effects assessments, however, was associated with the lack of toxicity studies involving the representative species.* Same as 16 above… "particularly in CT".

RESPONSE HEAL-16: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

18. (ES-50; line 16) *An assessment of risk downstream of the PSA indicated that tPCBs could potentially be causing adverse effects to benthic organisms in depositional areas as far as Reach 8, amphibians in floodplain areas as far as Reach 9, trout in Reach 7, mink as far as Reach 15, and river otter as far as Reach 15, and bald eagle in Reach 8. However, the magnitude of risks in these areas is lower than in the PSA.* HEAL believes that there is insufficient and inadequate data in CT for EPA to reach these conclusions.

RESPONSE HEAL-17: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

HEAL continues to be concerned that EPA does not adequately acknowledge the PCB contamination in the CT section of the river (primarily behind the dams). PCBs will continue to be transported into CT from the upper reaches until such time that the PSA (and beyond) are contained. We look forward to that decision.

RESPONSE HEAL-18: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

The revised EcoRA clearly shows adverse impacts to the species that live in the river system. We are disappointed that EPA made no mention of the global transport of GE/Housatonic River PCBs that adversely affect species throughout the world.

RESPONSE HEAL-19: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

We again ask EPA to acknowledge and embrace the Precautionary Principle.

RESPONSE HEAL-20: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Thank you for the opportunity to comment on the revised EcoRA.

Sincerely,

Judith A. Herkimer, Director

COMMENTS OF THE MASSACHUSETTS AUDUBON SOCIETY (MAS)

Comments of the Massachusetts Audubon Society (MAS)

On behalf of Mass Audubon, we submit the following comments on the revised Ecological Risk Assessment (ERA) for the Housatonic River. Mass Audubon appreciates the efforts the EPA has engaged in to make this document as complete and rigorous as possible. We urge that the cleanup planning process for the Rest of the River proceed expeditiously but in a continued rigorous manner in order that risks to wildlife and people will be mitigated as soon and as thoroughly as possible.

Mass Audubon owns and operates the 262-acre Canoe Meadows Wildlife Sanctuary, located in Pittsfield within reach 5A, not far downstream from the confluence of the East and West branches. The sanctuary, which fronts the Housatonic River for approximately one-half mile, is home to seven state-listed species of animals and plants, including American Bittern (state endangered) and Wood Turtle (special concern). A considerable amount of the sanctuary's acreage is within the 10-year floodplain directly affected by PCB contamination. The sanctuary, since its establishment in 1975, has been dedicated to natural resource conservation and education. As such, the negative impacts on wildlife as a result of PCB contamination weigh even more heavily upon the sanctuary than upon parcels dedicated to other uses.

Canoe Meadows Wildlife Sanctuary is located in Reach 5A, the first section (most northerly) dealt with in this report. The highest concentrations and frequency of detections of PCBs are found in Reach 5. The predicted risks to amphibians is highest in Reach 5A; a majority of the amphibians and 50% of the vernal pools are at risk. Fish are at risk in all reaches of the Prime Study Area. Other wildlife species deemed to be at high risk include birds (Bald Eagle, Wood Duck, and Osprey) and mammals (Mink, River Otter, Short-tailed Shrew). Several other species were estimated to be at intermediate risk. The studied species are representative of many other species of wildlife present in the area, which are likely to be at risk from exposure to PCBs.

Mass Audubon urges that the EPA and General Electric move expeditiously to the next phase of the cleanup planning, i.e. establishment of Interim Media Protection Goals (IMPG). The IMPGs should be set at levels that will protect human and ecological health, both on Mass Audubon property and throughout the Rest of the River. The associated remediation measures to achieve these goals should address the potential future spread of contamination through flooding events.

> **RESPONSE MAS-1:** The establishment of IMPGs and the evaluation of potential Corrective Measures are steps that are included in the Rest of River process, pursuant to the Consent Decree and the Reissued RCRA Permit, which is Appendix G to the Decree. Among the general standards for evaluating Corrective Measures is b. Control of Sources of Releases, which addresses how each alternative or combination of alternatives would reduce or minimize possible further releases, including (but not limited to) the extent to which each alternative would mitigate the effects of a flood that could cause contaminated sediments to become available for human or ecological exposure.

Mass Audubon requests that we continue to be kept informed about the restoration planning process, especially in regards to any activities or remediation on Mass Audubon property. Canoe

Meadows sanctuary director Rene Laubach can be reached at 413-637-0320 x 8351 or rlaubach@massaudubon.org.

