**U.S. Army
Corps of Engineers**

New England District
Concord, Massachusetts

**U.S. Environmental
Protection Agency**

New England Region
Boston, Massachusetts

RESPONSIVENESS SUMMARY TO THE PEER REVIEW OF THE HUMAN HEALTH RISK ASSESSMENT GE/HOUSATONIC RIVER SITE REST OF RIVER

DCN: GE-022404-ACBF

March 2004

**Environmental Remediation Contract
GE/Housatonic River Project
Pittsfield, Massachusetts**

Contract No. DACW33-00-D-0006

Task Order 0003

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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
Boston, Massachusetts

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LIST OF ACRONYMS

AFs	adherence factors
ATSDR	Agency for Toxic Substances and Disease Registry
COPC	contaminants of potential concern
CSF	cancer slope factor
CTE	central tendency exposure
EA	exposure area
ED	exposure duration
EDF	empirical distribution function
EF	exposure frequency
EPA	U.S. Environmental Protection Agency
EPC	exposure point concentration
FC	fraction contacted
FI	fraction ingested
FSEA	floodplain soil exposure area
GE	General Electric Company
HHRA	Human Health Risk Assessment
HI	hazard index
HQ	hazard quotient
HRA	Housatonic River Area
IDW	inverse distance weighting
IMPG	Interim Media Protection Goals
IR	ingestion rate
IRIS	Integrated Risk Information System
LOAEL	Lowest Observed Adverse Effect Level
MCP	Massachusetts Contingency Plan
MDEP	Massachusetts Department of Environmental Protection
MDPH	Massachusetts Department of Public Health
NAPL	non-aqueous phase liquid
ND	nondetect
NOAEL	No Observed Adverse Effect Level
PBA	probability bounds analysis
PCB	polychlorinated biphenyl
PRA	probabilistic risk assessment
PRGs	preliminary remedial goals
QAPP	Quality Assurance Project Plan

LIST OF ACRONYMS
(Continued)

RAGS	Risk Assessment Guidance for Superfund
RBCs	risk-based concentrations
RfDs	reference doses
RFI	RCRA Facility Investigation
RME	reasonable maximum exposure
ROR	Rest of River
RCRA	Resource Conservation and Recovery Act
SAB	Science Advisory Board
SIWP	Supplemental Investigation Work Plan
SRBCs	screening risk-based concentrations
SSSG	Supplemental Soil Screening Guidance
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
TEF	toxic equivalency factor
TEQ	toxicity equivalence
tPCBs	total PCBs
TRL	target risk level
UCL	upper confidence limit
WPA	Wetlands Protection Act
YOY	young-of-year

INTRODUCTION

This document presents the response from the U.S. Environmental Protection Agency (EPA) to the comments and questions raised by an independent Peer Review Panel of seven experts in the discipline following their review of the Human Health Risk Assessment for the GE/Housatonic River Site Rest of River (HHRA) released in June 2003. This document, referred to herein as the HHRA Responsiveness Summary, has been prepared as part of EPA's obligations under Paragraph 22.c and Appendix J of the comprehensive agreement relating to the cleanup of the General Electric Company (GE) Pittsfield, Massachusetts facility, certain off-site properties, and the Housatonic River (referred to as the "Consent Decree"). The Consent Decree was entered on October 27, 2000, by the United States District Court of Massachusetts - Western Division, located in Springfield, MA.

Under the terms of the Consent Decree, EPA was required to conduct a human health 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. The conclusions of the human health risk assessment, along with the conclusions from the ecological risk assessment that was also conducted by EPA, will be taken into account by GE when developing an Interim Media Protection Goals (IMPG) Proposal that will be submitted to EPA.

Prior to the Peer Review, the public comment period provided the opportunity for the public to submit written comments for consideration by the Panel on the Risk Assessment, within the context of the Peer Review Charge. On November 18-20, 2003, the HHRA Peer Review Panel ("Reviewers") met at a public forum in Lenox, MA, to review and discuss the HHRA within the framework of the Charge. During this meeting, the members of the public were provided the opportunity to present oral comments to the Panel, and the Panel was able to engage in a question/answer session with the public presenters. The Reviewers subsequently submitted final written comments to EPA's Managing Contractor for the Peer Review, SRA International, Inc., of Arlington, VA. This document is EPA's formal response to the final written Peer Review comments.

APPROACH AND ORGANIZATION OF THIS DOCUMENT

As stipulated in Appendix J to the Consent Decree, Peer Reviewers were discouraged from discussing their individual comments with each other outside the public Peer Review Meeting, to allow the full discussion to take place in public. In addition, the Reviewers were not required to reach consensus; therefore, the comments were prepared independently by each Reviewer. As observed during the Peer Review itself, many of the Reviewers noted some of the same issues with the HHRA and therefore submitted similar written comments on these issues. Conversely, as might be expected, at many times Reviewers had differing views on issues; this is also reflected in the written comments.

As a result of these considerations, and to avoid unnecessary repetition and to increase clarity in the HHRA Responsiveness Summary, EPA organized this document so that responses to general issues are presented first followed by responses to specific comments.

The first section, termed "Response to General Issues," deals with issues that were raised by a number of Reviewers and/or had broad implications for the HHRA. In this first section, EPA has identified 14 General Issues and has provided a Summary of Issue statement for each to frame the technical basis for the issue and to provide an indication of how often the issue was noted by the Reviewers. Each Summary of Issue statement is followed by EPA's response to the General Issue. In many cases, the breadth of the General Issue required a series of responses, each of which is numbered independently. Many of the responses to specific comments from the Reviewers (see below) refer to the responses to the General Issues.

The second section is entitled "Response to Specific Comments." In this section, each reviewer's comments are repeated verbatim and in their entirety, grouped according to the structure of the HHRA Peer Review Charge. Because some Reviewers also provided comments outside of the Charge questions, it was necessary to add a section entitled "Overview Comments" at the beginning of this section, and a section entitled "Additional Comments" at the end. In each subsection, the comments of the individual Reviewers are presented in alphabetical order, with responses from EPA inserted at appropriate intervals. As noted above, many of these comments refer the reader to one or more of the General Issues responses.

The third section presents References, and Appendix A presents a list and a brief synopsis of the comments received during the public comment period.

RELATIONSHIP OF THE RESPONSIVENESS SUMMARY TO THE HUMAN HEALTH RISK ASSESSMENT FOR REST OF RIVER

To better document and integrate the changes to the HHRA beyond the scope of the Responsiveness Summary, EPA will issue a revised HHRA that will provide additional technical information as described in the responses provided here.

In conclusion, EPA recognizes the hard work and thought that the Reviewers contributed in conducting the Peer Review. As Reviewers noted, the HHRA was a large and complicated document, with many difficult issues being addressed. Although EPA agrees with many of the comments provided by the Reviewers, EPA did not agree with some of the comments; these are documented in the responses and, in such cases, the technical basis for EPA's position is provided. EPA appreciates the effort from the Reviewers in providing their insights and believes that the resulting revised document will benefit greatly from them.

RESPONSE TO GENERAL ISSUES

1. BACKGROUND INFORMATION ON REST OF RIVER POPULATION

SUMMARY OF ISSUE:

Three Reviewers commented that the Human Health Risk Assessment (HHRA) did not provide adequate background information about the population residing in the Rest of River area, or who may use the river and its floodplain. Additional information was requested regarding the demographics of the area as well as any information about the number of people potentially involved in various activities such as fishing and hunting. Six Reviewers requested that the HHRA include a discussion of the polychlorinated biphenyl (PCB) biomonitoring (serum) studies conducted by Massachusetts Department of Public Health (MDPH). Five Reviewers recommended that health statistics, including cancer incidence ratios, of the population living in the vicinity of the Housatonic River be summarized, although one cautioned against overinterpreting the data with respect to PCB exposure and risk.

RESPONSE:

1.A. Demographics of the Population Residing in Rest of River Area

The HHRA (Volume I) will be revised to include a new section that describes the population living near the Housatonic River, and populations likely to utilize the river and its floodplain. Population sizes and demographic characteristics for the towns and counties that border the river from Pittsfield, Massachusetts, to Lake Zoar, Connecticut, will be summarized based on data obtained from the U.S. Census Bureau and Massachusetts and Connecticut state agencies. The section will also include data published by the MDPH (1997) regarding the population living within 0.5 miles of the Housatonic River from Pittsfield to the Connecticut border, and the population of the Schaghticoke Native Americans.

1.B. Estimates of Size of Population That May Engage in Activities Resulting in Exposure

The HHRA (Volume I) will be revised to include estimates of the size of the population engaging in various activities that take place on the river or its floodplain. The estimates will also be included in the relevant HHRA appendix volumes. The angler/hunter populations will be more fully characterized by summarizing the number of anglers interviewed during creel surveys, the size of the membership in local hunter/angler/sportsmen clubs, and the results of the Housatonic River Area PCB Exposure Assessment Study, as reported in MDPH (1997). Data from the MDPH study will also be used for population estimates of individuals who reside in the Massachusetts portion of the MDPH-defined Housatonic River Area (HRA) and who canoe the Housatonic River or engage in activities in the floodplain such as birdwatching or other recreational activities. The information presented will provide a general idea of how many people may be exposed under current land uses; these estimates may change in the future. However, the goal of the HHRA is to calculate risks to potentially exposed individuals, and not to calculate a population-level risk. Decisions will be based on the Reasonable Maximum Exposure (RME). As stated in the National Oil and Hazardous Substances Pollution Contingency Plan, Final Rule (40 CFR 300.55), "EPA defines 'reasonable maximum' such that only potential exposures that are likely to occur will be included in the assessment of exposures. The Superfund program has always designed its remedies to be protective of all individuals and environmental receptors that may be exposed at a site."

1.C. MDPH Biomonitoring Studies

The HHRA (Volume I) will be revised to include a new section that describes the biomonitoring (PCB serum studies) of the population living near the Housatonic River in Massachusetts that was conducted by MDPH (1997) and the comments provided by an expert panel on PCBs and health effects convened by MDPH. The section will also discuss the relevance of this study to the risk assessment results. However, MDPH does not release underlying data from its studies; therefore, EPA's analysis of these studies will be constrained by the available data.

1.D. Health Statistics

Cancer incidence data evaluated by MDPH will be summarized in the HHRA. Concerns about other potential health issues are generally directed to MDPH (http://masschip.state.ma.us/InstantTopics/).

2. LAND USE

SUMMARY OF ISSUE:

Six Reviewers requested that a more complete discussion of land use trends be provided to ensure that the future potential land uses in the area are properly understood and characterized. Four Reviewers were concerned that parcels eliminated in the Phase 1 Direct Contact Risk Assessment (Appendix A), based on current use, might have been retained for more detailed evaluation had foreseeable future uses been evaluated. One Reviewer questioned the assumptions of current use and why the land use survey performed on behalf of GE was not considered. Three Reviewers were concerned about the basis for the projection that current and future uses are the same for state-owned and industrial properties, with one Reviewer expressing particular concern about the impact of addition or relocation of trails or other facilities (such as canoe launches) on the risk assessment. Four Reviewers questioned whether or not future uses of privately owned properties were evaluated appropriately, with one Reviewer expressing concern that risks associated with future residential use were not evaluated. Finally, six Reviewers were concerned about trends in agricultural uses of the land, with two expressing particular concern about whether land not now currently in agricultural use could be used for agricultural purposes in the future. One Reviewer questioned whether the Massachusetts Wetland Protection Act would prohibit agriculture within 200 ft of the river and seemed to suggest there was little current agricultural use of the area.

RESPONSE:

2.A. Identification of Future Land Uses

The HHRA (Volume I) will be revised to include a new section that describes the current and potential future uses of the Rest of River area. The land use investigations conducted for the risk assessment will be described. These investigations included interviews with the Berkshire Regional Planning Commission and local planners in Pittsfield, Lenox, Lee, Great Barrington, Stockbridge, and Sheffield, as well as local agricultural officials, state wildlife officials, and managers of non-profit recreational areas. In addition, various Master Plans were reviewed to provide more detailed information.

2.B. Impact of Future Land Use on Screening Conducted in Phase 1 Direct Contact Risk Assessment

The HHRA (Volume I and the Phase 2 Direct Contact Risk Assessment, Appendix B) will be revised to include an expanded discussion of the Phase 1 approach and the potential impact of land use changes. If future land use may result in higher exposures than previously evaluated, the exposure area will be reevaluated using the more appropriate criteria.

2.C. Future Uses of State and Municipally Owned Land

The revised HHRA (Volume I and the Phase 2 Direct Contact Risk Assessment, Appendix B) will include a discussion of the basis for evaluating future uses of state-owned and municipally owned land. For state-owned land, this included discussions with the Massachusetts Department of Environmental Management and refuge managers, and examination of deed and other restrictions on land use. For municipally owned land, research included discussion with municipal and regional officials. The potential for relocation of trails and other more intensive uses of areas in the future will be evaluated using the analysis described below in Response 7.C.

2.D. Future Use of Privately Owned Land

The revised HHRA (Volume I and the Phase 2 Direct Contact Risk Assessment, Appendix B) will be expanded to include the basis for likely predicted future uses of privately owned land, including the criteria for deciding whether a property could become residential in the future.

2.E. Future Use of Land for Agriculture

The Agricultural Product Consumption Risk Assessment (Appendix D) provided information regarding current agricultural use of the floodplain in Massachusetts, and projections for the future. Current commercial and backyard agricultural activities were listed by river reach for Reaches 5 through 9 in Table 2-1, and Figures 2-1a through 2-1j depicted the same information by parcel for these river reaches. Dairy farming has historically been and continues to be the dominant commercial agricultural activity, although the number of dairy farms decreased between 1974 and 1997 (Holm et al., 2000). The discussion of potential future agricultural exposure pathways will be expanded in the revised HHRA to include available statistics regarding trends in dairy and other agricultural activities in Berkshire County. Past agricultural activities will be discussed to the extent necessary to understand trends in agricultural activities.

Portions of this section of Appendix D will be included in a new section in HHRA (Volume I) that will focus on current and future uses of the Rest of River area.

As noted in Section 2.1.2 of Appendix D, the Wetlands Protection Act (MGL Ch. 131, Sec. 40) and associated regulations (310 CMR 10.00) restrict some activities within wetland resource areas, including floodplains. The Act also restricts some activities within the "riverfront area," which is "that area of land situated between a river's mean annual high-water line and a parallel line located two hundred feet away, measured outward horizontally from the river's mean annual high-water line." However, the definition of riverfront area does not include any area beyond 100 ft of a river's mean annual high water in which agricultural land use or aquacultural use occurs.

The revised HHRA will include additional discussion of the Wetlands Protection Act (WPA) with respect to current and potential future agricultural activities within the 1-ppm tPCB isopleth.

3. HIGHLY EXPOSED OR SUSCEPTIBLE SUBPOPULATIONS

SUMMARY OF ISSUE:

Six Reviewers pointed out that some potentially highly exposed or susceptible subpopulations were not evaluated in the risk assessment. Six Reviewers suggested that nursing infants, noted as the breast milk exposure pathway in the comments, be explicitly evaluated in the HHRA. One Reviewer recommended that children in the 1-6 year old age group evaluated in the HHRA be evaluated in shorter time spans, such as an age 2-3 year group. A second Reviewer supported this approach if a subchronic toxicity value for PCBs were available. Three Reviewers recommended the inclusion of a subsistence angler in the fish consumption pathway, at least at a screening level.

RESPONSE:

3.A. Nursing Infants (Breast Milk Pathway)

A new section will be included in the revised HHRA (Volume I) that evaluates exposure and risk to nursing infants. The methodology for this evaluation will be based on available guidance including the *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Volumes 1, 2 & 3, Peer Review Draft* (EPA, 1998a) and *Region VI Risk Management Addendum – Draft Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (EPA, 1998b).

3.B. Very Young Child

Chronic exposure for a young child (ages 1-6) was evaluated in the baseline risk assessment. Although intake-to-body weight ratios for shorter duration exposures may be greater for younger age groups, and a younger child receptor may be more highly exposed during a particular susceptible life stage, toxicity values for shorter exposure durations (subchronic) are not available. Therefore, the HHRA will retain the young child (ages 1-6) as the child receptor. The uncertainty section for all exposure pathways will be expanded to discuss this potential underestimation of exposure and risk to the very young child.

3.C. Subsistence Angler

Three Reviewers suggested the addition of a subsistence angler to the fish consumption risk assessment, especially near the location of the Schaghticoke reservation in Kent, CT. EPA has been unable to verify the existence of a subsistence angler population near the Schaghticoke reservation. No existing subsistence population was identified for other reaches of the river. In the revised HHRA, EPA will evaluate if a subsistence angler is a viable future exposure scenario for the Kent, CT area.

4. CALCULATION OF EXPOSURE POINT CONCENTRATIONS

SUMMARY OF ISSUE:

Exposure point concentrations (EPCs) were calculated using various methodologies, which is somewhat different from the single approach typically used in EPA risk assessments, but necessary because of the mechanism of contaminant transport and the size of the area being assessed at this site. All Reviewers had multiple comments regarding the methodologies, in particular, the lack of discussion of the uncertainties associated with the approach. Three Reviewers questioned whether the use of a single method (bootstrapping or the Land H-statistic) would be simpler and add consistency. Four Reviewers requested additional information and explanation about the spatial weighting techniques used in the Phase 2 Direct Contact Risk Assessment and its integration with EPC calculations, especially the Hall corrected bootstrap methodology. These Reviewers also requested that summary statistics, including EPCs, be calculated for a number of exposure areas (EAs) using raw data and spatially weighted data so that the results of the spatial weighting approach on the final EPC could be evaluated. One Reviewer requested that the EPCs also be calculated using kriging (an alternative spatial weighting approach) and that kriging be compared to the habitat-constrained inverse distance weighting (IDW) approach that was used in the HHRA.

Five Reviewers questioned the use of the point estimate EPC for the concentration term in the probabilistic analyses, and one Reviewer questioned the selection of the lower bound for the EPC for fish and waterfowl consumption that was used in the probability bounds analysis.

Five Reviewers noted that the HHRA does not consider the potential for contaminant concentrations in environmental media (primarily soil, sediment, and biota) to be reduced over time via natural processes such as sedimentation, volatilization, and degradation. Two Reviewers were concerned that PCBs could increase in the future because of a dam break or flood event. Some Reviewers noted that the results of the fate and transport modeling, which will not be available for some time, would be valuable in addressing this issue.

Five Reviewers noted uncertainties associated with the regression models used in the Agricultural Production Consumption Risk Assessment and the Phase 2 Direct Contact Risk

Assessment to predict congener concentrations in floodplain soil from measured tPCB concentrations in floodplain soil and requested additional analyses.

RESPONSE:

4.A. Use of a Single Calculation Technique for All EPC Calculations

The different methodologies selected to calculate EPCs were based on the underlying distribution of the data. This approach is consistent with EPA guidance "Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites" (EPA, 2002b, OSWER 9285.6-10) and will be retained in the revised HHRA. To improve the clarity of presentation, a flow diagram indicating the process for method selection will be added to HHRA (Volume I) and appropriate appendices.

4.B. EPCs/Spatial Weighting

EPA recognizes that non-randomness of sampling is problematic. Spatial weighting was used to transform an observed sample distribution into one that is more nearly representative of the actual distribution of concentrations across an exposure area. The term "representative" implies in this case having a mean and shape that are similar enough to the underlying distribution that it will generate a UCL that would be appropriate if the underlying distribution had itself been accessible to analysts.

The presentation and discussion of the habitat-constrained IDW approach to spatial weighting used for the HHRA will be clarified and expanded in both the main text and Attachment 3 in response to the Reviewers' comments. The revised discussion in Attachment 3 will include a comparison of statistical results using different calculation methods for the six EAs requested by the Reviewers during the HHRA Peer Review public meeting. Those results will be expanded to include the results of spatial weighting conducted using kriging. Preliminary calculations for this presentation were completed during the preparation of this Responsiveness Summary and indicate no consistent bias or particular advantage of kriging over the IDW methodology used, and EPA at this time does not believe that the use of a kriging approach for spatially weighting the data will improve the assessment.

The revised HHRA will include a small simulation study to evaluate how and to what extent the spatial weighting used in the assessment was successful in accounting for the non-randomness of the sampling. EPA will conduct numerical simulations similar to the following. First, a spatial distribution of concentrations will be generated based on a hypothetical stochastic process. This will represent the true or "underlying distribution." From this hypothetical distribution, an "original distribution" will be obtained by sampling from it according to an idiosyncratic sampling plan (designed to mimic some of the plans actually employed in the PSA). To model laboratory measurement uncertainty, independent random error will be added to each sampled concentration value according to the patterns of analytical variability observed for the HHRA data. This original distribution will then be transformed by spatial weighting using the same scheme employed in the HHRA to obtain an "interpolated distribution." UCLs will be calculated for the original distribution, the interpolated distribution, and truly random samples collected from the underlying spatial distribution. These UCLs will be compared to estimate the magnitude of the effect of non-randomness in sampling and the potential to partially correct for non-randomness with spatial weighting.

EPA does not believe that convening a special panel as requested by one Reviewer to evaluate the uncertainties associated with the use of spatially weighted data is necessary. The technical basis for the spatial weighting and associated uncertainties will be documented in detail in the expanded spatial weighting discussion to be included in the revised HHRA.

4.C. Use of the Point Estimate EPC in the Probabilistic Analyses

Five Reviewers commented on the use of the point estimate EPC as the concentration term in the Monte Carlo analyses. The focus of the probabilistic analysis is variability in exposures across individual receptors, not variability in PCB concentrations among fish. EPA guidance on probabilistic assessment (EPA, 2001b, RAGS Volume 3 Part A Appendix C) acknowledges that environmental concentrations are variable, but assumes that an individual person samples over time from the same distribution of concentrations to produce an average intake. An individual's long-term exposure to the contaminant is, therefore, well characterized by the mean of the concentration distribution. The EPCs were developed as estimates of this mean, and are intended to reflect uncertainty associated with sample sizes. EPA guidance requires the use of point values for concentrations, even within probabilistic assessments, and relies on the specification of receptor populations and exposure areas to reflect significant differences in exposure scenarios. Appendix C of the guidance (EPA, 2001b) provides a detailed discussion of the rationale behind the derivation and the use of the EPC.

4.D. Use of Lower Bound of the Mean as the Lower Bound of the EPC in the Probability Bounds Analysis

One Reviewer commented on the use of the concentration term as the interval [sample mean, EPC] in the probability bounds analyses. The Reviewer suggested it would be more reasonable to use an unbiased symmetric estimate such as [*Z*, EPC] where *Z* is the left-tail analog of the EPC computed as the minimum of the observed concentration and the lower 95% confidence limit on the mean. This approach is inconsistent with EPA guidance. RAGS Volume III Part A Appendix C, "Characterizing Variability and Uncertainty in the Concentration Term" (EPA, 2001b), states that the reason for using the 95% UCL in place of the sample mean is to "account for uncertainty" regarding the actual value of the sample mean.

For the probability bounds analysis, the concentration input was characterized as an interval ranging from the observed sample mean to the 95% UCL. This corresponds to an interval that ranges from assuming that the sample mean equals the true mean to assuming that the sample mean underestimates the true mean. Because guidance is explicitly concerned only with the risk of underestimating the mean, the uncertainty analysis was limited to this concern. Using a symmetric estimate of the concentration term whose left bound would be based on the lower confidence limit on the mean would not lower the upper-bound estimates of the exposures or the resultant risks in the probability bounds analysis. It would lower only the lower-bound estimates.

Sensitivity studies (described in Table 7-5 in Section 7 of HHRA Appendix C) on how the various inputs affect the uncertainty of the final results demonstrated that the concentration term had, on average, only a 7% impact on the breadth of the final risk distribution. It is possible to project from this finding that widening the interval [sample mean, EPC] to [*Z*, EPC] might have resulted in the variable having perhaps at most only a 15% impact on the uncertainty of the result. This would not substantially change the relative ranking of the concentration variable with respect to other, more influential variables such as ingestion rate, exposure frequency, and exposure duration, whose impacts on uncertainty are between 30% and 46%.

4.E. Consideration of Trends in PCB Concentrations

The most comprehensive source of information relative to the issue of trends in PCB concentrations in environmental media in the Housatonic River PSA and reaches downstream of Woods Pond Dam is the RCRA Facility Investigation Report (RFI) prepared for GE (BBL and QEA, 2003). The RFI includes an analysis of all pertinent recent and historical data on contaminant concentrations in Housatonic River sediment and biota and in adjacent floodplain soil, and also includes specific discussion of any trends in concentrations over the period of record. The results of these analyses can be used to make inferences regarding the potential for any future reductions in contaminant concentrations due to both natural and anthropogenic processes.

With regard to trends in sediment PCB concentrations, the RFI (Section 4.6) notes that differences in sampling locations, sampling methods, and analytical methods over the long period of record combine to make demonstration of clear trends difficult. However, in spite of the fact that the data span a period of 20 years since the use of PCBs at the facility was terminated and that a wide variety of source control measures have been implemented and remediation of upstream sediment has been initiated, there is no indication that reach-wide decreases in sediment PCB concentrations are occurring in Massachusetts. Given that the activities most likely to produce significant decreases in sediment PCBs in the PSA and downstream have already taken place, significant reductions due to natural processes in the short to medium term are unlikely. The RFI does not include a similar analysis for temporal trends in floodplain soil, but concentrations in the floodplain are driven by deposition of riverine sediment during out-of-bank conditions, so that any lack of trends in sediment PCB concentrations would also be reflected in the floodplain.

The RFI also examined the data for indication of temporal trends in PCB concentrations in biota (fish) (Section 6.3.4), and notes several difficulties, similar to those noted above for sediment, in establishing trends for contaminant concentrations in adult fish in the Massachusetts sections of the river. The young-of-year (YOY) fish data, however, are noted as providing a reasonably consistent database that can be used for trend analysis. The report concludes that no trend in YOY fish PCB concentrations can be discerned over the 1994 to 2002 period of record, either on a wet weight or lipid-normalized basis.

For Connecticut, the RFI makes use of a particularly robust database of PCB concentrations in trout and smallmouth bass from the West Cornwall area of the river, in addition to data on other species from other locations. These data show a clearly discernible decrease in PCB tissue concentrations in Connecticut fish since the late 1970s. However, the rate of decrease has slowed markedly since the early 1990s, and the more recent collections show no statistically significant decrease over the last several years. These more recent data were used in the risk assessment.

In combination, these analyses indicate that there is, at this time, no demonstrable decrease in PCB concentrations in adult fish in either Massachusetts or Connecticut that could be used to assume a decrease in PCB concentrations in the future.

In summary, the available data have been extensively analyzed to determine if natural and/or anthropogenic processes are currently producing trends in PCB concentrations in the environmental media in the Housatonic River PSA and in the river reaches downstream of the PSA. At this time, the available data do not indicate that any decrease in PCB concentrations is occurring for any of the site media. Accordingly, EPA does not believe that the inclusion of assumed natural decreases in PCB concentrations in site media in the HHRA is either necessary or prudent.

With regard to the issue of the modeling study and the potential incorporation of modeling results into the HHRA, EPA notes that the work at the Housatonic River Rest of River site, and in particular the HHRA, is being conducted under the terms of a Consent Decree. As stated in Article 22.b of the Consent Decree, a work plan for the HHRA was provided to the parties at the time the Consent Decree was negotiated. That work plan was prepared with the understanding that the results of the modeling study would not be available for incorporation into the HHRA and that the HHRA, therefore, would be restricted to consideration of current (baseline) conditions. The model simulations of PCB concentrations under the no-action scenario will not be completed for at least 1 year. The model results will be comprehensively evaluated in the context of the HHRA, Interim Media Protection Goals, and other studies for consideration of remedial action alternatives.

4.F. Regression Approach for Predicting Congener Concentrations

The revised HHRA (Volume 1, Attachment 2) will provide expanded discussion of the following topics:

Data Used To Develop Regression Models

- Addition of descriptive statistics and scatter plots of the untransformed data to support log-transformation.

- Expanded discussion of analytical methods used to quantify tPCBs in floodplain soil and selection of tPCB data for use in the regression models.

Regression Model Development and Selection for Use in the HHRA

- Expanded rationale for why tPCB concentrations are a reasonable predictor of PCB, dioxin, and furan congeners. Dioxins and furans have been detected in samples of non-aqueous phase liquid (NAPL) at the GE facility and in sediment samples collected adjacent to and upstream of the GE facility, and these data indicate that, in addition to tPCBs, the East Branch is a source of PCDDs/PCDFs to the Rest of River (RFI, Section

8.6.2.1). Because of their similar physical and chemical characteristics, PCBs, dioxins, and furans are generally found in the same types of areas (e.g., within impoundments where sediment accumulates, banks, and floodplain soil) within the Housatonic River area (RFI, Section 8.9).

- Discussion about whether the four assumptions of linear regression are met.
- Additional discussion of criteria used to select regression models for use in the HHRA. Regression models based on the largest sample size available were selected regardless of p-values or r^2 values. Almost all models had p-values less than 0.05, and the few exceptions were not among the selected regression models. Some regression models based on a smaller data set had higher r^2 values than the corresponding regression model based on a larger data set. Even in these cases, EPA believes that the regression model based on the larger data set should be selected because the larger data set is likely to be more representative of floodplain conditions than the smaller data set.
- Additional discussion of the applicability of regression models to floodplain soil in all river reaches. Regression models were developed using floodplain soil data from Reach 5, and some Reviewers expressed concern that congener patterns in Reach 5 might differ from congener patterns in lower reaches due to factors such as weathering and variations in soil characteristics.

Use of Regression Models

- Brief interpretation of regression plots, including the range of tPCB concentrations over which predictions are best applied and the associated uncertainty, which will be further discussed in the Phase 2 Direct Contact Risk Assessment and explicitly characterized in the revised Agricultural Product Consumption Risk Assessment.
- Example calculation showing how the regression results are used to derive congener concentrations, including a discussion of uncertainty.

5. SELECTION OF COPCs

SUMMARY OF ISSUE:

All Reviewers agreed that PCBs should be included in all exposure pathways. Although no Reviewer suggested eliminating TEQ as a COPC, five Reviewers expressed concern regarding the method selected by EPA to evaluate dioxin-like PCB congeners, and a sixth Reviewer joined those five in suggesting the presentation of the method was unclear. Four Reviewers thought the methodology used by EPA to avoid “double counting” should be eliminated.

One Reviewer suggested that aluminum, manganese, and chromium should have been retained as COPCs in the evaluation of the direct contact with soil, and that chromium and thallium should have been retained as COPCs in sediment pathways, although they would have had minimal impact on the risk. Another Reviewer expressly disagreed with that position. One Reviewer assumed that only the Region IX residential preliminary remedial goals (PRGs) were used to screen agricultural exposure pathways and asked why agricultural screening risk-based concentrations (SRBCs) were not developed.

Two Reviewers commented that the initial summary presentation of the risk assessment lacked clarity regarding why COPCs other than PCBs and TEQ were evaluated in some exposure pathways and not others.

RESPONSE:

5.A. TEQ as a COPC

TEQ from dioxin-like PCB congeners, dioxin congeners, and furan congeners was selected, and will be retained, as a COPC in the HHRA for all exposure pathways. TEQ is being retained based on site-wide occurrence, concentration, and the association of these compounds, particularly furans, with the manufacture and heating of PCBs, and detection of these compounds in NAPL samples from the GE facility.

The revised HHRA will address the issue of double-counting the amount of dioxin-like PCBs accounted for in the PCB slope factor by not adding the cancer risk estimates for tPCBs to cancer risk estimates for TEQ. This revision avoids any overestimation of cancer risk due to the presence of dioxin-like congeners in the Aroclor test materials used in animal studies that form the basis of the PCB cancer slope factor (CSF). In the revised Phase 2 Direct Contact Risk Assessment, all TEQ risk estimates will be addressed in the uncertainty section instead of the risk characterization section due to the uncertainty associated with predicting floodplain soil congener concentrations using regression models.

In the revised Fish and Waterfowl Consumption Risk Assessment, all TEQ risk estimates will remain in the risk characterization section because all congeners were measured in fish and waterfowl.

In the revised Agricultural Product Consumption Risk Assessment, all TEQ risk estimates will be addressed in the uncertainty section instead of the risk characterization section. All Reviewers noted the uncertainties associated with regression models for predicting floodplain soil concentrations and congener-specific soil-to-plant transfer factors and bioconcentration factors. Two Reviewers recommended that at least some congener-specific risk estimates be removed from the risk characterization section and be included only as a "sensitivity analysis." EPA believes that some congener-specific risk estimates are sufficiently certain to remain in the risk characterization section (e.g., risk from dioxin congeners in soil for the dairy and poultry exposure scenarios). However, to avoid the confusion of having some aspects of the TEQ pathway for a given exposure scenario divided between the risk characterization and uncertainty sections, all congener-specific risk estimates (except for fish and waterfowl) will be moved to the uncertainty section in the revised HHRA.

5.B. COPCs Other Than PCBs and TEQ

EPA agrees that aluminum, manganese, chromium, and thallium would have minimal impact on the risk if they had been retained as COPCs in the Direct Contact Risk Assessment for soil and/or sediment. Because of the conservative nature of the screening criteria (0.1 Hazard Index), the low degree of exceedance of the criteria, and the minimal impact of the inclusion of these metals in the risk assessment, they will not be added to the list of COPCs evaluated in soil and sediment. The MDEP background concentrations for aluminum and manganese in natural soil are 10,000 mg/kg and 300 mg/kg, respectively. In both cases, the PRGs (with an HI=0.1) are below what is considered background in Massachusetts. Discussion of the MDEP background concentrations for aluminum and manganese will be added to the revised HHRA.

COPC screening for the agricultural exposure pathways was not limited to Region IX PRG comparisons. In recognition of the fact that Region IX PRGs do not address food consumption pathways, the HHRA (Volume V, Section 2.2.2) describes additional COPC screening that was performed as a practical alternative to developing highly uncertain, non-site-specific SRBCs for a long list of chemicals, many of which were detected infrequently and/or were within the range of typical background concentrations.

5.C. Clarity of the Presentation

The initial introductory sections of the HHRA and appendix volumes were intended to briefly summarize the contents of the individual reports rather than to provide details of the assessment. In the revised HHRA, the text preceding these summaries will be expanded to include a discussion of the conceptual site model and a summary of the chemical analyses conducted in site media. It will also include a brief overview of COPC selection that will indicate why the risk assessment focused on PCBs, why TEQ was retained as a COPC for all exposure pathways, and why other contaminants (i.e., pesticides) were included as COPCs in some exposure pathways but not others.

6. DIRECT CONTACT EXPOSURE – SCREENING RISK ASSESSMENT

SUMMARY OF ISSUE:

Six Reviewers questioned the use of different target risk levels (TRLs) for different receptors. Three Reviewers thought the TRLs were not adequately conservative and should have been set to 1×10^{-6}, whereas one Reviewer thought the TRLs were too conservative and should have been set to 1×10^{-5}. One Reviewer questioned why the TRLs were more stringent for utility workers and groundskeepers than for residents or recreationalists. Three Reviewers commented on the need to use and appropriately reference the Soil Screening Guidance (EPA, 1996, OSWER 9355.4-23) or the more recent Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites - Peer Review Draft (EPA, 2001a, OSWER 9355.4-24) as it pertains to the calculation of the SRBCs in the Phase 1 Direct Contact Risk Assessment.

RESPONSE:

6.A. Approach to Establishing TRLs and the Development of the SRBCs

All target risk levels established for the Phase 1 screening are at the low end of the EPA acceptable risk range of 10^{-6} to 10^{-4}. The SRBCs were developed based on the assumption that PCBs, dioxins, and furans are the only contaminants of potential concern (COPCs), after reviewing the data for other COPCs. The default screening level of 1 x 10^{-6} found in the EPA Soil Screening guidance takes into account the presence of a combination of chemicals typically found at most Superfund sites such that the cumulative risks are within the risk range.

The Performance Standards that are part of the Consent Decree include a standard for residential areas termed "actual/potential lawns." This concentration was used for floodplain areas that are current lawn areas or could conceivably be lawn areas in the future, which includes the high-contact residential areas designated in Phase 1.

The Performance Standard for actual/potential lawns is based on the Massachusetts Department of Environmental Protection (MDEP) Method 1 Generic Soil Cleanup Level for residential use, which is 2 mg/kg (MDEP, 1994). As described in the EPA memo on "Protectiveness of Cleanup Levels for Removal Actions Outside the River" (EPA, 1999a), a cancer risk of 4 x 10^{-6} and a noncancer hazard index of 0.8 are associated with the 2 mg/kg PCB concentration. Because this TRL is within the lower end of the acceptable risk range, EPA concluded that these risk levels were acceptable for residential exposure.

In the Phase 1 Direct Contact Risk Assessment, other exposure parameters were applied to less intensive land-use scenarios. For example, the frequency of exposure to residential property that is not currently or potentially future lawn area (i.e., steep slopes and banks or inundated wetlands) would be less than for the lawn areas. In this case, modified exposure parameters were combined with a TRL of 5 x 10^{-6}, which results in the derivation of SRBCs of 5 mg/kg for residential non-lawn areas (low-contact residential areas) and high-contact recreational areas; and 7 mg/kg for low-contact recreational areas. While EPA acknowledges that a TRL of 4 x 10^{-6} would have been more consistent with the residential TRL that was based on the Performance Standard, the difference is small and a retrospective analysis indicates that no additional properties would have been retained based on the more stringent TRL.

A TRL of 2 x 10^{-6} was used for the groundskeeper and utility worker exposure pathways. Although use of a 4 x 10^{-6} screening concentration might have eliminated additional properties from consideration in Phase 2, in practice, it did not, because properties that would have been eliminated were retained for evaluation in Phase 2 because of their potential residential or recreational use. (Table 2-6 in the Phase 1 Direct Contact Risk Assessment [Appendix A] inadvertently lists the TRL as 1.1 x 10^{-6} for the groundskeeper; this was a typographical error and the correct number is 1.6 x 10^{-6}, the same value that was used for the utility worker. Thus, both TRLs are 2 x 10^{-6} when rounded to one significant figure.)

The preceding discussion evaluates only cancer risk because the TRL for noncancer exposure was the default hazard quotient value of 1.0 in all cases.

6.B. Consistency with Supplemental Soil Screening Guidance

Three Reviewers noted the lack of a specific reference to the Supplemental Soil Screening Guidance (SSSG) (EPA, 2001a). Site-specific risk-based screening levels (SRBCs) were developed to identify areas that require a more comprehensive HHRA. This approach is consistent with the SSSG. References to both the 2001 SSSG (EPA, 2001a) and its predecessor guidance document (EPA, 1996) will be provided in the revised HHRA.