Thank you for considering these comments.

Sincerely,

E. Heidi Ricci	René Laubach
Senior Environmental Policy Specialist	Sanctuary Director
	Berkshire Wildlife Sanctuaries

COMMENTS OF THE TECHNICAL ASSISTANCE GRANT RECIPIENT – HOUSATONIC RIVER INITIATIVE/ENVIRONMENTAL STEWARDSHIP CONCEPTS (TAG)

Comments of the Technical Assistance Grant Recipient – Housatonic River Initiative/Environmental Stewardship Concepts (TAG)

Introduction and disclaimer

This review of the Final Ecological Risk Assessment of the Housatonic River/GE Site was conducted under a grant from the Environmental Protection Agency to the Housatonic River Initiative. The materials and conclusions presented here are those of the authors and do not represent the position of the EPA, ACOE or any other federal or state agency.

This report was prepared by: Dr. Peter L. deFur and Mr. Kyle Newman of Environmental Stewardship Concepts, under contract to the Housatonic River Initiative.

The context of this report is to provide feedback on the Final Ecological Risk Assessment to the EPA and to inform the citizens (through Housatonic River Initiative and Housatonic Environmental Action League) of the strengths and weaknesses of the Ecological RA. This feedback and evaluation is intended to identify major issues that remain particularly in light of the earlier comments provided to EPA. It is the intent of the reviewers and authors of this report to improve the Ecological RA and eventually result in a more protective site cleanup.

The purpose of these comments is to evaluate if the Ecological Risk Assessment adequately protects the ecological health of the environment of western Massachusetts and Connecticut from the toxic chemicals released from the GE facility in Pittsfield, MA. This review examines the scientific information and methods used, the underlying information, both quantitative and qualitative, the assumptions, logic and reasoning and other significant aspects of the Ecological RA.

General Comments

Overall, the report was comprehensive and well informed. ESC agrees that risks remain significant throughout the study area to most forms of wildlife. Changes made to the document are helpful and provide the reader with much more useful information that leads to a more comprehensive document. ESC recommends few substantial changes to the document.

We appreciate EPA's efforts to satisfy reviewer's comments that the chapters are too technical for general readers and contain too little information for technical use. However, in attempting to satisfy these concerns, EPA is attempting to write a single document for two completely different audiences. The result can be, and in this case, seems to be text in the main report that is insufficient for the technical audience. EPA would have been better off to have kept the risk assessment written for a technical audience and prepared a completely separate and substantially shorter document for public consumption.

> **RESPONSE TAG-1:** This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness

Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Revisions to the document seem to give added weight to field studies, even when those studies are flawed. In several instances (fish, insectivorous birds, and piscivorous birds), field studies that did not accurately represent endpoints associated with chronic PCB exposure were given more weight than the computer modeling that indicated high levels of risk for target species. The belted kingfisher field study that led to the conclusion that kingfishers were at intermediate risk in spite of high risks predicted by models was even criticized by the EPA as in Appendix H saying that "EPA does not believe the study can be used to conclude that tPCB exposure did or did not adversely affect kingfisher reproductive output in the PSA." Without evidence from the studies to specifically discredit the modeling, field studies should not be given more weight than comprehensive modeling efforts.

RESPONSE TAG-2: In response to a number of Peer Review comments, EPA committed to "reconsider the WOE designation for the field studies in the revised ERA" and to "provide a more transparent assessment of how field studies are used in the risk characterization" (response to General Issue 8.B in Responsiveness Summary). The revised weighting of the field study measurement endpoints followed the methodology proposed by the Massachusetts Weight-of-Evidence Workgroup (Menzie et al. 1996; see Section 2.9 of November 2004 ERA for details).

The weight assigned to the two field study endpoints for fish (F-1: Community studies; F-2: Largemouth bass reproduction study) was increased from "low/moderate" to "moderate." A third field study endpoint (F-3: population demographics) was added to the formal WOE based on Peer Reviewer recommendations (see response to General Issue 13.F), but was assigned a "low/moderate" weighting. The changes in weighting were appropriate because:

- The revised weightings are consistent with the opinion of some Peer Reviewers that the fish field studies should be weighted more strongly relative to the July 2003 ERA (Responses 3.3-VF-12 and 3.3-TT-17).
- Revised weightings were based on a systematic and transparent averaging of the individual attributes, as requested by some of the Peer Reviewers (Response to General Issue 8.A; Specific Responses 3.3-BS-6 and 3.3-JO-16). This resulted in a change of overall weighting for both F-1 (community studies) and F-2 (bass reproduction study) from "low/moderate" to "moderate," even though most individual attribute weightings remained unchanged from the November 2004 ERA.
- The revised weightings include a small number of revisions to individual attribute weightings, based on feedback from the Peer Review Panel. The rationales for individual attribute assignments are detailed in Table F.4-3(c). The "degree of association" attribute weighting for F-2 was increased to "moderate" from "low/moderate." This change was based on

the comments from the Peer Reviewers that the reproductive study, although of narrow scope, was an important summary of bass ecology and reproduction (Response 3.3-TT-5). The “spatial representativeness” attribute weighting for F-1 and F-2 was also increased to “moderate” from "low/moderate.” The reproduction study was described as "very comprehensive" by one Reviewer (Response 3.3-TT-5), but several Reviewers also indicated that the linkage between reproductive success and variations in PCB exposure over space was not addressed (Responses 3.3-TT-5, 3.3-VF-1, 3.3-BS-1, 3.3-MO-2, and 3.3-JO-5). The “quantitative measure” attribute weighting for F-2 was increased to “low-moderate” from "low.” Although some measurements of reproduction were assessed qualitatively, other parameters, such as YOY catch-per-effort and YOY growth rates, were quantified.

The overall weighting of the tree swallow field study was “high” in both the July 2003 and November 2004 ERA. The study was location- and species-specific and measured parameters directly relevant to the assessment endpoint. Further, the study was conducted over a period of 3 years and was well designed and well executed. More information on the weighting of the tree swallow field study can be found in Table G.4-7 of the November 2004 ERA. Compared to the tree swallow field study, the corresponding modeled exposure and effects line of evidence had several shortcomings that resulted in it being given an overall weighting of moderate. For example, sample size was small for concentrations of tPCBs and TEQ in prey; other exposure parameters were literature based, as were effects metrics. A detailed description of the weighting of the tree swallow modeling line of evidence is presented in ERA Table G.4-8.

As with the tree swallow field study, the weighting given to the American robin field study and modeling line of evidence did not change between the July 2003 and November 2004 ERAs. There were some concerns regarding the American robin field study (e.g., only one breeding season, small sample size at low end of the concentration gradient), but overall the study was given a moderate/high weight. ERA Table G.4-9 provides more information on the weighting of the American robin field study. The American robin modeling line of evidence had many of the same shortcomings as the tree swallow modeling, resulting in an overall weight of moderate (see ERA Table G.4-10 for more information).

As indicated in the TAG comment above, EPA had some concerns regarding the belted kingfisher field study. As a result, it was given a lower overall weight (moderate) than the tree swallow and American robin field studies. These concerns are outlined in Table H.4-6 of the November 2004 ERA. Some of the concerns included short duration of study (i.e., one field season), low sample size, lack of a reference area, and narrow dose gradient. However, the study did directly investigate reproduction of belted kingfishers in the PSA. The modeling line of evidence suffered from many of the same shortcomings as did the tree swallow and American robin modeling line of evidence, resulting in an overall weight of moderate (see ERA Table H.4-5 for more information).

Reference:

Menzie, C., M.H. Henning, J. Cura, K. Finkelstein, J. Gentile, J. Maughan, D. Mitchell, S. Petron, B. Potocki, S. Svirsky, and P. Tyler. 1996. Special report of the Massachusetts Weight-of-Evidence Workgroup: A weight of evidence approach for evaluating ecological risks. *Human and Ecological Risk Assessment* 2(2):277-304.

The revisions have not addressed most of ESC's previous comments, in particular those regarding Connecticut. The lack of samples in the Connecticut section of the river constitute a large data gap that must be resolved. This gap exists despite evidence that a substantial floodplain exists in the state (please refer to our previous comments for more information regarding this). The recent floods of January 2005 support the point that the Connecticut flood plain requires evaluation. Without more comprehensive data on this section of the river, uncertainties will remain regarding the conclusions for the Connecticut reaches. More sampling locations should be defined and more sediment samples taken for a complete risk assessment that addresses Connecticut.

RESPONSE TAG-3: Please refer to Response CT-6.