7. DIRECT CONTACT – PHASE 2 ASSESSMENT

SUMMARY OF ISSUE:

Overall, five Reviewers commented that the approach, including the selection of exposure scenarios, receptors, exposure parameters, and risk estimates used to estimate risk from direct contact, was reasonable and consistent with EPA policy. All Reviewers agreed with the exposure scenarios selected, although Reviewers recommended additional receptors such as nursing infants (see the response to General Issue 3.A), a construction worker (one Reviewer), and an adult dirt biker/ATV rider (two Reviewers). One Reviewer considered the selection of exposure parameters reasonable, but thought that the combination of exposure parameters resulted in overly conservative risk estimates for most of the scenario/receptor combinations (see the response to General Issue 13.A). One Reviewer commented that individual exposure parameters were too high and the combination of exposure parameters resulted in extreme estimates of risk, rather than risk to an RME.

Reviewers had several concerns with the approach used to define exposure areas (EAs). One concern was the size of the EAs, with the assumption that a receptor accesses the EA randomly, especially because some EAs are quite large and exposures may be focused in a smaller area. This concern was either based on whether there were localized areas of high contamination where the risk may be underestimated based on the evaluation of exposure to the larger area (three Reviewers), or conversely that risks may be lower because the more contaminated areas were not accessed equally.

Another concern was the use-weighting methodology that was applied to account for differential access to areas that would be underwater for only part of the year or otherwise less accessible. Four Reviewers questioned the derivation of the methodology, and if it realistically accounted for the differences in accessibility in different habitat types that comprised the larger EAs.

A third concern expressed by four Reviewers was that current and future uses of the EAs were not clearly distinguished and future use may lead to more intensive exposure than addressed in the HHRA. This issue is integrally related to the definition of exposure areas and use weighting, because future use may alter the vegetation, and thus alter use-weighting factors that are based on density of vegetation.

Six Reviewers provided comments about one or more of the exposure parameters used in the calculations. Four Reviewers commented that the exposure frequency (EF) for the farmer was too low; two commented the EF for the residential scenario may be too low; one commented the

EF for the utility worker was too low; and three commented that the EF for fishing was too high. Two Reviewers commented that the exposure duration (ED) for the ATV/dirt biker was too low (adults should have been included), whereas one Reviewer commented that the ED, along with all other EDs, was too high. This same Reviewer also commented that all EFs were too high. Two Reviewers referred to the Floodplain User Survey submitted by GE as a source of information on EFs. Several Reviewers offered suggestions on the soil ingestion rates used in the different exposure scenarios. In some cases, notably for soil ingestion for residential and general recreational exposure, Reviewers did not agree on the approach used. Six of the Reviewers thought the dermal exposure parameters were appropriate, although one of these six suggested the explanation for their selection be enhanced.

Reviewers provided many comments regarding the treatment of uncertainty in the direct contact risk assessment, all of which suggested that the HHRA needed a more comprehensive, in-depth analysis of the uncertainties.

RESPONSE:

7.A. Random Access

EPA guidance, "Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites" (EPA, 2002b), states:

> *"An exposure unit is the area throughout which a receptor moves and encounters an environmental medium for the duration of the exposure. Unless there is site-specific evidence to the contrary, an individual receptor is assumed to be equally exposed to media within all portions of the exposure unit over the time frame of the risk assessment."*

Further, EPA's "Supplemental Guidance to RAGS: Calculating the Concentration Term" (1992b) states:

> *"While an individual may not actually exhibit a truly random pattern of movement across an exposure area, the assumption of equal time spent in different parts of the area is a simple but reasonable approach."*

In developing the Phase 2 Direct Contact Risk Assessment, several strategies were used to define or modify exposure areas to conform to the assumption that an individual receptor came into contact equally with soil throughout the exposure area. These strategies were:

- Define EAs that were natural units for more intense exposure activities. Examples of these are the EAs that are utility corridors, known paths or trails in the area, and canoe launches.

- Define EAs by access points and uninterrupted unconstrained access (such as parcels of state wildlife management areas serviced by a parking lot or entry point).

- Examine EAs that are large parcels and determine if subareas may have more intensive use than the general area. Examples include subareas known as teenage "hangout" spots or areas near homes that may be more frequently used due to proximity.

- Apply use-weighting factors to areas where frequency of contact may be decreased because of hydrological factors, e.g., they are underwater part of the year or they have dense vegetation.

In the revised HHRA, EPA will continue using these guidelines with the following modifications

1. Modify and better describe the use-weighting approach and documentation (see Issue 7.B).

2. Identify additional subareas with potentially different uses from the larger EA based on revisiting site-related documents such as land use maps and the *GE Floodplain User Survey* (Triangle Economic Research, 2003).

3. Identify areas of high concentrations of PCBs within exposure areas and evaluate separately (see Issue 7.C).

7.B. Use Weighting

The use-weighting methodology will be reevaluated. Objective criteria for assigning wetland habitats to different accessibility categories will be developed and habitats in each exposure area will be reassigned based on these criteria. The use weights assigned to the different accessibility categories will also be reassessed. In addition, habitats that could potentially be developed in the future will be identified, and will be evaluated differently in current and future use scenarios. The future use evaluation will consider applicable wetland protection regulations.

7.C. Localized Areas of High Concentrations

If random exposure occurs in a smaller section of the EA with elevated concentrations of contaminants, an under- or overprediction of risk may result.

These localized areas will be evaluated as part of the uncertainty analysis in the revised HHRA. The evaluation will be conducted as a bounding analysis that will quantify the maximum and minimum risks that would be predicted if all exposure were to take place in the area of high or low concentrations.

7.D. Current versus Future Use

The revised HHRA will clearly distinguish between scenarios based on current uses and those based on potential future uses. Both current and future use calculations will be presented in each exposure area and subarea. Differences between the current and future use risk calculations will be based on changes to accessibility (changing the use weighting factors and, subsequently, the EPC) and/or changes to the receptor evaluated.

7.E. Exposure Parameters

As part of the revision of the HHRA, EPA will review the exposure parameters used in all the exposure scenarios. EPA will change the basis of the farmer scenario from an individual on a tractor contacting floodplain soil only during planting and harvest to a scenario in which the farmer hand-cultivates a vegetable crop such as squash throughout the growing season (May-October). This revision is based on personal communication with local farmers regarding farming practices. Several of the exposure frequencies that were based on professional judgment, such as the exposure frequency for anglers, will instead be based on data obtained from similar populations, such as Maine anglers. The exposure frequencies for individual exposure areas for the general recreation scenario will be reviewed, and the exposure frequencies for current and future scenarios will be differentiated. Observations provided in the Housatonic River Floodplain User Survey will be considered in the development of the exposure frequencies for the current use scenarios.

The basis for soil ingestion rates, especially for child and adult residents and general recreational users, will be fully described in the text, and include references to the original literature and non-EPA summary literature (e.g., the Simon [1998] reference provided by the Reviewers) in addition to the EPA *Exposure Factors Handbook* (EPA, 1997).

EPA will continue to use the MDPH survey as the appropriate, site-specific basis for the determination of exposure duration for the direct contact scenarios. The revised HHRA will expand the discussion of the basis for selecting the exposure durations in each scenario as well as the uncertainty involved in the selection.

7.F. Uncertainty Analysis

EPA will perform probability analyses for each exposure pathway to quantify the uncertainty associated with the point estimate and discuss the results of these analyses in the revised HHRA.

8. FISH CONSUMPTION POINT ESTIMATE EXPOSURE PARAMETERS

SUMMARY OF ISSUE:

The HHRA provided both point estimate and probabilistic analyses of the risks associated with consumption of fish from the Housatonic River. The point estimate RME was based on the following exposure parameters: ingestion rate (32 g/d); exposure duration (60 years); fraction ingested from the Housatonic River (1); and no cooking loss. The sensitivity analysis provided in the probabilistic assessment indicated that the risk was most sensitive to the ingestion rate (IR) and, for cancer risk, the exposure duration (ED).

Overall, four Reviewers commented that the approach, including the selection of exposure scenarios, most exposure parameters, and point estimate risk approaches, were reasonable and consistent with EPA policy for the RME. Two Reviewers considered most exposure parameters defensible on an individual basis, but questioned whether too many upper-bound estimates were incorporated into the RME risk calculation. One Reviewer commented that all or most of the individual exposure parameters were too high and the combination of exposure parameters resulted in extreme estimates of risk, rather than risk to an RME.

The most widely expressed concern was the basis of the ingestion rate used in the RME calculation. Although all Reviewers agreed with the use of the Maine angler survey as the basis of the ingestion rate, five expressed concerns regarding the method applied to derive the rates used in the assessment. These Reviewers were particularly concerned about the appropriateness of the assumption that anglers do not share fish and the use of a consumption rate for all waters rather than flowing water or non-flowing water (lakes and ponds).

RESPONSE:

8.A. Fish Consumption Rate from the Maine Angler Survey

EPA believes that a recreational fish consumption rate of approximately one meal per week is appropriate to assess RME from the Housatonic River, which includes non-flowing areas such as Woods Pond, Rising Pond, Lake Lillinonah, and Lake Zoar. These are large water bodies and attractive resources for fishing. A one-meal-per-week consumption rate for these areas is supported by the site-specific and regionally appropriate studies cited in the HHRA. The rationale for this approach and a description of the calculations from the Maine Angler Survey and those in the HHRA are provided below.

The fish consumption rate was based on the Maine Angler Survey conducted by ChemRisk in cooperation with HBRS, Inc. The results were published in the report "Consumption of Freshwater Fish by Maine Anglers," revised 24 July 1992, and a peer-reviewed publication "Estimating Consumption of Freshwater Fish Among Maine Anglers" (Ebert et al., 1993). Ms. Ebert also provided additional raw data from the study to EPA.

The Maine Angler Survey was a 1-year recall study based on a 19-page survey mailed to 2,500 individuals holding residential fishing licenses in Maine.

Overview of Survey

- Target group: resident recreational anglers and their families.
- Sample population: individuals holding a valid Maine residential or complementary fishing license in 1989. All categories of licenses were sampled (fishing; fishing and hunting; fishing and archery; servicemen combination; supersport; over 70 - fishing and combination; disabled veterans - fishing and combination; paraplegics - fishing and combination; blind - fishing; mental disability- fishing; and Indian - combination). Every 75th license holder was selected from the list, for a total of approximately 3,000 names.
- A pretest survey (50 individuals) was sent out and revised based on telephone interviews and returned surveys.

- 2,500 (revised) surveys were mailed out on 16 October 1990 with questions about fishing activity in the previous 12 months. 1,612 completed surveys were returned.

Calculation of Fish Consumption Rates

The approach for calculating fish consumption rates in this study was:

- For each household, ChemRisk calculated the total mass of freshwater fish consumed in the household that was caught by members of the household or obtained as gifts (separate calculations were done for ice fishing, open water-flowing, and open water-standing).

- Individual consumption rates were calculated by dividing the total household mass consumed by the number of freshwater fish consumers in the household. No distinction was made between males and females or children and adults.

- The fish mass consumed was calculated from the responses to the questions regarding length and number of fish consumed (see below). These data were combined with a species-specific relationship between fish length and mass, and the percent edible portion of fish (assuming only fillets were consumed).

- The consumable portion of the fish was assumed to be 30% for all species except landlocked salmon (40%) and smelt (78%). The 30% value was based on studies of smallmouth bass in Maine and EPA default values (EPA, 1989a).

The specifics of how this was done are provided below.

The Maine Angler Survey asked questions regarding the species and number of freshwater fish caught by the respondent (with separate questions for ice and open water season) and the disposition of the fish. One portion of a question asked for the number and average length of the fish consumed by the respondent and/or household member (for each of 14 named species and other). A summary of the questions that formed the basis for the household total mass consumed calculation are given below.

Summary of Questions Used To Calculate Household and Individual Fish Consumption Rates

- How many fish of each of 14 named species had the respondent caught during ice fishing season and eaten? What was the length of these fish? (Q11)

- How many fish of each of 14 named species had the respondent caught during open water fishing season and eaten? (Q23) How many of these fish were from flowing waters and how many from standing waters? What was the average length of these fish? (Q24)

- How many of each of 14 named species caught by other members of the household during ice fishing and open water season were eaten by the respondent and/or other family members (also average length)?(Q29)

- How many of each of 14 named species caught by non-household members during open water fishing season were eaten by the respondent and/or other family members (also length)?(Q31)

- Please describe the age and sex of each household member and indicate whether they eat freshwater fish caught in Maine. (Q32)

To calculate fish mass consumed in each respondent's household, the average lengths provided in response to questions 11, 23, 24, 29, and 31 for the species consumed were converted to fish mass using the following relationship:

$$W = CL^n$$

Where:

W = the mass of the whole fish
C = species-specific constant
L = length of whole fish
n = species-specific constant, generally around 3, but depends on shape of fish.

Parameter values (n) were obtained from regressions of fish caught in Maine (unpublished data from Maine Inland Fisheries and Wildlife) and literature values.

Uncertainties and Potential Biases of the Results

A discussion of the uncertainties and potential biases that were considered in applying the Maine Angler Survey results will be discussed in the revised HHRA.

EPA Approach

No Sharing Method

The RME fish consumption rate that was used in the Fish and Waterfowl Consumption Risk Assessment was based on the assumption of no sharing; that is, that the household consumption rate applies to the individual angler. The reason for this decision was that the division of the household rate by the number of consumers, i.e., the assumption of equal sharing among household members, would underestimate the fish consumption rate for the RME individual.

In the Fish and Waterfowl Consumption Risk Assessment, an estimate was made of the grams consumed by a nonsharing adult based upon the simple assumption that the nonsharing adult consumed at the rate that was reported as the household consumption rate in the Maine Angler Survey. The resulting consumption rate (57 g/d) appeared to be biased high, even under an RME scenario, so the 90th percentile of the distribution of consumption rates was used, rather than the 95th percentile. The resulting RME consumption rate was 32 g/d.

However, upon receipt of the Reviewers' comments, EPA further evaluated the raw data provided by Ms. Ebert and realized that the information existed to construct the distribution of consumption rates for the respondents to the Maine Angler Survey who reported that they did not share their catch.

Eighty-seven of the respondents reported that they did not share their catch with members of their household and eat only what they catch. An additional 51 respondents reported they did not share their catch with family members, but consumed fish caught by others in addition to (or instead of) themselves. Based on fish consumption from all waters, the following statistics were derived for all non-sharing respondents (138) and those who eat only their catch (87).

Statistic	All Non-Sharing (n=138) (g/d)	Non-Sharing, Who Only Eat Their Catch (n=87) (g/d)
Median (50th percentile)	2.9	3.4
Mean	8.9	8.5
90th percentile	21.5	18.7
95th percentile	31.1	31.4

This analysis of consuming anglers is based on only those who reported that they do not share their catch (9% of all respondents), thus an overestimation of consumption rates is unlikely and the 95th percentile is appropriate for the RME exposure. For both subsets of non-sharing anglers, the 95th percentile consumption rate is 31 g/d for consumption from all waters (rivers, streams, lakes, ponds, and ice fishing).

Sharing Method

With regard to the majority of respondents who reported sharing their catch, the Maine Angler Survey assumed equal sharing of fish among all household consumers. However, males (roughly 80% of respondents) generally consume larger portions than females and children. This is demonstrated by the following consumption rates for male and female adults for freshwater and estuarine fish (all, not just recreationally caught), which are published in the EPA Exposure Factors Handbook (EPA, 1997):

Mean of distribution	male: 98.1 g/d	female: 74.7 g/d	Ratio: 1.3
90th %-ile of distribution	male: 246.9 g/d	female: 181.1 g/d	Ratio: 1.4
95th %-ile of distribution	male: 325.5 g/d	female: 239.6 g/d	Ratio: 1.4

If one assumes sharing of fish among adult household members only, and adjusting for non-equal sharing among males and females based on a 1.3 ratio, the 95th percentile of the distribution for adult male consumers is approximately 32 g/day. This value is derived by apportioning the 57 g/d (95th percentile, no sharing, mass per household from the Maine Angler Survey) among an adult male and female consumer with a male/female ratio of 1.3. This yields an RME (male) of 32 g/d and an RME (female) of 25 g/d. Since 80% of anglers are male, the RMEs are weight-averaged resulting in an overall sharing method RME of about 31 g/d.

Conclusion

In the revised HHRA, both the sharing and no sharing methods support a revised RME consumption rate of 31 g/d. This represents a slight downward revision from the 32 g/d value. This corresponds to 50 8-oz meals/year. The central tendency exposure (CTE) rate will be 8.7

g/d (average of the means of the two subsets), which is a downward revision from the 15 g/d consumption rate used in the current HHRA. This corresponds to 14 8-oz meals/year.

All Waters

Five Reviewers questioned whether the use of the all water consumption rate was appropriate, rather than using the flowing water rate for some stretches of the river and the standing water rate for other stretches. EPA believes that the all waters consumption rate is appropriate, except for trout consumption, for the reasons provided below:

1. Each of the four areas of the Housatonic River evaluated has stretches that are both flowing and stretches that are standing (lakes and ponds). The areas (and the risk assessment) are structured on the basis that all of a person's freshwater fish consumption originates in this area. To the extent that anglers consume fish from other areas of the Housatonic River, the risk should be fractionated among areas, not summed. The rationale for assuming that all fish consumed originate from the Housatonic River is provided in the next section.

2. Anglers may fish in different locations and different seasons, with different characteristics of standing/flowing water in each area evaluated. Data collected in the Maine angler survey indicate that, on average, a recreational angler travels 30 miles to fish. The areas evaluated for this assessment have lengths that are less than 30 miles, determined either in river miles or by road. The distances below are in river miles:

    - Reach 5: 10.12 miles
    - Reach 6: 0.57 miles
    - Reach 7: 18.47 miles
    - Reach 8: 0.70 miles
    - Reach 9: 23.9 miles
    - Reach 10: 7.4 miles
    - Reach 11: 11.5 miles
    - Reach 12: 13.1 miles
    - Reach 13: 10.9 miles
    - Reach 14: 12.5 miles
    - Reach 15: 10.2 miles

3. The fish species that are most likely to be consumed by anglers are bass, perch, trout, and bullhead. To a lesser extent, sunfish such as bluegill or pumpkinseed may also be consumed. Bass, perch, bullhead, and sunfish may be caught in either flowing or standing waters as demonstrated in the following table, which presents the biomass survey data obtained during the ecological characterization of Reaches 5 and 6, the Primary Study Area. The species of trout in the Housatonic River are primarily harvested in flowing waters; therefore, only a flowing-water consumption rate was used for trout.

	BIOMASS SURVEY- Housatonic River					
	No. Fish Caught, Sum of Single Pass and Multipass Runs					
	5A	5B	5C	Backwaters	WP	Totals
LM Bass	**52**	**70**	**115**	**36**	**76**	**349**
SM Bass	4	2	0	0	0	6
Yellow Perch	**97**	**439**	**324**	**116**	**183**	**1159**
Pike	11	26	15	8	29	89
Pickerel	5	63	45	1	2	116
Trout (brown and rainbow)	3	0	0	0	0	3
Bluegill/pumpkinseed	**135**	**328**	**805**	**284**	**1419**	**2971**
Brown bullhead	**0**	**0**	**13**	**32**	**97**	**142**
	BIOMASS SURVEY- Housatonic River					
	Biomass Captured, g/m^2, Sum of Single Pass and Multipass Runs					
	5A	5B	5C	Backwaters	WP	Totals
LM Bass	**5.19**	**6.86**	**10.27**	**5.73**	**4.18**	**32.23**
SM Bass	0.22	0.095	0	0	0	0.315
Yellow Perch	**2.6**	**8.441**	**6.23**	**8.75**	**4.55**	**30.571**
Pike	0.94	1.67	1.36	1.76	1.88	7.61
Pickerel	0.2	0.364	0.55	0.2	0.04	1.354
Trout (brown and rainbow)	0.17	0	0	0	0	0.17
Bluegill/pumpkinseed	**1.414**	**3.371**	**6.67**	**10.32**	**2.02**	**23.795**
Brown bullhead	**0**	**0**	**0.52**	**4.93**	**4.46**	**9.91**

Source: WESTON, 2003.

The species in **bold** in the table above are those for which PCB data are available and also the species included in the EPC calculation based on species preference for Reaches 5/6. The bass/bullhead combination and perch/bluegill/pumpkinseed combination are weighted equally for consumption, based on preferences expressed in the MDPH survey. Based on the biomass estimates, the major contributors are largemouth bass, yellow perch, and bluegill/pumpkinseed, and these species are caught in both flowing stretches (Reaches 5A, 5B, 5C) and non-flowing stretches (backwaters, Woods Pond).

Consistency of Fish Ingestion Rates with Other Sources of Data

The use of 31 g/d for an RME fish consumption rate is consistent with other studies, including the MDPH survey (MDPH, 1997) and the Connecticut Creel Survey (Ebert, 1996). These studies, and how they are consistent, will be discussed in greater detail in the revised HHRA, and data from the Maine Angler Survey will be used to show the extent or direction of uncertainties (e.g., impact of fish consumption advisory in the Connecticut Creel Survey; the impact of store-bought meals and meal size in the MDPH survey).

Child Consumption Rates

The HHRA calculated the fish consumption rate for children by assuming the ratio of child to adult consumption rate for all fish consumed. The national average per capita consumption of freshwater/estuarine finfish and shellfish (EPA, 2002a) would be the same as the ratio of child to adult consumption rate of Housatonic River fish. The ratio based on these national averages, 0.5, was then multiplied by the adult consumption rates.

The basis for the selection of the 0.5 factor was provided in detail in the HHRA (Appendix C, pp. 4-41 to 4-43). Two Reviewers considered the value of 0.5 too high, but one based his comment on a child aged 2-3 years, rather than the child aged 1-6 years considered in the assessment. This Reviewer also noted that the highest ratio between food intake and body weight is anticipated for the youngest age groups, which makes it inappropriate to calculate child consumption rates based on the body weight ratio of child and adults.

The revised HHRA will expand the discussion regarding the derivation and selection of fish consumption rates for children.

8.B. All Fish Caught/Consumed from Housatonic River (FI=1)

Several Reviewers questioned whether the assumption that all freshwater fish consumed were caught in the Housatonic River was reasonable. This assumption is based on data available from both the Maine Angler Survey and the Connecticut Creel Survey. Specifically, anglers were asked about the number of water bodies they typically fish. The results of both studies indicate that the assumption of fishing only the Housatonic River was reasonable for 10% or more of the anglers.

In a summary statement of Maine Angler Survey results, Ebert et al. (1993) state "over 80% of Maine's resident anglers fish two or more bodies of water each year, approximately 50% fish three or more, and nearly 40% fish four or more." An alternate way of stating this is that nearly 20% of Maine's resident anglers fish only one body of water.

Ebert et al. (1996) summarized fish consumption-related information from a creel survey of Housatonic River anglers in Connecticut from the Massachusetts border to Stevenson Dam (downstream end of Lake Zoar) that was conducted from 1984-86. With respect to a preference for fishing the Housatonic River, Ebert et al. (1996) reported "Twenty three respondents (1.5%) indicated that all their angler effort was spent fishing the Housatonic, and 150 respondents (9.9%) reported that at least 95% of their fishing trips were to that river." The median value was 30% of total fishing trips were taken to the Housatonic. It should be noted that a fish consumption advisory due to PCBs was in place during the period when the survey was performed.

Although these two studies support the assumption that more than 10% of anglers fish the Housatonic River nearly exclusively, the fraction ingested (FI) from the Housatonic River for the RME and the CTE will be revised to address concerns raised by the Reviewers.

The FI for the RME in the HHRA is currently 1.0. EPA will reevaluate existing data from the two studies, and search for additional relevant data, to determine the appropriate FI to be applied in the revised HHRA. The revised FI will be lower than 1.0.

The FI for the CTE in the HHRA is currently 1.0. The median value of 30% (FI=0.3) from the Housatonic River creel survey is too low an estimate for two reasons. First, the presence of the fish advisory likely decreased the number of trips and the preference for the Housatonic River. Second, the underlying distribution of trip frequencies to the Housatonic is not available, but most likely the average trip frequency is higher than the median frequency as distributions contributing to exposure are frequently skewed. The Maine Angler Survey indicates that approximately 80% of anglers fish from two or more water bodies. Assuming that anglers fish equally from each of two water bodies results in a FI of 0.5. The FI for the CTE will be reevaluated in the revised HHRA and, based on an evaluation of the existing studies, will likely be reduced to the 0.3 to 0.5 range.

8.C. Cooking Loss

Numerous studies have examined the loss of PCBs from fish during food preparation and cooking. Experimental results range considerably, both between various cooking methods and within the same method. Cooking losses, expressed as percent loss based on tPCB mass before and after cooking, were as high as 74% reported in one study (Skea et al. 1979). However, several studies reported net gains of PCBs (Moya et al., 1998; Armbruster et al., 1987). These net gains are likely within experimental measurement error and essentially indicate zero loss. Most PCB losses (expressed as percent loss based on tPCB mass before and after cooking) were between 10 and 40%.

PCB losses from cooking are a function of the cooking method (i.e., baking, frying, broiling, etc.), the cooking duration, the temperature during cooking, preparation techniques (trimmed versus untrimmed, with or without skin), the lipid content of the fish, the fish species, the magnitude of the PCB contamination in the raw fish, congeners in the fish, and the extent to which the lipids separated during cooking are consumed. Experimental factors such as the reporting method and experimental design may also influence the reported cooking loss. In addition, personal preferences for various preparation and cooking methods and other related habits (such as consuming pan drippings) might result in consumption of PCBs reported in studies as “lost” from the fish upon cooking.

Based on the studies by Moya and Armbruster, the large variability in study results, and the possibility that pan drippings are consumed, the RME cooking loss was assumed to be zero. An evaluation was performed to estimate cooking loss for the CTE by combining literature data on cooking loss for a specific cooking method and tissue (skin-on or skin-off fillet) with estimates of the percentage of meals cooked using each method (based on data that originated in the Maine Angler Survey). This resulted in cooking loss estimates of 24% and 21% for skin-on and skin-off fillets, respectively. These values are considered to be statistically the same.

Data from Zabik et al. (1979) and Salama et al. (1998) showed greater losses of PCBs from fish cooked with the skin off as compared to skin on. Zabik et al. (1995) observed minimal differences in PCB losses between fish with skin on or skin off. The calculations in the HHRA are consistent with Zabik et al., 1995. No meaningful difference was calculated regarding cooking loss for skin-on and skin-off fillets.

The revised HHRA will more fully describe the range of studies of cooking loss and the consideration of these studies. The assessment will retain the calculation of cooking loss by preparation method, although it will not distinguish between skin-on and skin-off fillets. For the

RME, the cooking loss will remain zero based on the studies by Moya and Armbruster. However, to partially address the concern of compounding conservatism and consistent with the EPA policy of using a mixture of high end and central tendency estimates in the RME risk calculation (EPA, 1992a, see Section 13.A), EPA will apply the CTE cooking loss in the calculation of total risk for both the RME and CTE scenarios. The CTE will be reevaluated based on all available data in the revised HHRA, but is likely to fall in the 20% range.

8.D. Exposure Duration

Two Reviewers commented that the exposure duration was too long; one of these Reviewers wondered whether respondents could have been reporting consumption of fish from restaurants or grocery stores rather than recreationally caught fish, potentially leading to an overestimate of exposure duration. However, a question on the MDPH survey asked how these fish were usually obtained. Respondents were given the following choices:

- Have no idea,
- Catch their own,
- Receive fish from family/friend,
- Other local fishermen, and
- Supermarket/grocery store.

In the exposure prevalence study, 18% of all those who ate freshwater fish said they usually obtained their fish from the grocery store and another 5% had no idea where they usually obtained their fish. Over 75% usually caught their own fish or obtained recreationally caught fish from family or friends. The 52 individuals in the exposure prevalence study who had ever consumed fish from the Housatonic River reported they typically consumed fish they caught (73%) or those caught by family and friends (25%). The remaining 2% typically obtained fish from other local fishermen. Similar percentages were reported for the volunteer portion of the study (MDPH, 1997).

The ED of 60 years for the RME will be reevaluated in the revised HHRA. This value is less than the 95th percentile of the distribution of the 705 individuals who reported the length of time they consumed freshwater fish in the Housatonic River Area PCB Exposure Assessment Study (MDPH, 1997). The 95th percentile of the distribution of individuals who consume fish and had ever fished the Housatonic River was somewhat higher at 65 years.

The revised HHRA will include an expanded discussion of the basis for the selection of point estimate values for exposure duration for consuming fish and waterfowl.

9. WATERFOWL CONSUMPTION

SUMMARY OF ISSUE:

Overall, five Reviewers commented that the approach, including the selection of exposure scenarios, most exposure parameters, and the point estimate risk, was reasonable and consistent with EPA policy. Two Reviewers commented that all or most of the individual exposure parameters were too high and the combination of exposure parameters resulted in extreme, rather than reasonable maximum, estimates of risk.

Reviewers questioned certain aspects of the determination of risk due to ingestion of contaminated waterfowl (duck and goose) tissue. One Reviewer questioned whether the assumption that individuals consume only breast tissue with skin on would underestimate risk for individuals consuming dark meat portions (e.g., leg). Another Reviewer questioned whether the smaller meal size assumed for waterfowl, approximately half that of the amount assumed for fish, would also result in an inappropriate underestimate of risk.

Three Reviewers questioned whether the risk assessment properly considered the potential for harvesting of migratory birds that had not spent sufficient time on the Housatonic River to become contaminated and/or for individuals harvesting birds from other uncontaminated locations. Two of these Reviewers also questioned whether the productivity of the river could result in a sufficient number of resident waterfowl to support the consumption estimates.

Three Reviewers commented on the issue of risk from waterfowl consumption in Connecticut. Three Reviewers felt that not estimating risk was either a general weakness that should be acknowledged or that some effort should be made to calculate risk. One Reviewer, while mentioning the issue as a potential concern, felt the approach taken in the risk assessment was proper.

RESPONSE:

9.A. Consumption of Breast vs. Leg Meat

The underlying basis for this concern is the difference in lipid content, and therefore potentially in lipophilic contaminant concentration, between light versus dark poultry meat. The well-known difference in composition between muscles that are used regularly (e.g., leg, or dark meat) as compared with muscles that are used rarely (e.g., breast, or light meat) is a characteristic of gallinaceous birds such as chicken or turkey that are adapted for walking rather than flying. The difference in coloration is due to a higher concentration of the protein myoglobin in dark meat (Labensky & Hause, 1995). In the case of ducks, particularly wild ducks, all muscles are used regularly and therefore both breast and leg consist exclusively of dark meat (Gisslin, 1995).

Gisslin also notes that in culinary terms, dark meat contains more fat and connective tissue and takes longer to cook than light meat, and further indicates that the legs and breasts of ducks and geese differ in the amount of connective tissue, but not in the amount of fat, which is the most important consideration for the question of whether individuals consuming legs would receive higher exposure to lipophilic contaminants such as PCBs than would individuals consuming breast meat. In addition, the majority of the meat in a wild duck is contained in the breast. Therefore, EPA believes that basing the risk due to waterfowl consumption on skin-on breast meat does not potentially underestimate risk due to this pathway.

9.B. Meal Size for Waterfowl

The smaller meal size for waterfowl (112 g cooked, equivalent to 165 g uncooked) than for fish was based on published data for poultry consumption (Pao et al., 1982). This value is generally consistent with the average size of the ducks collected for this study in the Housatonic River PSA and reference areas (approximately 90 g per sample, consisting of a half breast with skin [uncooked]), and assumes that a meal would consist of both sides of the breast. A higher value would also be inconsistent with a single duck sometimes providing two meals (Cameron and Jones, 1983; Beard, 1972) for consumers of wild waterfowl. Although these assumptions result in a meal size that is approximately half that for fish, it is appropriately reflective of the portion size available from a wild duck, but may be biased low when considering meals from a wild goose.

9.C. Resident vs. Migratory Waterfowl

The question of migratory birds and residence time is related to the waterfowl meal frequency selected for the RME and CTE individuals. The meal frequency used for calculation of risk due to waterfowl consumption was 11 meals/year for the RME individual and 5.4 meals/year for the CTE individual (derived from the MDPH Survey results). The assumption used in the selection of this meal frequency was that all of these meals would be of ducks that had been resident in the PSA. Assuming, as discussed above, that one duck provides a single meal, this is equivalent to an annual bag from the PSA resident duck and goose population of 11 birds for the RME hunter and 5 or 6 birds for the CTE.

This rate is well within the legal bag limit for waterfowl. The waterfowl hunting regulations for 2002-2003 allowed 6 ducks in a daily bag and 12 in possession, 5 Canada geese in the daily bag and 10 in possession from the early season, and 2 Canada geese in the daily bag and 4 in possession from the regular season. The early Canada goose season and the early portions of the regular season occur before the start of migration of the resident birds, and some geese and mallards were observed to be year-round residents of the PSA. In addition, the estimated population and annual production of ducks in the Housatonic River PSA, based on observations of waterfowl broods, and duck capture and banding work conducted in the PSA during the course of this study, are adequate to support these meal frequencies (Woodlot Alternatives, Personal Communication, 2004).

9.D. Harvest of Ducks from Other Areas

Although it is possible that some individuals may harvest ducks from other uncontaminated areas, it is also possible and indeed likely that other individuals may hunt the PSA exclusively. The time and effort necessary to locate a suitable area for waterfowl hunting and the additional effort often expended by hunters in establishing blinds and similar improvements dictate that the same areas are visited consistently. Numerous blinds and frequent occupancy of these blinds in the PSA was observed by EPA and its contractors in 1998 prior to the consumption advisory in 1999, after which hunting was still observed, but less frequently. In addition, waterfowl collected from a background location downstream in the watershed (Threemile Pond in Sheffield) at the same time as the collection in the PSA had varying concentrations of PCBs in tissue samples. EPA believes that these considerations, in addition to the information provided in the previous sections, are sufficient to justify the exposure frequency assumed for the waterfowl consumer.

9.E. Risks from Consuming Waterfowl from Connecticut Reaches of the River

Although EPA concurs with the Reviewers that not estimating risk to waterfowl consumers in Connecticut is of some concern, duck sampling in Connecticut was not undertaken and a quantitative evaluation was not performed because the PCB concentrations in waterfowl in Connecticut due to contamination of the Housatonic River and its floodplain are anticipated to be low for both resident and migrating birds.

Resident Waterfowl

PCBs bioconcentrate and bioaccumulate in Housatonic River waterfowl that ingest contaminated water, river sediment, floodplain soil, and dietary items. The surficial (0 to 0.5 ft) sediment concentrations of PCBs are 200 to 800-fold lower in Connecticut than in Reaches 5 and 6 in Massachusetts (where resident ducks were sampled). Specifically, the recent data (2001) show a maximum Connecticut sediment concentration (as presented in the HHRA, Volume IIA, Section 6) of 0.47 mg/kg, whereas the EPC and maximum sediment concentrations from the perimeter of Woods Pond (as presented in HHRA Volume II, Figure 5-94) are 111.6 and 379 mg/kg tPCB, respectively. These data indicate that resident Connecticut Housatonic River waterfowl would have substantially lower exposure to PCBs than those from Reaches 5 and 6.

Migrating Waterfowl

Risk estimates for Woods Pond were based on mallard and wood duck data, assuming the concentrations were the same in all waterfowl in the Woods Pond area, including some species that include year-round residents (e.g., Canada goose). The specific migration routes from Woods Pond are not known, and although some individuals reared in Woods Pond may migrate to the Housatonic River in Connecticut, quantification of these individuals is not possible. In general, a low percentage (<10%) of banded birds are recovered; however, information from state wildlife officials regarding the number of birds from the Woods Pond area that were banded and recovery rates, if available, will be presented in the revised HHRA.

In the revised HHRA, risks associated with the consumption of waterfowl resident on the Housatonic River in Connecticut will be estimated based upon PCB concentrations in environmental media in Connecticut, and will be substantially lower than the risk estimates for Reaches 5 and 6 in Massachusetts. In addition, the available data for background concentrations in waterfowl will be examined for use in estimating risk due to migratory waterfowl.

10. PROBABILITY BOUNDS ANALYSIS FOR FISH AND WATERFOWL

SUMMARY OF ISSUE:

One Reviewer questioned the appropriateness of the probabilistic approaches used in the HHRA. This Reviewer recommended that a wholly different approach to assessment be employed in its stead. This new approach would feature two fundamental changes: (1) focus on the exposures likely to be received by an individual under an average or high exposure scenario, and (2) use of Bayesian methods based on subjective probability. The same Reviewer characterized the probabilistic assessments conducted for consumption of fish and waterfowl as "deficient and biased toward extreme values," and stated that the description of epistemic uncertainty at the high and low ends of the exposure distributions is implausibly high as characterizations of realistic exposures received by avid anglers. The Reviewer suggested there are multiple reasons for this. The first is that a biased estimate of the concentration term (the EPC) was used. The second reason is that the HHRA did not take into account the uncertainty in the cancer slope factors or reference doses used to characterize effects. The third reason was that probability bounds analysis was used to project uncertainty through calculations.

RESPONSE:

10.A. Focusing on Receptors with Average and High Exposures

One Reviewer suggested that the variability among individuals could be reduced by changing the focal question from one about individuals within a population of receptors to one that instead focuses on (stylized) individuals that have average or high exposures. This suggested approach does not reduce inter-individual variability, but ignores it by changing the question. This approach is inconsistent with EPA guidance and the intended purpose of the assessment process. EPA guidance clearly states that the purpose of the probabilistic assessments is to characterize the variability *among individuals in the receptor populations* (EPA, 2001b, RAGS Volume 3 Part A Chapter 1 Section 1.2.1, and Chapter 3 Section 3.1).

10.B. Frequentist Versus Subjectivist Probability

One Reviewer characterized probability bounds analysis as "non-probabilistic." What is meant by this comment is that probability bounds analysis is based on the classical frequentist idea of probability rather than the Bayesian subjectivist view of probability. The essence of the debate is that frequentists hold a probability to be a ratio of *frequencies* of events in the real world, while subjectivists hold that a probability is an assessment of one's personal *belief* that an event will occur given the information one currently has at hand.

It is entirely possible to apply probability bounds analysis within a subjectivist interpretation of probability. There is nothing necessarily frequentist about the methodology. Thus, the Reviewer's criticism is not so much against probability bounds analysis per se as against the more fundamental interpretation of probability adopted in the HHRA. However, EPA guidance encourages the development of assessments that are objective insofar as possible and based on demonstrable empirical facts rather than the personal beliefs of the analysts who conducted the assessment. Where subjectivity is inescapable, such as in interpreting expert judgment or opinion, it must of course encroach to some extent into the formal assessment. Most critics of EPA assessments generally call for assessments to be less subjective, not more. Accordingly, EPA rejects the recommendation that the HHRA adopt any subjectivist interpretation of probability.