We remain opposed to EPA insisting that a sustaining population of sick fish is an acceptable condition at this site or any other. Comments on the original draft of the Ecological Risk Assessment explained why EPA is wrong in this position. A fish population that has 30, 40 or 50% of the individuals with an abnormality that prevents or impairs reproduction or performance is not a healthy population. The number of animals in a population over time is NOT the only measure of population sustainability. This point cannot even begin to discuss the evolutionary implications of such a condition of animals.

RESPONSE TAG-4: Please refer to Response HEAL-11 regarding the incorporation of abnormality information in the revised ERA. The abnormalities that were observed in adult fish (e.g., glob-eye in yellow perch; growths on goldfish in Woods Pond) and summarized in the November 2004 ERA have not been identified to impair "reproduction or performance" and should not be confused with the reproductive and developmental abnormalities that were explicitly considered in the USGS Phase I and Phase II assessments.

Other points raised in this comment do not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Executive Summary

The more detailed highlights section is an improvement, but we would like to see the language saying that high risks are unacceptable be reinserted into the text.

RESPONSE TAG-5: During the Peer Review, some Reviewers indicated that the evaluation of risks as acceptable or unacceptable is a value judgment that should be left to risk managers rather than included as part of the risk assessment per se. Accordingly, such language was removed from the risk assessment in response to the Peer Review and is consistent with the Responsiveness Summary.

Section 3

3-1, lines 34-37: Even pockets of high risk can be significant- flooding or other natural disturbances to the sediment bed can expose other areas to higher levels of risks to invertebrate populations in other areas. We also maintain that there is not enough data to substantiate the claim that risks are low in Connecticut.

RESPONSE TAG-6: Please refer to Response CT-6.

Appendix D

D-66-68, Section D.3.2.3: The use of concentration analysis alone cannot accurately determine if secondary COCs are influencing toxicity tests. The data from Locations 7 and 8 does not explain the results obtained. Simultaneous exposure to several metals at once including lead, magnesium, and arsenic has been demonstrated to cause more serious effects than expected when individuals are exposed to them singly. It is therefore possible that Locations 7 and 8 have mixtures of metals that exhibit greater levels of toxicity than at other sites.

RESPONSE TAG-7: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

The COC interaction does not seem to be correct. The text that discusses differences between reaches 7 and 8 does not explain the results. Positive correlation does not provide evidence for negative results at other locations.

RESPONSE TAG-8: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Section 4/ Appendix E

Removal of Barium from the list is highly questionable (E-9)- this was in previous draft

RESPONSE TAG-9: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer

Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

E-15, lines 16-17: There should be clarification as to if the leopard frogs in the EPA study were captive bred or wild caught. Other studies mentioned used wild caught frogs obtained from a biological company as controls.

RESPONSE TAG-10: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

E-17, Line 10-19: There should be a better explanation of why no frogs were captured from reference sites. Have any researchers returned to collect frogs from the reference site since? If none have, plans should be made for them to. Without the data those collections would provide, uncertainty will remain regarding the results of the study.

RESPONSE TAG-11: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

E-21, Lines 17-18: Units of measure for larval density not listed in GE study. These should be included.

RESPONSE TAG-12: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Section 5

The conceptual model section of the highlights should be reinserted for consistency.

RESPONSE TAG-13: The July 2003 version of the ERA for the fish endpoint (Section 5) included in the list of highlights the statement that "Conceptual model for fish indicates that the most important exposure pathways are diet and contaminated sediment." This highlight was inadvertently omitted in the November 2004 revised ERA.

The inadvertent deletion of this statement (which remains accurate) does not in any way affect the ERA approach or conclusions. The information contained in this statement was, and remains, included in more detail in ERA Section 5.1.1, so the November 2004 ERA is not lacking the appropriate technical content regarding the importance of diet and contaminated sediment as exposure pathways for fish.

We respectfully disagree with the change in risk probability in fish from high to intermediate. The decision to lower this probability seems based on the magnitude of effects on endpoints rather than the probability of them occurring. The data presented does not seem to support this conclusion. In Table 5.4-3, the overall endpoint values are mostly in the moderate to high range. The lowest values occur where there is the most uncertainty, specifically the field studies. Table 5.4-4 shows that there is evidence of harm for all assessment endpoints, even if of only intermediate harm.

RESPONSE TAG-14: The risk characterization for fish (as with all other Assessment Endpoints in the November 2004 ERA) was based upon a combination of probability and magnitude of response, as described in Section F.4 of the November 2004 ERA (page F-85, lines 10-16). The term "intermediate" was applied to risk magnitude, not to "risk probability," which was characterized as "generally high" (page F-89, line 16) and was not changed in the November 2004 ERA. The overall risk characterization was revised from "low" to "low to moderate" in the November 2004 ERA, so the reference in the comment to a change from "high to intermediate" risk is not correct.