10.C. Comparison of Final Numerical Results

The controversy between frequentism and subjectivism is largely about the *meaning* of probability and its interpretation, and much less about numerical discrepancies in the results of calculations. In fact, the numerical results produced by the two schools of thought are often similar or even identical. As a part of the comments, the Reviewer conducted an assessment based on the subjectivist interpretation of probability and stylized individuals receiving average (CTE) or large exposures (RME). The comparison of the results of this reanalysis with the results of the HHRA that are provided by the Reviewer reveals largely comparable numerical results. Thus, EPA believes that a reanalysis such as that conducted by the Reviewer would not qualitatively change the final conclusions in the HHRA regarding risks from exposures of humans to PCBs through fish and waterfowl consumption.

10.D. Realism of the Bounds

One Reviewer criticized the probability bounds analyses as yielding upper-bound estimates that are unrealistically high, even for a population of avid anglers. This criticism seems to miss the point of the probability bounds analysis. It is *intended to bound* the distributions of risk that could arise from the inputs, given their respective uncertainties. It does not imply or conclude that risks must be as high as the right edge of the probability box. Indeed, all it says is that the risks are *no larger than this edge*. The Monte Carlo assessments that accompany each of the probability bounds analyses are intended to project what analysts expect to be the central estimates of the risk distributions. The bounding results serve as a check on these Monte Carlo results such as might be obtained via a comprehensive sensitivity analysis.

Some Reviewers expressed concern that the upper probability bounds on inputs are somehow combined to produce decision-points for the risk assessment. For example, one Reviewer pointed out that a maximum exposure frequency of 1,042 meals per year multiplied by a 227 gram meal size leads to a maximum consumption rate of 648 grams per day, and that this is well over the RME. However, the probability bounds are meant to comprehensively bound all the possible results, in a true uncertainty analysis sense, not just 95% of them. This is what is meant when probability bounds are referred to as a comprehensive uncertainty analysis. At each probability level, the upper and lower bounds are akin to 100% confidence limits. Probability bounds provide assurance that, at each probability level, the risk is no greater than the upper bound and no less than the lower bound. In fact, the maximum exposure frequency cited here corresponds to 2.9 meals per day, every day of the year, which is not impossible as an upper consumption limit. For this reason, the bounds primarily tell analysts and decision makers where the distribution could be, rather than specifying precisely where it is. The lower rather than the upper bound may be more useful in informing decision makers. For almost every receptor and model in the HHRA, the lower bound was very near or above the risk range or threshold.

11. AGRICULTURAL PRODUCT CONSUMPTION

SUMMARY OF ISSUE:

Five Reviewers were concerned that providing risk estimates at assumed tPCB concentrations in floodplain soil of 0.5 mg/kg and 2 mg/kg resulted in an evaluation of hypothetical farms instead of actual farms. They recommend estimating risk for tPCB concentrations measured in floodplain soil on land used for agricultural purposes now or possibly in the future.

All Reviewers expressed concern that the site-specific data used to predict concentrations of COPCs in plants were not sufficient to estimate reliable soil-to-plant transfer factors. One Reviewer expressed concern about using congener patterns in grass to estimate congener concentrations in corn, and two Reviewers were concerned about selecting garden transfer factors from a data set that includes washed produce. Five Reviewers recommended collection of additional site-specific data.

All Reviewers noted the uncertainties in the agricultural assessment, and four Reviewers specifically requested quantitative uncertainty analysis of the agricultural exposure pathways. They mentioned uncertainties in the regression models used to predict floodplain soil concentrations of congeners, soil-to-plant transfer factors, and bioconcentration factors. Two Reviewers were particularly concerned with uncertainties associated with congener-specific risk estimates and recommended that at least some congener-specific risk estimates be removed from the risk characterization section and included only as a “sensitivity analysis.”

RESPONSE:

11.A. Approach to Assessing Agricultural Risks

The approach in the HHRA was not meant so much as to represent a hypothetical farm, but to provide the ability to calculate the risks for any parcel by mathematically adjusting the percentage of activity in the floodplain and the average concentration of tPCBs for the parcel, to allow the calculation for any existing set of scenarios. However, to respond to the Reviewers' comments, the revised HHRA will include risk estimates in a matrix format that shows risk associated with different combinations of the two agricultural model inputs: (1) tPCB concentration in floodplain soil on current or possible future agricultural land, and (2) fraction of cultivated land or pasture that is in the floodplain. Each matrix will represent a single agricultural scenario. For example, risk estimates will be provided for a dairy farm employing management practices (e.g., animal housing and feed) typical for the area across the range of tPCB concentrations on current and potential dairy farms and the range of fractions of farmland within the 1-ppm tPCB isopleth. Quantitative uncertainty analysis will be used to explicitly characterize uncertainty in agricultural model inputs and their contribution to uncertainty in risk estimates.

The matrix can then be used directly to estimate risk on any farm with a given mean tPCB soil concentration and fraction of farmland in floodplain. Note that an underlying assumption of this approach is that the tPCB concentration in floodplain soil in farm areas outside the 1-ppm tPCB isopleth is zero. This assumption is likely to underestimate risk slightly, depending upon site-specific background concentrations of COPCs.

11.B. Soil-to-Plant Transfer Factors

EPA believes it is not necessary to collect more data to evaluate this issue. The revised HHRA will address Reviewer concerns about soil-to-plant transfer factors by adding:

- Quantitative uncertainty analysis that explicitly characterizes uncertainty in agricultural model inputs, including the soil-to-plant transfer factors and their contribution to uncertainty in risk estimates.
- Documenting and updating the extensive literature search for data and models to define the possible quantitative relationship between COPC concentrations in plants and the soil in which they are grown.
- Discussion of site-specific dairy modeling in light of tPCB concentration data for milk samples collected from the William DeVos farm in the early 1970s that General Electric provided to EPA on 4 November 2003.

Also, all congener-specific risk estimates will be moved from the risk characterization section to the uncertainty section, including those that incorporate uncertain soil-to-plant transfer factors.

11.C. Quantitative Uncertainty

The revised HHRA will incorporate quantitative uncertainty analysis that explicitly characterizes uncertainty in agricultural model inputs and their contribution to uncertainty in risk estimates. Quantitative uncertainty analysis will be performed on those agricultural exposure pathways that result in risk estimates above the EPA criteria.

Results of the quantitative uncertainty analysis will be summarized in the matrix format described in Section 11.A. Consequently, some agricultural model inputs will be held constant to represent specific agricultural scenarios:

- Fractions of farmland within the 1-ppm tPCB isopleth (using a range of values that represent typical land use patterns on current and potential future farms).
- Total PCB (tPCB) exposure point concentrations (using a range of tPCB concentrations measured on current and potential future farms).

Other inputs will be subjected to quantitative uncertainty analysis that adheres to applicable EPA guidance. Specifically, EPA will follow the tiered approach described in *Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment* (EPA, 2001b).

12. TOXICITY/DOSE RESPONSE

SUMMARY OF ISSUE:

Reviewers raised several questions regarding the presentation and methods for quantifying dose response and the descriptions of the toxicity of the COPCs. One Reviewer commented that the uncertainties associated with EPA-derived toxicity factors; namely, cancer slope factors (CSFs) and Reference Doses (RfDs), were not adequately described. Two Reviewers commented that the description of uncertainty associated with these toxicity values was inadequate; and four Reviewers commented that the description of the uncertainties associated with PCB toxicity factors in particular was inadequate.

Two Reviewers did not think any calculations based on the dioxin slope factor derived in EPA's Dioxin Reassessment should have been included in the report. Another Reviewer thought the Dioxin Reassessment slope factor should have been part of the risk characterization (main evaluation) rather than part of the uncertainty assessment. One Reviewer thought risk calculations based on dioxin-like PCBs (slope factor unspecified) should be placed in the uncertainty sections. Three Reviewers did not agree with the use of the point estimate toxicity factors in the probabilistic analysis conducted for fish and waterfowl consumption; however, they acknowledged this was consistent with current EPA guidance.

Five Reviewers commented that the discussion of noncancer effects of dioxins was incomplete.

RESPONSE:

12.A. General Description of Toxicity Factors

The discussion of the uncertainty associated with toxicity values (CSFs and RfDs) in HHRA Volume I, Section 2, "Toxicity Assessment," will be expanded. A summary of this discussion will be added to the discussion of uncertainties in Volume III, "Direct Contact Risk Assessment"; Volume IV, "Consumption of Fish and Waterfowl Risk Assessment"; and Volume V, "Agricultural Product Consumption Risk Assessment." The following definitions of cancer slope factors and noncancer reference doses will be added to each volume of the report:

Cancer Slope Factors

CSFs are plausible upper-bound estimates of carcinogenic potency used to calculate cancer risk from exposure to carcinogens, by relating estimates of lifetime average chemical intake to the incremental probability of an individual developing cancer over a lifetime. The CSFs developed by EPA are plausible upper-bound estimates, which means that EPA is reasonably confident that the actual cancer risks are likely to be less than the risks estimated with the upper-bound slope factor. It is not possible to estimate how much less, but risks to some individuals could be zero.

Reference Doses

The chronic RfD represents an estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime.

12.B. Uncertainty Associated with PCB Toxicity Factors

The revised HHRA will expand the discussion of the uncertainties specific to the toxicity values for PCBs, including ranges of CSFs, uncertainty factors associated with the RfD, and toxicity implications of PCB mixture alterations following release to the environment. Recent literature that was unavailable at the time these toxicity values were developed will be summarized.

In the probabilistic risk assessment, toxicity factors were incorporated as single values. As three Reviewers noted, this approach follows EPA guidance, which states: "At this time, this guidance does not propose probabilistic approaches for dose-response in human health assessment and, further, *discourages undertaking such activities on a site-by-site basis*. Such activities require contaminant-specific national consensus development and national policy development." (Italics in original, EPA, 2001b, RAGS Vol. 3 Part A Chapter 3 Section 3.1.2; see also RAGS Vol. 3 Part A Chapter 1 Section 1.4.1.)

12.C. Toxicity and Toxicity Factors Associated with Dioxins, Furans, and Dioxin-like PCBs

The concentration of TEQ from 2,3,7,8-TCDD and other dioxin-like congeners will be assessed using the approach described in the response to General Issue 5.A. For the direct contact and agriculture consumption pathways, the risks associated with TEQ will be quantified in the uncertainty section instead of the risk characterization section.

The revised HHRA will continue to evaluate cancer risk from TEQ based on the slope factor published in HEAST. EPA noted in the HHRA that the Dioxin Reassessment has not been formally released, and provided risk calculations based on the cancer slope factor in the draft Dioxin Reassessment as a point of comparison and a measure of uncertainty. The discussion in the HHRA will be revised to acknowledge the planned review of this document by the National Academy of Sciences. The uncertainties associated with the cancer slope factor were described in the HHRA and will be retained in the revised HHRA.

The science associated with noncancer effects of dioxin is also under review by the National Academy of Sciences. Additionally, EPA has not published a noncancer toxicity factor for individual dioxins or TEQ. For these reasons, the noncancer effects will not be quantified in the revised HHRA. However, the revised HHRA will provide a perspective on the potential underestimation of noncancer health effects and provide a comparison of estimated site-related intake of TEQ to estimated background dietary intake. The revised HHRA will also include an expanded discussion of the noncancer adverse health effects associated with dioxin and dioxin-like congeners.

13. RISK CHARACTERIZATION AND PRESENTATION

SUMMARY OF ISSUE:

Risk characterization includes the combination of exposure parameters and toxicity parameters to predict cancer and noncancer risks associated with the modeled exposure scenarios. Six of the seven Reviewers commented that the scenarios modeled were appropriate, as was the selection of the majority of the exposure parameters. Concerns over several specific exposure parameters were discussed in previous sections. Six Reviewers agreed that the HHRA was consistent with EPA guidance in its usage of toxicity factors. Five Reviewers thought that the combination of exposure parameters used was appropriate, with some specific exposure scenario recommendations for changes. One Reviewer commented that, even though there was a sound basis for selecting individual exposure parameter values, the use of multiple high-end values to characterize the risk leads to the problem of compounding conservatism. One Reviewer thought that all exposure parameters used in the risk assessment were too conservative and the combination of them unreasonable.

Reviewers offered a range of opinions regarding the adequacy of the HHRA in the discussion and summary of risks. Three Reviewers thought the discussion lacked sufficient clarity and transparency, whereas three considered the discussion adequate, with an appropriate level of detail. Two Reviewers commented that RME and CTE risks should not be combined on a single bar chart, whereas two other Reviewers thought the graphics clear and helpful.

RESPONSE:

13.A. Compounding Conservatism

EPA defines the RME as ". . . the maximum exposure that is reasonably expected to occur at the site." This was further defined by EPA in 1992 guidance that defines the high end of a risk distribution as "a plausible estimate of the individual risk for those persons at the upper end of the risk distribution. The intent of this descriptor is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates which are beyond the true distribution. Conceptually, high-end risk means risks above about the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk."

The HHRA was intended to be fully consistent with EPA guidance and policy, including the following:

> "For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at the site. Under this approach, some intake variables may not be at their individual maximum values but when in combination with other variables will result in estimates of the RME. " (EPA, 1989b, RAGS A, p. 6-21.)

> “Contact rate reflects the amount of contaminated medium contacted per unit time or event. If statistical data are available for a contact rate, use the 95th percentile value for this variable.” (RAGS A, p. 6-22).”
>
> “Exposure frequency and duration are used to estimate the total time of exposure. These terms are determined on a site-specific basis. If statistical data are available, use the 95th percentile value for exposure time.” (RAGS A, p. 6-22).
>
> “If only limited information on the distribution of the exposure or dose factors is available, the assessors should approach estimation estimating the high end by identifying the most sensitive exposure parameters and using maximum or near-maximum values for one or a few of these variables, leaving others at their mean values. (EPA, 1992a).
>
> “The sensitivity of a parameter generally refers to its impact on the exposure estimates, which correlates with the degree of variability of the parameter values. Parameters with a high degree of variability in the distribution of parameter values are likely to have a greater impact on the range of risk estimates than those with low variability. For one or a few of the sensitive parameters, the maximum or near-maximum values should be used, with central tendency or average values used for all other parameters. The high-end estimates are based, in some cases, on statistically based criteria (95th or 90th percentiles), and in others, on best professional judgment. In general, exposure duration, exposure frequency, and contact rate are likely to be the most sensitive parameters in an exposure assessment” (EPA, 2001c, RAGS Part E, page 3-1)

The point estimate risk assessment used the upper bound (usually 95th percentile), but not maximum values for assessing contact rate and exposure duration to the RME. EPA does not consider any of the parameter values used in the exposure assessment to be implausible. However, EPA recognizes the comments from the Reviewers regarding the need to reexamine the parameters that were used to estimate risks and has responded by doing so for some of the parameters that are described in this Responsiveness Summary, and will do so for others during the revisions to the HHRA.

A probabilistic risk assessment for the fish and waterfowl consumption assessment was included in the HHRA, and will be included for the agricultural product consumption pathway in the revised HHRA, as described in the responses to General Issues 7.F and 11.C. For fish and waterfowl, the probabilistic assessment used the full distribution of intake (contact) rates and exposure duration. The upper range of risks predicted by the PRA was consistent with the RME risks based on the point estimate approach.

13.B. Presentation

EPA will examine different graphical approaches to the presentation of risks for use in the revised HHRA. RME and CTE risks will be presented on separate charts accompanied by a discussion of how to read and interpret them.

The revised HHRA will include additional graphics and text to enhance the clarity and transparency of the risk characterization. For example, the revised HHRA may include a flow chart style graphic that shows all types/sources of input data in the risk calculation.

14. COMBINATION OF EXPOSURE PATHWAYS

SUMMARY OF ISSUE:

Four Reviewers commented that the HHRA did not adequately characterize the potential risks associated with exposure to a combination of pathways (direct contact, fish and waterfowl consumption, and agricultural product consumption). One Reviewer expressed particular concern about the omission with respect to combinations of direct contact pathways, and that total risks could be underestimated. Two other Reviewers expressed this viewpoint more generally. The fourth Reviewer was concerned that members of the public would be "left to their own devices," add all the different scenarios and pathways, and become overly concerned about their personal risk.

RESPONSE:

The revised HHRA will include expanded presentation and discussion of risks from multiple exposure pathways in several areas. First, a new section will be added to the revised HHRA, Volume I, that lays out the strategy for the risk assessment. The appropriate way to combine pathways will be fully discussed as part of that strategy. Second, the risk summary section of Volume I will be expanded to include more examples of how to combine risks, including for the direct contact risk assessment, how to combine the same activity in different exposure areas, and different activities in different exposure areas. Finally, EPA will consider presentation methods other than text examples to clarify how to combine risks from multiple exposure pathways.

RESPONSE TO SPECIFIC COMMENTS

OVERVIEW COMMENTS

Holly Hattemer-Frey

Overall, the risk assessment documents provide a thorough evaluation of potential risks for a very complicated site. I commend the authors. My comments are intended to be a source of constructive criticism from an individual who has prepared several assessments for other large Superfund sites as well. Since risk assessment is an evolving, flowing process, there are varying approaches that can be adopted that would be considered reasonable and appropriate. While I may disagree with an approach adopted in this assessment does not necessarily mean that it is wrong or inappropriate.

My biggest criticism of this report is that lack of discussion on uncertainty. Several complicated approaches were used (e.g., spatial weighting and regression analyses to name the two most obvious) and little or no attempt was made to characterize in a meaningful way the extent to which such an approach may have over or underestimated risks. I offer more detailed comments on this issue throughout my review.

F. Owen Hoffman

Overall, I conclude that the HHRA for the Housatonic River is a very detailed, comprehensive and extensively documented analysis. Clear attempts have been made to ensure conformity to EPA guidance. Nevertheless, discrepancies are evident in the calculation of 95% UCLs for the exposure point concentration (EPC) for designated exposure areas.

RESPONSE 1:

Please refer to the responses to General Issues 4.A, 4.B, and 4.C.

There is a definite need for quantitative uncertainty analysis to be extended to the Phase II direct exposure pathway and to the analysis of exposure and risks from the consumption of agricultural products.

RESPONSE 2:

Please refer to the responses to General Issues 7.F, 11.A, and 11.C.

The uncertainty analysis performed for consumption of fish and waterfowl is deficient and biased toward extreme values. The values produced by the probability bounds analysis (PBA) approach to describe epistemic uncertainty at the high and low end of the distribution of exposures are implausibly high for describing realistic exposures received by avid recreational anglers. I recommend a more rigorous probabilistic approach be used to address epistemic uncertainty in characterizing RME and CTE exposures and that all sources of known bias be removed from the uncertainty analysis.

RESPONSE 3:

Please refer to the responses to General Issues 4.C, 4.D, 10.B, and 12.B.

The quantitative uncertainty analysis should include an evaluation of uncertainty in the EPA cancer slope factors and reference doses for non-cancer health effects.

RESPONSE 4:

Please refer to the response to General Issue 12.B.

Suggestions are given at the end of my review for using information in addition to EPA's risk range of 10-4 – 10-6 lifetime cancer risk and the HI of 1.0, in order to properly put exposures and risks from the Housatonic River into perspective.

Roger O. McClellan

I. Executive Summary

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

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

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

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

RESPONSE 5:

Please refer to the responses to General Issues 7.D and 7.E regarding revisions to the direct contact risk assessment. Please refer to the response to General Issue 11.A regarding revisions to the agricultural products consumption risk assessment.

The assessment builds on a remarkable amount of soil sampling and analysis data and a very limited number of environmental samples.

RESPONSE 6:

The environmental samples (assumed to mean biota samples) for fish and waterfowl were considered to be adequate for risk assessment purposes. Overall, they included more than 300 individual fish fillet samples and 25 duck breast samples. The grass, corn, fern, squash, and milk samples were more limited, and the limitations and uncertainties were discussed in the agriculture consumption products risk assessment. The revised HHRA will address these limitations, as described in the responses to General Issues 11.A, 11.B, and 11.C.

It is not at all clear as to the strategy used to guide the collection of the soil samples. As a result there are major questions as to the end use of the soil data. I see a major void between the soil data collection and its use.

RESPONSE 7:

Soil samples that provided data for the HHRA were collected as part of multiple sampling programs with different strategies and objectives. These programs are detailed in the Supplemental Investigation Work Plan (SIWP) (WESTON, 2000) and the RFI (BBL and QEA, 2003). Although most of these samples were collected by EPA, some were collected by GE. The soil sampling that was conducted was performed as a series of efforts, each to support a different data quality objective as outlined in the SIWP; one of the objectives was to collect samples specifically for the HHRA, to provide an adequate number of samples with which to evaluate individual exposure areas.

EPA recognizes that the soil samples were neither evenly distributed nor randomly located, and used spatial weighting to account, in part, for the nonrandom collection. Please also refer to the response to General Issue 4.B for additional discussion on spatial weighting.

The fish and duck flesh samples are very important but are so limited in number that controversy arises as to the true variability of contaminant concentrations. However, the limited number of fish and waterfowl samples provides insight into the likely productivity of the river.

RESPONSE 8:

Data from 25 samples of duck breast tissue (5 mallard, 20 wood duck) were used in the HHRA to evaluate risks from consuming waterfowl taken from Woods Pond and its backwaters. The sample size was determined both by a statistical approach, *Power and Precision: A Computer Program for Statistical Power and Analysis and Confidence Intervals (*Borenstein et al., 1997, as cited in the SIWP, Appendix 23*),* and Massachusetts Division of Fisheries and Wildlife (MADFW) collection permit restrictions. Data from over 300 fish fillet samples were used in the HHRA to evaluate risks from fish consumption in four stretches of the river. EPA considers these sample sizes to be adequate for computation of exposure point concentrations while taking into account variability. Please refer to the responses to General Issues 8.A and 9.C for information on productivity of the river.

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

RESPONSE 9:

Please refer to the responses to General Issues 11.B and 11.C. It is incorrect to say that there is an "absence of analyses" of milk and vegetable samples. Milk and vegetable data are described in Sections 2.3.1, 2.3.3, and 2.3.4 of HHRA Volume 5. Since the HHRA was prepared, General Electric provided analytical results for milk samples collected from DeVos farm in the early 1970s, and these data will be discussed in the revised HHRA.

From this very modest, and indeed limited, data base the assessment proceeds to calculate the exposure to "hypothetical individuals" using a series of assumptions and parameters.

RESPONSE 10:

For a discussion of individuals consuming fish and waterfowl, please refer to the responses to General Issues 8.A, 8.B, 8.D, and 13.A. For a discussion of agriculture consumption, please refer to the responses to General Issues 11.A, 11.B, and 11.C. Because management practices and animal types on any given farm may change over time, a farm-specific assessment will become obsolete when these changes occur. To address this situation, hypothetical scenarios were assessed that reflect the range of current and potential future farm types and management practices.

In my opinion, the selection of specific assumptions and parameters appear to have resulted from interpreting EPA guidance as "rules" requiring the use of extreme upper range and, in some cases, likely implausible, values.

RESPONSE 11:

The HHRA was intended to be fully consistent with EPA guidance and policy, including the following:

"For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at the site. Under this approach, some intake variables may not be at their individual maximum values but when in combination with other variables will result in estimates of the RME." (EPA, 1989b, RAGS A, p. 6-21.)

"Contact rate reflects the amount of contaminated medium contacted per unit time or event. If statistical data are available for a contact rate, use the 95th percentile value for this variable." (RAGS A, p. 6-22).

"Exposure frequency and duration are used to estimate the total time of exposure. These terms are determined on a site-specific basis. If statistical data are available, use the 95th percentile value for exposure time." (RAGS A, p. 6-22).

The point estimate risk assessment used upper-bound (usually 95th percentile), but not maximum values for assessing contact rate and exposure duration to the RME. EPA does not consider any of the parameter values used in the exposure assessment to be implausible.

The Agricultural Product Consumption Risk Assessment (HHRA Volume V) includes a table that summarizes the selection of input values from the range of possible values for the agricultural exposure pathways (Table 6-1). To avoid compounding conservatism, a mix of mean and upper percentile values was selected. The question of compounding conservatism will be addressed further with quantitative uncertainty analysis of agricultural pathways in the revised HHRA.

The layering of multiple upper-range values very likely over-estimates the exposure of individuals either at the upper end or the middle of a distribution of a resident or user population.

RESPONSE 12:

Please refer to the response to General Issue 13.A for additional discussion on the issue of compounding conservatism for the fish and waterfowl consumption pathway. Please refer to the responses to General Issues 7.F and 11.C for discussion of additional uncertainty analyses in the direct contact and agricultural products consumption risk assessments, respectively.

The HHRA included a probabilistic risk assessment for the fish and waterfowl consumption assessment. The probabilistic assessment used the full distribution of intake (contact) rates and exposure duration. The upper range of risks predicted by the probabilistic risk assessment (PRA) was consistent with the RME risks based on the point estimate approach. The revised HHRA will include a probabilistic risk assessment for agricultural product consumption that will also use the full distributions of exposure parameters.

The exposure values are then translated into risk through the use of point estimate slope factors for cancer potency and point estimates of reference dose for non-cancer health effects. The use of linear exposure-excess cancer slope factors to calculate cancer risks down to the lowest quantity of measurable contaminant without acknowledging that the true cancer risk for low levels of PCB exposure may be zero is misleading.

RESPONSE 13:

Please refer to the response to General Issue 12.A.

The portrayal of the single point estimates of Reference Dose, which incorporate uncertainty factors of 100 and 300, as measures of absolute risk is misleading.

RESPONSE 14:

Please refer to the responses to General Issues 12.A and 12.B.

Reference Doses by definition are estimates (with an uncertainty spanning perhaps an order of magnitude) of a level of continuous intake for the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious non-cancer health effects during a lifetime. Thus, it is not a risk level but rather a level of exposure where there an absence of risk.

RESPONSE 15:

Please refer to the response to General Issue 12.A.

It follows then that exposure at 2 times or 10 times the Reference Dose does not equate to twice or ten times as much non-cancer risk.

RESPONSE 16:

Please refer to the response to General Issue 12.B. The HIs are not interpreted in the HHRA in the manner described by the Reviewer.

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

RESPONSE 17:

The revised HHRA will expand the quantification of uncertainty, as described in responses to General Issues 7.F and 11.C. The discussion of the uncertainty in the toxicity factors will be expanded, as described in the responses to General Issues 12.A and 12.B.

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

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

RESPONSE 18:

EPA recognizes the comments from the Reviewers regarding the need to reexamine the parameters that were used to estimate risks and has responded by doing so for some of the parameters that are described in this Responsiveness Summary, and will do so for others in the revised HHRA. However, EPA believes that the HHRA, contrary to the Reviewer's opinion, was based upon a synthesis and integration of the best available scientific information when written.

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

RESPONSE 19:

The HHRA will be revised. The description of current and future land use will be expanded and described in a new section of Volume I of the HHRA. Please refer to the response to all subsections of General Issue 2.

This will include agricultural products if there are plausible projections of agricultural use of the flood plain recalling that the Massachusetts Wetlands Protection Act limits agricultural activities within 200 feet of river banks.

RESPONSE 20:

Please refer to the response to General Issue 2.E.

II. Introduction

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

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

III. Over-Arching Issues

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

A. EPA Guidance versus Rules

A recurring theme is whether the appropriate EPA Guidance was used in the preparation of the Human Health Risk Assessment (HHRA). The short answer to the question is "yes." However, in this case a "yes" answer is not reassuring nor informative. Let me explain. The EPA Guidance documents provide useful guidance for conducting risk assessments. Unfortunately, the staff preparing the Human Health Risk Assessment have tended to not always use the documents as guidance, but rather have generally interpreted them as rigid "rules" to be followed. Thus, in many instances the staff have failed to exercise professional judgment and "common sense" in developing the risk assessment.

RESPONSE 21:

EPA does not agree that guidance documents were used rigidly without looking at other data or other arguments. For example, site-specific data were used as the basis for exposure parameters such as exposure duration, rather than default exposure values published by EPA. For many other parameters (including fish consumption rates, waterfowl consumption rates, bioconcentration factors for milk and beef, and soil-to-plant transfer factors), site-specific and/or published scientific literature were evaluated, discussed, and summarized in the HHRA. The selection of these parameters included a thorough review of the literature and professional judgment. In addition, new methodologies were developed and incorporated into the HHRA for calculating EPCs based on spatially weighted data and use weights, and for quantitative evaluation of uncertainty using probability bounds analysis rather than a two-dimensional Monte Carlo method. While these new methodologies are not inconsistent with EPA guidance, they go well beyond "rigid rules" and even standard practices.

This approach has resulted in a product that documents the "rules" have been followed. However, it fails to always clearly communicate what was done and the rationale for the specific action and how it relates to other actions in the assessment process. In my professional judgment, the collective result is an assessment that systematically over-estimates the likely exposures and risks associated with the baseline (as is) case for use of the Housatonic River and environs and future uses.

RESPONSE 22:

The revised HHRA will include several additional sections in Volume I to enhance the clarity of the presentation. These sections will include a presentation of the overall strategy used to conduct the risk assessment (please refer to the response to General Issue 14), and clearer descriptions and presentations of the uncertainty surrounding the risk estimates (please refer to the responses to

General Issues 13.A and 13.B). In addition to these new sections, throughout the revised HHRA EPA will enhance the discussions of parameter selection, toxicity factors, current and future uses of the site, population size, and other topics suggested by Reviewers.

B. Population versus Personal Risk

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

RESPONSE 23:

EPA will continue to use individual risk as the basis for decision-making, as required under the National Contingency Plan. However, as context for the risks to individuals, the revised HHRA will provide additional information on the size, exposure, and health statistics of the population living along the Housatonic River, as described in the response to General Issue 1.

C. Cancer Risk Potency Values

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

RESPONSE 24:

Please refer to the response to General Issue 12.B.

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

RESPONSE 25:

Please refer to the response to General Issue 12.B.

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

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

RESPONSE 26:

Please refer to the responses to General Issues 5.A and 12.C.

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

RESPONSE 27:

Please refer to the response to General Issue 12.C.

E. Mis-use of Reference Doses and Hazard Index

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

RESPONSE 28:

Please refer to the response to General Issue 12.A.

It is erroneous to view exposure at the RfD level as causing harm and that an exposure at 2 times or 10 times the RfD causes 2 times or 10 times as much harm as implied in the assessment. The

RfD is not a quantitative measure of harm. It is a reference level for guiding subsequent evaluations of the potential for harm. This should be made clear in the assessment.

RESPONSE 29:

EPA recognizes that the ratio of exposure to a COPC and its RfD, known as a hazard quotient (HQ), is not a quantitative measure of harm. The following text was included in the HHRA to describe the HQ, or the Hazard Index (HI), which is the sum of individual HQs for an exposure pathway: "HIs of less than 1 indicate that adverse health effects associated with the exposure scenario are unlikely to occur. EPA considers action when the HI exceeds 1."

F. Selection of Various Model Inputs

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

RESPONSE 30:

The HHRA was intended to be fully consistent with EPA guidance and policy, including the following:

"For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at the site. Under this approach, some intake variables may not be at their individual maximum values but when in combination with other variables will result in estimates of the RME." (EPA, 1989b, RAGS A, p. 6-21.)

"Contact rate reflects the amount of contaminated medium contacted per unit time or event. If statistical data are available for a contact rate, use the 95th percentile value for this variable." (RAGS A, p. 6-22).

"Exposure frequency and duration are used to estimate the total time of exposure. These terms are determined on a site-specific basis. If statistical data are available, use the 95th percentile value for exposure time." (RAGS A, p. 6-22).

The point estimate risk assessment utilized upper-bound (usually 95th percentile), but not maximum values for assessing contact rate and exposure duration to the RME. EPA does not consider any of the parameter values used in the exposure assessment to be implausible. However, EPA recognizes the comments from the Reviewers regarding the need to reexamine the parameters that were used to estimate risks and has responded by doing so for some of the parameters that are described in this Responsiveness Summary, and will do so for others during the revisions to the HHRA.

In addition, a probabilistic risk assessment for the fish and waterfowl consumption assessment was included in the HHRA, and will be included for the agricultural product consumption pathway in the revised HHRA. Also, an assessment of the impacts of the selection of exposure parameters in the direct contact assessment will be presented. The probabilistic assessment utilized the full distribution of intake (contact) rates and exposure duration. The upper range of risks predicted by the PRA was consistent with the RME risks based on the point estimate approach. The quantification of uncertainty will be expanded in the revised HHRA, as described in General Responses 7.F and 11.C.

G. Consideration of Site-Specific Data

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

RESPONSE 31:

Please refer to the response to General Issue 1.C.

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

RESPONSE 32:

Please refer to the response to General Issue 1.D.

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

RESPONSE 33:

Please refer to the response to General Issue 1.D.

Stephen T. Washburn

Overall, EPA should be commended for its efforts in preparing the risk assessment, which addresses most of the important issues at the site and reflects careful consideration of these issues. The documentation of the risk assessment approaches, assumptions, and results is also generally very good, particularly given the complexity of the evaluation. However, I strongly believe that several areas of the risk assessment merit further attention and, in some cases, revision. Specific recommendations include the following:

- The HHRA should more clearly emphasize the hypothetical nature of the exposures and risks that have been estimated. The human health risk assessment (HHRA) states that a point estimate approach was used to evaluate Reasonable Maximum Exposure (RME) and Central Tendency Exposure (CTE), with the RME intended to represent the 90th percentile or greater of actual expected exposure and the CTE intended to represent an average exposure (p. ES-9). A probability bounds analysis was also included in the HHRA for the fish and waterfowl assessments, in an effort to better understand uncertainty and variability in estimating the RME and CTE. The discussions of these mathematical approaches tend to suggest that actual exposed populations in the vicinity of the Housatonic have been carefully defined and their behavior patterns studied. However, based on the combination of exposure parameters used in the HHRA and the sources of these parameters, it appears that the populations for which the RME and CTE are calculated are hypothetical (at least as defined by the exposure parameters selected for the HHRA).

RESPONSE 34:

See next three responses.

For example, while recreational angling occurs along the Housatonic, it is not clear that the combination of exposure assumptions that are used in the HHRA are representative of an existing or reasonably expected future population of anglers.

RESPONSE 35:

For recreational anglers, the basis of the exposure duration and extent of fishing in the Housatonic River (fraction ingested [FI]) were based on site-specific surveys, as discussed in the HHRA. As noted in the HHRA, fish consumption advisories for the Housatonic River have been in effect since 1977 in Connecticut and since 1982 in Massachusetts. Thus, although it is clear from the results of the Connecticut creel survey and observations in the Massachusetts portion of the river that some individuals consume fish even in the presence of advisories, the risk assessment used data from the Maine Angler Survey as the basis for determining fish consumption rates. Please refer to the responses to General Issues 8.A, 8.B, 8.D, and 13.A for additional details regarding the exposure assumptions. Please refer to the response to General Issue 1.B regarding the size of the angling population.

Relatively little is known of the actual population of individuals who consume fish from the Housatonic; thus, the RME and CTE risks estimated in the HHRA are hypothetical rather than necessarily reflecting actual conditions.

RESPONSE 36:

For fish consumption exposure, please refer to the responses to General Issues 8.A, 8.B, 8.D, and 8.E regarding the exposure assumptions. As noted in the HHRA, fish consumption advisories for the Housatonic River have been in effect since 1977 in Connecticut and since 1982 in Massachusetts. The objective of the fish consumption exposure pathway, in accordance with EPA guidance, was to evaluate risks that would occur from behaviors that are likely in the absence of any advisories, thus of necessity these risk estimates are hypothetical in nature.

Similarly, given current and expected future land use, the CTE and RME for the assumed agricultural scenarios do not represent points on an actual distribution of exposure, but instead seem more directed toward answering hypothetical "what- if" questions.

RESPONSE 37:

Please refer to the responses to General Issues 11.A, 11.B, and 11.C. As noted above, because management practices and animal types on any given farm may change over time, a farm-specific assessment will become obsolete when these changes occur. To address this situation, scenarios were assessed that reflect the range of current and potential future farm types and management practices.

- The HHRA should include a more complete discussion and interpretation of available serum data in interpreting the results of the hypothetical exposure assessment. The Massachusetts Department of Health (MPDH) has been collecting data on PCB levels in serum from volunteers for several years. A report issued by MPDH in 1997 concluded that PCB levels in serum from individuals who are expected to be most highly exposed to PCBs associated with the Housatonic River are generally within the background range reported for non-occupationally exposed populations in the U.S. A panel of nationally recognized experts convened by MPDH later supported this conclusion. On the other hand, the MPDH report appears to suggest that there may be higher serum PCB levels in older residents of the Housatonic who are frequent or long-term fish eaters, than in younger residents or those who consume relatively little fish. While it is understood that the MPDH serum data may have limitations, they should be evaluated in the context of the results of the hypothetical exposure assessment in the HHRA.

RESPONSE 38:

Please refer to the response to General Issue 1.C.

- The congener-specific evaluation for PCBs should be included only as a sensitivity analysis in the HHRA, given the uncertainties in the derivation of both the toxicity values and environmental fate and transport characteristics for individual dioxin-like congeners. As discussed in the HHRA, there are significant uncertainties each element of the congener-specific evaluation for PCBs, including the development of TEF values for "dioxin- like" congeners in PCBs, and the estimation of concentrations of dioxin-like congeners in soil, fish, waterfowl, and produce. For example, under the agricultural scenarios, the congener-specific risk assessment is dominated by exposures to PCB-126, for which little data on environmental behavior is available. Given these uncertainties, it is strongly recommended that the congener-specific evaluation for PCBs, if retained in the HHRA, be more properly placed in a sensitivity analysis.

RESPONSE 39:

Please refer to the responses to General Issues 4.F, 5.A, 11.A, and 12.C.

- The HHRA should provide a more complete assessment of the potential for non-cancer effects from exposure to dioxins and furans, and clarify the discussion of potential non-cancer effects from exposure to "dioxin-like" compounds. In the HHRA, EPA states that potential non-cancer risks from exposure to dioxins and furans along the Housatonic are not quantified because a review of potential noncancer effects associated with these compounds is on-going. This leads to the conclusion in the HHRA that potential non-cancer health risks for some scenarios (e.g., direct contact) are underestimated (see, for example, p. 7-9, Volume IIIA, Appendix B). To address public concerns, EPA should use the available toxicity information on dioxins and furans to semi-quantitatively evaluate the potential noncancer risks for the dioxins and furan levels along the Housatonic, relative to those for PCBs, to indicate if this potential underestimation is significant or not.

RESPONSE 40:

Please refer to the response to General Issue 12.C.

In addition, EPA should clarify statements regarding the assessment of non-cancer effects for "dioxin-like" compounds. For example, EPA states "Because an RfD has not been developed for PCDDs and PCDFs, the potential for noncancer effects from exposure to dioxin- like compounds is not quantitatively evaluated in this assessment" (p. 2-35, Volume I). However, the presence of dioxin-like compounds in PCBs is included in the RfD for total PCBs, since the Aroclors used in the animal experiments included both dioxin- like and non dioxin-like congeners. What EPA cannot quantify in the HHRA is the relative contribution of the dioxin-like PCB congeners to the RfD for total PCBs.