The entries in Table 5.4-3 refer to the weighting value for each measurement endpoint, and are unrelated to either probability or magnitude of harm. The values presented in Table 5.4-4 indicate high evidence (probability) of harm and intermediate magnitude of harm for most endpoints – these results are fully consistent with, and in fact are largely responsible for, EPA's rationale for the overall risk characterization for fish, which is provided in Section F.4.9: "Two of the three lines of evidence (site-specific toxicity, fish tissue concentrations compared to MATCs) suggest intermediate risk to fish in the Housatonic River. However, the field surveys suggest that PCBs and/or other COCs are not causing obvious effects to fish populations. Therefore, the overall risk conclusion for fish is low/intermediate risk."

We continue to argue that supporting reproducing populations of sick fish is unacceptable. There is the potential for these illnesses to magnify within the population over long periods of time and cause significant harm. Additionally, populations of sick but still reproducing fish are more susceptible to other stressors. Allowing fish populations to remain in this state would leave them vulnerable and less able to respond to changes in habitat brought on by man-made influences or natural disasters. This point was covered in original comments and EPA is referred to the literature and documents for that submission.

RESPONSE TAG-15: Please refer to Response HEAL-11 and Response TAG-4 regarding the incorporation of abnormality information in the revised ERA. Other points raised in this comment do not pertain to new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Section 7

Without evidence as to why the modeling was wrong, the weight of evidence for the field studies should not have as significant weight as they are given in this section. There is a fair amount of uncertainty in the threshold range derived in Custer's field study (2002), stemming from the fact that the ecological significance of the observed effects (abnormal nest abandonment and larger clutch sizes), and if those levels were effecting hatchling success. The time limitations of the study did not allow for researchers to examine the long term effects of such exposure. Considering that Custer's study found the highest tPCB tissue concentration recorded in literature lends additional evidence to the model's results. Considering the tremendous amount of literature suggesting that those concentrations do lead to serious adverse effects for bird populations, the ramifications of the Custer study should be reexamined because the data suggests the possibility for serious harm to bird populations from PCB exposure. Because of this, ESC disagrees strongly with the conclusion that insectivorous birds such as tree swallows and robins are at low risk.

RESPONSE TAG-16: This comment does not address new information added to the November 2004 revised Ecological Risk Assessment in response to Peer Review comments. As stated in the introduction to this Responsiveness Summary, EPA solicited public comment only on new information and is responding only to comments that pertain to the new information.

Section 8

While we agree with the decision to raise the estimated level of risk for belted kingfishers to intermediate, this still may be underestimating actual risks. Though the belted kingfisher study exceeded the requirements for degree of association according to Menzie et al (1996), the limitations of the study make the data obtained by it irrelevant. There was no data on clutch size or hatchling success, two significant reproduction endpoints affected by PCB exposure. By only sampling during one breeding season, no long term trends could be obtained and therefore no useful reproductive data. Sample sizes were small, and the modeling of diet to estimate PCB intake of birds was imprecise. These are all problems noted by EPA in Appendix H, and as stated in lines 28-30 on page H-51 EPA does not believe that the study can be used to determine whether or not tPCB exposure is adversely effecting kingfisher populations. Because of these limitations, the field study should be dropped from the WOE and more weight given to the modeling as done for osprey.

RESPONSE TAG-17: EPA agrees with the comments outlined above regarding the belted kingfisher field study. However, the study did indicate that kingfishers foraging and residing in the PSA are breeding successfully. Whether the observed rate of reproductive success is sufficient to sustain the local population without recruitment from other populations of kingfishers, is not known.

Nevertheless, the observation that kingfishers can successfully reproduce in the PSA likely indicates that they are not at severe risk. In consideration of these results and the moderate weight assigned to the modeling line of evidence (see Response TAG-2), the WOE conclusion that belted kingfishers are at intermediate risk in the PSA seems reasonable. There is uncertainty about this conclusion, as is acknowledged and discussed in Sections H.4.5 (Sources of Uncertainty) and H.4.6 (Conclusions) of the November 2004 ERA.

Section 12

The expanded and more detailed highlight section is an improvement, though we would like the language referring to high risks as unacceptable be reinserted.

RESPONSE TAG-18: Please refer to Response TAG-5.