RESPONSE 41:

The Reviewer is correct that the relative contribution of dioxin-like PCB congeners to the RfD for total PCBs (tPCBs) cannot be quantified, and this will be clarified in the revised HHRA.

A. PHASE 1 – DIRECT CONTACT EXPOSURE SCREENING (VOLUME II)

Were the procedures used in Phase 1 of the HHRA to screen out properties and areas from further evaluation as well as the application of those procedures appropriate under the evaluation criteria? In addressing this question, consider:

- ***the general procedures used;***
- ***the SRBCs used for the COPCs; and***
- ***the land use and exposure categories considered and the classification of particular parcels and areas into those categories.***

COMMENTS

Holly Hattemer-Frey

The Phase I assessment uses SRBCs (either calculated or those dictated in the Consent Decree) based on direct exposure to PCBs only. Receptors evaluated include residential, agricultural, and commercial/industrial. Except for the following comments, the receptors and procedures used are acceptable.

It is acceptable to focus the Phase I screening on PCBs only, but the process needs to be sufficiently conservative to ensure that areas where risks could occur are not eliminated. Thus, I recommend that the Phase I screening use primarily upper-bound exposure factors and assumptions to reduce the possibility of getting a false negative result.

RESPONSE 42:

EPA gave careful consideration to evaluating potential exposure and believes that the Phase 1 assessment used sufficiently conservative and health protective exposure parameters to estimate the screening risk-based concentrations (SRBCs). Please refer to the response to General Issue 6.A for further discussion.

Page 2-3: In the Phase 1 screening process, if the maximum measured concentration exceeded the SRBC, the 95% UCL was calculated and compared to the SRBC for data sets with a sample size of five or greater. I disagree with this approach in a Phase 1 screening. It would be more conservative (and health-protective) to use the maximum measured concentration for comparison to the SRBC, which is done in some cases. Given the small number of measured samples relative to the large area affected, I recommend that this approach be adopted. If the UCL value is used, I recommend using the maximum value for data sets with a sample size of 10 or less.

RESPONSE 43:

EPA believes that the process of using the 95% UCL as a screening concentration is sufficiently conservative. The 95% UCL represents a conservative estimate of the mean and is "a reasonable estimate of the concentration likely to be contacted over time" (EPA, 1989b). An individual is assumed to be equally exposed to soil within all portions of the parcel or floodplain soil exposure area (FSEA). Thus, a concentration that is representative of the entire area being evaluated is appropriate. The Phase 1 screening results for 8 areas of the total number of areas evaluated would be affected if the maximum detected concentration were used as the screening concentration. These include tax parcels J4-3-8 (Section 3.2.1.2.15) and J2-2-2 (Section 3.2.3.3) in Reach 5, utility easement 5 (Section 3.2.4.5) in Reach 5, and FSEAs 18 (Section 4.2.2.18), 20 (Section 4.2.2.20), 25 (Section 4.2.2.25), 28 (Section 4.2.2.28), and 56 (Section 4.2.2.56) in Reach 7. The table below lists the sample size, the maximum concentrations detected, the 95% UCLs, and the SRBC for these areas. The sample size for two areas (tax parcel J4-3-8 and FSEA 20) was small (5 and 9 samples, respectively). For these two areas, the maximum detected concentrations only marginally exceeded the SRBC; therefore, EPA believes these properties do not require further evaluation in Phase 2.

Area	Sample Size	Maximum Detected Concentration (mg/kg)	95% UCL (mg/kg)	SRBC (mg/kg)
J4-3-8	5	5.7	4.24	5
J2-2-2	41	2.84	0.548	2
UE 5	91	31.9	4.18	20
FSEA 18	14	7.71	3.83	5
FSEA 20	9	7.09	5.34	7
FSEA 25	19	6.2	4.84	5
FSEA 28	33	16	3.41	7
FSEA 56	21	6	3.12	5

Within Section 2.5.1 and associated tables, references for many of the exposure parameters used as well as justification as to why a particular value was selected are lacking and should be incorporated.

RESPONSE 44:

The bases for exposure parameters as well as references will be included in Volume I of the revised HHRA.

Table 2-1: I disagree with the use of a target risk level (TRL) of 5×10^{-6} (versus 1×10^{-6}) in the calculation of SRBCs. The reason given for using 5×10^{-6} (that there was so much data from such a large area to evaluate that a higher TRL would screen out more areas more quickly) is not acceptable. The more conservative target risk level of 1×10^{-6} should be used in the Phase 1 screening for all scenarios and receptor groups.

RESPONSE 45:

Please refer to the response to General Issue 6.A.

Tables 2-5 and 2-6: A TRL of 1.6x10-6 was used for the utility worker, while a TRL of 1.1x10-6 was used for the groundskeeper. The text needs to justify why different TRLs were used for workers versus residential and recreational receptors, or use a consistent TRL for all receptor groups. I recommend a TRL of 1x10-6 be used for all receptor groups.

RESPONSE 46:

Please refer to the response to General Issue 6.A.

Section 2.6.1.1, page 2-23: The text states that "if the 2 mg/kg benchmark value was exceeded on a high-contact, residentially zoned but undeveloped property, it was retained for analysis in Phase 2." The text needs to clarify which specific EAs that are zoned residential or that could be used for residential purposes in the future were retained.

RESPONSE 47:

There are four tax parcels in Reach 5 that are residentially zoned but undeveloped. They are J4-8-8 (Section 3.2.1.2.11), J4-8-10 (Section 3.2.1.2.13), 18-85 (Section 3.2.1.2.40), and 9-18 (Section 3.2.1.2.41). Two of these parcels, 18-85 and 9-18, do not meet the criteria for high-contact residential (actual/potential lawns). These parcels are located close to Woods Pond where the floodplain is broader and are characterized by densely vegetated wetlands. Based on an SRBC = 5 mg/kg for low-contact residential, parcel 18-85 (maximum detected concentration = 2.6 mg/kg) was eliminated from further consideration and 9-18 (EPC = 321 mg/kg) was retained for evaluation in Phase 2.

It is possible that parcels J4-8-8 and J4-8-10 could be developed at some point in the future with a portion of that area being considered subject to high-contact residential use. However, all PCB concentrations at J4-8-8 were below the limit of detection. At J4-8-10, the maximum PCB concentration detected was 0.7 mg/kg, below the high-contact residential SRBC of 2 mg/kg. Thus, although these two parcels were eliminated from further evaluation in Phase 1 based on low-contact residential land use, this reexamination shows that they would also have been eliminated if they had been evaluated based on high-contact residential land use in the future.

A similar comment applies to agricultural areas. While the assumption that individuals spend 100% of their recreational time in areas (i.e., FI=1) contaminated at the upper-bound (95% UCL) level is very conservative. I do agree that a Phase 1 assessment should err on the side of conservatism; hence, these values seem reasonable for Phase I (but would be overly conservative for Phase II).

Section 2.5.1.1, page 2-6: I disagree with the exposure frequencies used to calculate SRBCs for high contact residential areas. Residential land use means that individuals live on that property; hence they could potentially be exposed to floodplain soils 7 days a week (versus 5 days a week) for 7 months a year (the number of months the ground is not frozen or covered by snow).

RESPONSE 48:

The Performance Standard for actual/potential lawns established in the Consent Decree, and thus for the high-contact residential exposure, was based on the Massachusetts Department of Environmental Protection (MDEP) Method 1 Generic Soil Cleanup Level for residential use, which is 2 mg/kg (MDEP, 1994). This value is based, in part, on an exposure frequency of 5 days/week for 7 months/year. Both EPA and MDEP consider this an appropriately conservative frequency of exposure to residential soil based on Massachusetts climate.

Section 3: It would be helpful if the tables in Section 3 also included information on the size of the parcel or EA under evaluation.

RESPONSE 49:

EPA has provided area information for each of the tax parcels and FSEAs in each area-specific write-up and the corresponding figure. The area-specific write-ups are presented in Sections 3 and 4 of Appendix A, Volume IIA. The area-specific figures are presented in Appendix A, Volume IIB.

Section 3.2.3: The process used to screen agricultural areas is confusing. My understanding is that agricultural areas were screened based on exposure to PCBs in soil via ingestion and direct contact with soil only (i.e., screening did not include possible consumption of crops affected by site soils). If agricultural areas were eliminated based on direct contact with soil only, I strongly disagree with this approach. If agricultural areas were screened for direct contact only and retained for Phase II analysis, this fact needs to be clarified in the Phase I report.

RESPONSE 50:

The Phase 1 screening risk assessment focused only on direct contact (ingestion and dermal contact) with soil and sediment as stated in Section 3.1 of Volume I of the HHRA. The results of the Phase 1 analysis did not have an impact on the evaluation of indirect exposures via agricultural products (e.g., milk, produce, poultry). In addition, please refer to the responses to General Issues 5.B and 5.C.

Results of the agricultural exposure analysis (Phase II) show that consumption of some agricultural products originating from areas with a soil concentration of 2 mg/kg (the SRBC) could result in a risk level as high as 1x10-3. Since the consumption of agricultural products originating from areas with PCB levels greater than 2 mg/kg could result in elevated risk levels, all areas that are or could be used for agricultural purposes in the future should be retained for Phase II analysis.

RESPONSE 51:

See previous response and please refer to the response to General Issue 11.A.

I recommend including a summary table of EAs that are or could be used for agricultural purposes in the future as well as information on whether each area was eliminated in Phase 1 or retained for further analysis in Phase II.

RESPONSE 52:

See previous response and please refer to the response to General Issue 11.A.

Section 7: Phase 1 screenings were based primarily on current land uses (and zonings). How future land use conditions were incorporated into or affected the results of the Phase 1 analysis is confusing. Page 7-4, lines 30-33 state that only Reaches 7 & 8 have areas where land use could change and Reaches 5 & 6 have "no properties that could have their screening result changed based on realistic future land use." It appears that all of the EAs listed in Table 7-1 would be retained for further analysis if screenings were based on potential future land uses, yet all of these EAs were eliminated from further analysis based on current land use only. If this interpretation is correct, clarification of why these EAs were eliminated is needed.

RESPONSE 53:

Please refer to the response to General Issue 2.B. The primary reason that the Phase 1 screening result for the tax parcels eliminated in Reaches 5 and 6 would not change is that the EPCs were less than the SRBCs for the current land use and the feasible potential future land use, as demonstrated in the detailed response to a previous comment. The revised HHRA will clarify this point. The properties listed in Table 7-1 are those areas in Reach 7 and 8 that do not meet the criteria presented in the bulleted list on page 7-4. It should be noted that not all of the areas presented in Table 7-1 were eliminated; rather about one-third were retained for Phase 2. These are FSEAs 3, 4, 8, 9, 10, 13, 21, 23, 31, 32, 35, 40, 44, 48, and 53. EPA believes that the remaining areas were eliminated based on an adequately conservative screening analysis, and that these parcels were accurately classified regarding both current land uses and reasonably anticipated future land uses. This classification is based on visits to these areas, discussions with the local planning officials, and review of planning documents. (Please refer to the response to General Issue 2.A.) When the land use for an area was in question, the most restrictive land use was assumed.

F. Owen Hoffman

In general, the approach is consistent with EPA guidance for initial screening. There should be a reference to the EPA Guidance for Soil Screening, however.

RESPONSE 54:

Please refer to the response to General Issue 6.B.

A more transparent discussion is needed to clearly demonstrate that the degree of conservatism included in the Phase I screening approach is sufficient to minimize false negative conclusions, without producing an extreme number of false positive cases requiring more in-depth evaluation.

RESPONSE 55:

Conservative exposure assumptions were made by EPA to reduce the potential for false negatives. In addition to the conservative assumptions used to develop SRBCs, whenever the amount of data for a particular area caused some concern regarding the calculation of an appropriate EPC, alternative approaches were used to ensure that these properties were not improperly eliminated. For example, initially, parcels with the potential for the highest risk (i.e., high-contact residential properties) were screened. If the property had concentrations greater than the screening value (2 mg/kg), the property was transferred to GE for more comprehensive sampling and evaluation, as required by the Consent Decree. However, a number of properties were transferred to GE for additional sampling even when no samples were taken (due to access issues), or when the concentrations on the parcel were less than 2 mg/kg, but adjacent parcels had higher concentrations. These included tax parcel 5-22 (Section 4.2.1.80) in Reach 7, and four tax parcels in Reach 7—parcels 29-85 (Section 4.2.1.16), 29-84 (Section 4.2.1.17), 9-56.02 (Section 4.2.1.72), and 9-57 (Section 4.2.1.73).

Second, three other tax parcels (one low-contact residential and two recreational) in Reaches 5 and 6 would have been eliminated from consideration based on PCB concentrations on the parcels in the Phase 1 screening, but were retained for the Phase 2 analysis because of elevated PCB concentrations on nearby or adjacent properties. These parcels were H6-4-13 (Section 3.2.2.1), J3-2-6 (Section 3.2.1.2.30), and 19-2 (Section 3.2.2.33).

Third, there were no samples collected from tax parcel J6-2-3 (Figure 3-6), a low-contact residential area in Reach 5, because of the very small amount of area of the parcel in the floodplain. However, given its proximity to the confluence and the high concentrations in sediment and properties nearby, this property was retained for evaluation in Phase 2. Further, although utility easement 3 (Section 3.2.4.3) in Reach 5 was eliminated from consideration in Phase 1 based on commercial/industrial use, it is also used for recreational purposes; therefore, it was included in the Phase 2 evaluation.

A discussion of these situations is presented in greater detail in Sections 3 and 4 of Appendix A, Volume IIA. The process followed illustrates EPA's commitment to eliminating the potential for false negatives.

It is also necessary to clearly state that screening in Phase I is only for direct contact with contaminated surface soil and sediment. Phase I screening is not intended for nor is it applicable to land that could be used for agricultural purposes in which contamination of food products would be an issue.

RESPONSE 56:

EPA agrees with this comment and specifically stated this in Section 3.1 of Volume I of the HHRA. The revised HHRA will include a new section that discusses the strategy of the risk assessment. The use of the Phase 1 screening assessment only for direct contact exposure will be made clear in this new section as well. Please refer also to the response to General Issue 5.C.

It would help reviewers and other readers of the HHRA if a discussion could be included that presents the degree of conservatism associated with each parameter and assumption applied for screening, so that an overall impression can be given as to the robustness of the Phase I approach.

RESPONSE 57:

EPA's approach to Phase 1 was intended to be a conservative screen, with more detailed information presented in Phase 2 for those exposure areas that were retained. A more detailed discussion of the uncertainty associated with the Phase 1 direct contact parameters will be provided in the revised HHRA.

The justification of a target risk level of 5 ×10-6 needs to be strengthened.

RESPONSE 58:

Please refer to the response to General Issue 6.A.

The selection of a cancer risk level substantially higher than 1 × 10-6 appears to have been an arbitrary decision made by EPA to avoid including too many exposure areas for more detailed analysis in Phase II.

RESPONSE 59:

Please refer to the response to General Issue 6.A.

The use of a six-year exposure duration for the non-cancer risk evaluation for children exposed to PCB's should be discussed further. The maximum ratio between body weight and soil intake would be for a child in the first two years of life, and this time period could result in a higher estimate of a PCB HI per unit soil concentration than produced using an averaging time and exposure duration of 6 years.

RESPONSE 60:

Please refer to the response to General Issue 3.B.

The validity of the procedures used to estimate an upper confidence limit of the mean should be re-examined. I have a concern with the reliability of the statistical procedures used to determine a 95% UCL of the mean when samples are not taken at random and when less than detected data are assumed to be at a PCB concentration that is one-half the detection limit. The non-randomized sample design and the mixing of non-detects with detected values to determine the underlying shape of the true distribution of soil and sediment concentrations could produce a misleading result, albeit the direction of bias is probably still towards overestimating the true mean concentration.

RESPONSE 61:

The UCLs for the Phase 1 direct contact assessment were calculated based on 1992 EPA guidance (*Supplemental Guidance to RAGS: Calculating the Concentration Term* (EPA, 1992b), and not in the manner used for the Phase 2 direct contact assessment. For the Phase 1 direct contact assessment, all 95% UCLs were calculated using the Land H-statistic. Because the Land H-statistic provides a very conservative estimate of the 95% UCL of the mean when distributions deviate from lognormality (EPA, 2002c, OSWER 9285.6-10), EPA is confident that the any bias will represent an overestimate of the mean in the Phase 1 screening.

The extent to which the current procedures produce a reliable over-estimate of the upper 95% confidence limit of the mean PCB concentration in soil and sediment should be discussed.

RESPONSE 62:

Please refer to the previous response.

If the variability of the observations is very large, or the number of samples is very small, I anticipate that it will be difficult to exclude the likelihood that the underlying distribution is lognormal, unless the majority of samples are below the limit of detection and assumed to be at a concentration that is just one-half the limit. As stated above, this assumption will distort the shape of the underlying distribution.

RESPONSE 63:

The UCLs for the Phase 1 direct contact assessment were calculated based on 1992 EPA guidance (EPA, 1992b), and not in the manner described for the Phase 2 direct contact assessment. For the Phase 1 direct contact assessment, all 95% UCLs were calculated using the Land H-statistic.

The substitution of the maximum value observed for the 95% UCL to determine the exposure point concentration when the maximum value is lower than the 95% UCL is consistent with EPA guidance for baseline risk assessment. For Phase I screening, however, I would prefer that the upper 95% confidence limit of the mean still be used for comparison with the SRBC, even in those cases when it is higher than the maximum value observed. As stated by the authors of the HHRA in Attachment 4 of Vol. I, the maximum observed concentration may be lower than the upper 95% confidence limit of the mean simply because the number of samples taken is few and because of the fact that the initial sample obtained was not randomized.

RESPONSE 64:

As the Reviewer acknowledges, EPA followed the applicable guidance and considers the approach contained therein to be sufficiently protective.

In those cases where the upper 95% confidence limit of the mean is greater than the SRBC, but the maximum value observed is below the SRBC, additional sampling should be considered in Phase II to obtain a more reliable estimate of the mean concentration. The substitution of the maximum value observed for the EPC when the maximum value is less than the upper 95%

confidence limit of the mean would be appropriate in a Phase II evaluation when the number of samples taken is considered to be of a sufficient size and sufficiently randomized to characterize the extent of contamination within a given exposure area.

RESPONSE 65:

Following the completion of Phase 1, EPA performed a substantial amount of additional sampling prior to Phase 2 to fill data gaps and increase sample sizes in exposure areas. As stated in the previous response, EPA followed applicable guidance by basing the screening on the maximum concentration detected rather than the 95% UCL when the latter was higher.

John C. Kissel

EPA has developed guidance for soil screening at Superfund sites. However, I can find no mention in the Rest-of-River Human Health Risk Assessment (ROR HHRA) of EPA's Soil Screening Guidance (OSWER 9355.4-23, July 1996) or the more recent Supplemental Guidance For Developing Soil Screening Levels for Superfund Sites - Peer Review Draft (OSWER 9355.4-24, March 2001). Given that those documents were produced by OSWER specifically for this type of application, it is unclear why they are not cited. Potentially relevant guidance related to future land use (Land Use in the CERCLA Remedy Selection Process (OSWER Directive No. 9355.7-04, 1995) is also not cited.

RESPONSE 66:

Please refer to the responses to General Issues 2.A and 6.B.

Screening procedures should be conservative and generally err on the side of retention rather than exclusion of exposure areas. In three respects the screening procedure appears to be neither conservative nor consistent with guidance cited above. These are 1) Use of variable target risk levels (from 1 to 5·10-6) rather than a single default value of 10-6;

RESPONSE 67:

Please refer to the response to General Issue 6.A.

2) Consideration of direct contact only when screening agricultural lands when the SGDSSL appears to indicate that other pathways should be considered;

RESPONSE 68:

The Phase 1 screening risk assessment focused only on direct contact with soil and sediment (ingestion and dermal contact), as stated in Section 3.1 of Volume I of the HHRA. It was not used for screening for risk from consumption of agricultural products.

and 3) consideration of current land uses only.

RESPONSE 69:

Future uses were considered as presented in Section 7 of Appendix A, Volume IIA. In addition, please refer to the response to General Issue 2.B.

Roger O. McClellan

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

RESPONSE 70:

Please refer to the response to General Issue 6.A. EPA believes the level of conservatism in the screening risk assessment was appropriate. Other Reviewers have expressed concern that it was not adequately conservative and that some parcels may have been prematurely eliminated. It should be noted that the screening risk assessment affected the number of parcels retained for, but not the outcome of, the more detailed direct contact risk assessment conducted in Phase 2.

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

RESPONSE 71:

EPA believes the level of conservatism used in the Phase 1 risk assessment, which was intended for screening purposes only, was appropriate. The more detailed assessment conducted in Phase 2 incorporated different parameters to estimate exposure (see Section 4.5 of Appendix B). As part of the revised HHRA, EPA will review the exposure parameters used in all the exposure scenarios. The exposure frequencies for individual exposure areas will be reviewed, and the exposure frequencies for current and future scenarios will be differentiated. Observations provided in the Housatonic River Floodplain User Survey will be considered in the development of the exposure frequencies for the current use scenarios. Please refer to the response to General Issue 7.E.

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

RESPONSE 72:

EPA does not agree that the Mayes value is more appropriate than the Wester value. EPA concluded that the Mayes study has several critical flaws and the weight of evidence does not support changing the dermal absorption factor for PCBs from 0.14. The issues with the Mayes study were discussed in detail in the HHRA, Volume I, Section 2.3.1.2. One flaw is that after application of the soil to the test monkeys, the animals were not restrained during the 24-hour exposure period. There is concern that movement during the exposure period would disturb the soil contact with the skin. Another flaw is that the study did not control for monolayer conditions based on the soil particle size.

EPA remains convinced that the current absorption factor of 0.14 is the best available value, as described in Section 2.3.1.2 of Volume I. This value is also recommended in RAGS Part E (EPA, 2001c).

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

RESPONSE 73:

EPA is concerned with the potential exposures to the contaminated areas of the floodplain (which extends laterally to the 1-ppm tPCB isopleth, approximately the 10-year floodplain.) Potential exposures that could occur within the 1-ppm tPCB isopleth were evaluated for each identified EA and the exposure frequency was selected to reflect this restriction; therefore, areas outside the site boundary were not considered further.

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

RESPONSE 74:

Please refer to the response to General Issue 6.A.

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

RESPONSE 75:

Please refer to the response to General Issue 6.A. EPA believes the level of conservatism, including the selection of exposure parameters, in the screening risk assessment was appropriate. Other Reviewers have expressed concern that the screening was not adequately conservative and that some parcels may have been prematurely eliminated. It should be noted that the screening risk assessment affected the number of parcels retained for, but not the outcome of, the more detailed direct contact risk assessment conducted in Phase 2.

P. Barry Ryan

- ***The general procedures used***

The general procedure used in the HHRA was to develop a two-phase plan involving initial screening, followed by more detailed risk estimation where warranted. This method is certainly consistent with EPA policy and generally accepted scientific practice. Typically, one adopts conservative estimation procedures for the initial screening - a procedure that eliminates only those locations with very little likelihood to give rise to any appreciable risk. This is usually done by assuming a "highly exposed" scenario and evaluating it given the concentrations of selected pollutants to estimate a risk. If the risk is still low under these conservative conditions, one may reasonably expect it to be very low under the conditions actually present. In the current HHRA, an approach involving Screening Risk Based Concentrations (SRBCs) was used. In this method, the typical risk calculation was inverted; an acceptable screening level risk was adopted for each scenario and the concentration associated with this risk was determined. Several examples of the calculation are given in the document itself. Measured concentrations were then compared with this value and an algorithm applied to determine if these concentrations exceeded the SRBC was implemented (See later discussions). Parcels exceeding the SRBC through this algorithm were retained for later, more detailed (Phase II) analysis.

- ***The SRBCs used for the COPC***

The screening-based risk concentrations (SRBCs) for the contaminants of potential concern (COPCs) are those normally used in the risk assessment field, namely a range of 10^{-4} – 10^{-6} risk inferred for potentially carcinogenic compounds or those giving rise to a hazard index (HI) of 1 for non-cancer effects. These values are consistent with EPA policy as I understand it and also are consistent with those commonly used in community settings. In my preliminary assessment, I found these SRBCs reasonable, and still do. However, I have not received sufficient justification for the varying choice of SRBCs. The risks deemed acceptable that were used to calculate the SRBCs are, themselves, variable over a relatively small range (essentially 1-10 x 10^{-6}). In my opinion, this reduces the *a priori* argument that these are risk-based, but rather suggests that the values are "concentration based concentrations" and that some other criterion was used for their selection. This was then *post hoc* justified by the SRBC appellation.

RESPONSE 76:

Please refer to the response to General Issue 6.A.

While I have some concern regarding the details of the calculations, I do not believe that small differences in the way the SRBCs were determined, or in the way they were used would affect the outcome in any substantial way. It appears that few parcels were "on the margin" and such small differences are unlikely to move a significant number of parcels off the Phase II list that were originally on it, or *vice versa*. To quote panel member Owen Hoffman- "The goal is to minimize the number of false negatives without getting an irrationally high number of false positives." One may argue that taking all of the parcels above Wood's Pond into the Phase II analysis may be appropriate in that most of the contamination is in those reaches and that few parcels were eliminated. In some sense, this would be equivalent to removing all of the Connecticut reaches from more complete analysis- a geographic stratification.

It is odd that a few of the parcels are eliminated in Phase I for the upper reaches, despite being surrounded by other parcels that are included.

RESPONSE 77:

In general, the parcels that were eliminated were separated from the other parcels by barriers such as railroad tracks or had extremely small portions of their area within the floodplain.

But, I still believe that the method is solid and defensible, given the caveat about selection of risks mentioned in the previous paragraph.

- ***The land use and exposure categories considered and the classification of particular parcels and areas into those categories***

This is a difficult question to address since the number of parcels involved is very large. In general, I am in agreement with the land use and exposure categories considered and the classification of those particular parcels and areas into those categories. However, I have not evaluated each and every parcel in a rigorous manner. Further, as discussed later, I may have selected a different overall scheme that may have resulted in different, and doubtless more conservative, classification of some (very few, actually) differently.

It is my assessment that, in general, the land use exposure categories considered and the classification of specific parcels and areas into those categories is adequate for the screening process involved in the Direct Contact Exposure Assessment. It may not be directly on point to discuss here, but I do have some concerns regarding the "accessibility factor" included in some parcels. The values for this factor appear arbitrary and not based on any data or observation.

RESPONSE 78:

Please refer to the response to General Issue 7.B.

Summary Under Direct Contact Screening Approach

The screening approaches used attempt to fulfill Dr. Hoffman's "minimize false negatives; control false positives" criterion quite well. One may quibble about the weighting of each, e.g., fewer false positives coupled with more false negatives, but the method chosen would seem adequate and sufficiently protective of the exposed population as to pass muster. As in any risk assessment, the Devil is in the details. One may argue with a specific intake rate, risk chosen, exposure frequency, calculated concentrations, etc., but little is to be gained in such an exercise.

There is another level of risk assessment to be accomplished and that will address the details even more.

Lee R. Shull

Overall review conclusion: For screening purposes and as related to the specific, stated objectives of the Phase 1 assessment, the general procedures used are acceptable and appropriate. Also, for the most part, EPA's risk characterization criteria of transparency, clarity, consistency and reasonableness, and the additional "objectivity" criterion are met. A few items lacking some of these areas are noted under specific comments below.

- ***The general procedures used***

Following are a few of the more key concerns and issues:

- To the extent that the Consent Decree dictates procedures, methods, etc as related to the Phase 1 should be identified and briefly summarized in Section 2 to improve transparency. More than simply a reference to the Consent Decree (Appendix J) is needed.

  RESPONSE 79:

  The revised HHRA will expand the description of the procedures and methods used in the Phase 1 Direct Contact Risk Assessment. Also, please refer to the response to General Issue 6.A.

- Rationale for why the Phase 1 assessment did not utilize, or even make mention of, EPA's "Soil Screening Guidance for Developing Soil Screening Levels for Superfund Sites" should be presented. Also, a reference for this guidance is not included in the reference list (Section 9). This guidance is directly applicable to the process undertaken in this Phase 1 screening analysis. Without some justification for not following this guidance, lack of consistency with EPA guidance is an issue. Section 1.2 would be the appropriate place for this discussion.

  RESPONSE 80:

  EPA agrees that the reference should be included. Please refer to the response to General Issue 6.B.

- Clarification is needed as to why only PCBs were addressed in the Phase 1 and not other chemicals detected in samples in the area. While I do not necessarily disagree with the approach, it is nonetheless inconsistent with EPA guidance. A better explanation as to why the deviation from standard screening practice is needed.

  RESPONSE 81:

  PCBs are the major contaminant associated with the GE facility in Pittsfield and concentrations far exceed those of any other contaminants of potential concern

(COPCs). The Phase 1 screening identified areas that have some contamination originating from the GE site and for which potential risks are a concern. Other potential contaminants of concern were evaluated for these areas in Phase 2. Based on the conservatism of the Phase 1 screening risk-based concentrations (SRBCs), and the subsequent Phase 2 evaluation demonstrating that PCBs and related contaminants (dioxin, furans, and dioxin-like PCBs) are the only COPCs, EPA is confident that the approach is appropriately conservative and consistent with guidance.

- Further clarification is needed as to why only EPA/USACE-collected data, and not all data, are used in the Phase 1 screening evaluation.

RESPONSE 82:

As discussed on Page ES-3 of Volume IIA, the EPA/USACE-collected data were used in the initial screening analysis because of the lack of availability in electronic format of the other data at that time. When the other data became available in a usable format, an additional evaluation was performed to determine the impact of using both the EPA/USACE- and GE-collected data (see Section 8 of Appendix A, Volume IIA).

Also, the chemical form of PCB data used in this screening evaluation is unclear as to whether it is total PCBs (tPCBs), summed Aroclors, or something else.

RESPONSE 83:

The majority of the approximately 12,000 soil and sediment samples collected by EPA for this study were analyzed for tPCBs as the sum of Aroclors by Modified EPA Method 8082 (GC/ECD). Approximately 500 of these samples were analyzed for tPCBs as the sum of congeners using Modified EPA Method 1668 (GC/MS). An appendix providing additional detail on the analytical methods used by EPA for all environmental media will be added to the revised HHRA.

- Page 4-51, Section 4.5.3.9: It is unclear why no future agriculture land use was evaluated; only current agriculture land use. If it is assumed future land use of floodplain areas are not believed to be transformed into agriculture areas, rationale/justification for this assumption should be provided here, or a reference to a location in the report where such information can be found should be provided.

RESPONSE 84:

Please refer to the response to General Issue 2.E.

- ***The SRBCs used for the COPC***

The SRBCs used generally meet the evaluation criteria. Following are key concerns:

- Page 2-6, lines 1-2: The application of the atypical target risk levels (e.g., 5 x 10^{-6} for residential and recreational; 1.6 x 10^{-6} for utility worker; 1.1 x 10^{-6} for groundskeeper) is not consistent with EPA guidance, and the explanation given is not transparent. Typically, selection of a target risk level (TRL) is either a site-specific risk management decision, or is codified in guidance. In this Phase 1 assessment, it appears these TRLs are risk management decisions, which is acceptable. A more thorough risk management explanation is needed.

RESPONSE 85:

Please refer to the response to General Issue 6.A.

- In Section 2, in particular the tables, none of the exposure parameters and assumptions are referenced and should be. Parameters that are based on a source that can be referenced should be referenced. For those that are based on professional judgment, rationale should be given that the parameter or assumption meets EPA's criteria of transparency, clarity, reasonableness and consistency.

RESPONSE 86:

The references for the exposure parameters used to calculate the SRBCs will be included on the tables in the revised HHRA.

- The screening of agricultural areas based on direct exposure to PCBs (soil ingestion and direct contact), which does not include food chain transfer exposure, could result in elimination of some parcels for consideration in Phase 2. The document should present clear rationale for not developing agricultural SRBCs, or should provide clear and transparent explanation as to why it is believed that the SRBCs will not result in elimination of parcels that should be included in the Phase 2 analysis.

RESPONSE 87:

The Phase 1 screening risk assessment focused only on direct contact with soil and sediment (ingestion and dermal contact), as stated in Section 3.1 of Volume I of the HHRA. The evaluation of indirect exposures via agricultural products (e.g., milk, produce, poultry) is presented in Volume V of the HHRA.

- Page 2-6, Section 2.5.1: Exposure frequencies for residential and recreational receptors assumes 5 d/wk for 7 months for high contact and 3 d/wk for 7 months for low contact. Additional rationale for these values should be provided. These values could be considered low, especially for children who are likely to play outdoors during good weather months as much as 7 d/wk.

RESPONSE 88:

The Performance Standard in the Consent Decree for actual/potential lawns, and thus residential exposure, was based on the Massachusetts Department of Environmental Protection (MDEP) Method 1 Generic Soil Cleanup Level for residential use, which is 2 mg/kg (MDEP, 1994). This value is based, in part, on an exposure frequency of 5 days/week for 7 months/year. Both EPA and MDEP consider this an appropriately conservative frequency of exposure to residential soil based on Massachusetts climate.

- Page 2-6, lines 21-23: Text should indicate here that age-adjusted SRBCs are developed, as indicated in Tables 2-2 and 2-3.

RESPONSE 89:

This will be clarified in the revised HHRA.

- Page 2-8, line 12: RAGS Part E (EPA, 2001) suggests 2,800 cm^2/d for a childs surface area rather than 2900 cm^2/d

RESPONSE 90:

The SRBCs were calculated prior to the release of the 2001 RAGS Part E guidance. The values used were taken from the 1998 version of the guidance. The impact on the SRBCs of using 2,900 cm^2/d versus 2,800 cm^2/d would be minimal and would not change any decisions based on the Phase 1 results.

- Tables 2-1 to 2-6: All values for individual parameters presented in these tables should be referenced. A column can be easily added to each table in which the appropriate reference can be cited.

RESPONSE 91:

The references for the exposure parameters used to calculate the SRBCs will be included on the tables in the revised HHRA.

- Page 2-16, line 19: RAGS Part E (EPA, 2001) suggests a utility worker soil adherence factor of 0.9 mg/cm^2 instead of 0.8 mg/cm^2.

RESPONSE 92:

The SRBCs were calculated prior to the release of the 2001 RAGS Part E guidance. The values used were taken from the 1998 version of the guidance. The impact on the SRBCs of using 0.8 mg/cm^2 versus 0.9 mg/cm^2 would be minimal and would not change any decisions based on the Phase 1 results.

- Page 2-19 and Table 2-6. Soil ingestion of 50 mg/d for the groundskeeper seems low. Suggest using at least 100 mg/d for outdoor worker (EPA, 2002 – Supplemental Soil Screening Guidance for Developing Soil Screening Levels for Superfund Sites).

RESPONSE 93:

EPA developed the SRBCs prior to the release of the 2002 Supplemental Soil Screening Guidance. They were calculated using the available exposure parameters at the time. The 50-mg/day ingestion rate for the groundskeeper is based on 1991 EPA guidance (EPA, 1991a). The groundskeeper SRBC would be 14 mg/kg if a 100-mg/day ingestion rate were used, rather than the SRBC of

20 mg/kg used in the HHRA. A review of all properties indicates that the results of Phase 1 would not change based on the more stringent SRBC.

- ***The land use and exposure categories considered and the classification of particular parcels and areas into those categories***

The land use and exposure categories considered and the classification of particular parcels and areas into those categories generally meets the evaluation criteria. Following are key concerns:

- Although the stated focus of the Phase 1 screening is current land use (*e.g.,* page ES-9, line 10), it is not clear that all of the exposure scenarios assessed are, in fact, representative of current land uses vs. future land uses. Further clarification is needed as to how future land use was factored into this screening analysis.

  RESPONSE 94:

  Please refer to the response to General Issue 2.B.

- Page 2-23, line 8: The basis of these land use designations should be briefly discussed here, or reference made to a place in the document where such an explanation can be found.

  RESPONSE 95:

  The land use designations are discussed on pages ES-1 and ES-2 and in Section 1.2 (Page 1-2) of Volume IIA of the HHRA. In addition, page 3-1 of Volume I provides a discussion of the land use designations.

ADDITIONAL REVIEWER COMMENTS

Lee R. Shull

- The Executive Summary generally provides a very good overview of the screening process, including the purpose, the methods and assumptions, and the results.

- Page ES-2, lines 26-29: Because "integrated SRBCs" play such an important role in this screening risk assessment, the executive summary should better define and provide a bit more basic information on how these "integrated" SRBCs are derived, and explain why "integration" is relevant and appropriate.

  RESPONSE 96:

  Additional clarification will be provided in the revised HHRA.

- Page ES-8, lines 21-25: This sentence is unclear. Is the statement being made that no floodplain or riverbank soil samples were collected because there is no evidence of upstream contamination?

  RESPONSE 97:

  EPA collected only sediment data from the Connecticut reaches because there is minimal floodplain (therefore minimal exposure potential) adjacent to the river in Connecticut due to the change in topography and large impoundments. These samples (and previous sampling performed by other parties) indicate low concentrations of PCBs in sediment (see Table 6-1 of Appendix A, Volume IIA). EPA believes that because the only mechanism for contamination to reach the floodplain is out-of-bank high-flow events transporting suspended solids (and associated contaminants) out of bank onto the floodplain soil, the concentrations of PCBs in sediment reflect the worst-case concentrations in the floodplain. If elevated PCB concentrations are not present in the sediment, it is not expected that elevated PCB concentrations would be present in the floodplain soil. Further, the non-detect or low concentrations of PCBs in floodplain soil along the 27 miles in Reach 9 upstream of the Connecticut border (see Table 5-1 of Appendix A, Volume IIA) also supports EPA's conclusion of little or no contamination being present at concentrations that would pose a risk in the floodplain in Connecticut. EPA believes the approach followed is conservative and reasonable.

- Page ES-8, line 23. The statement refers to the "known relationship between sediment concentrations and associated floodplain concentrations", but does not explain what this relationship is or what downstream sediment concentrations mean relative to downstream floodplain soil concentrations. Clarification is needed.

  RESPONSE 98:

  Contamination of floodplain soil is a result of suspended solids (and associated contaminants) being deposited onto the floodplain during out-of-bank high-flow events. If the concentrations of PCBs in sediment are not elevated above SRBCs, then based upon the relationship that was observed between floodplain and sediment concentrations in the upper reaches (BBL & QEA, 2003), it is highly unlikely that the floodplain soil concentrations will exceed those observed in sediment and the SRBCs. EPA will expand this discussion in the revised HHRA.

- Page 1-2, Section 1.2 and elsewhere, as needed: Further explanation of differences in soils (e.g., floodplain vs. riverbank) is needed. The document appears to treat these two floodplain and riverbank soils the same with the only distinction being high vs. low contact. Why use floodplain and riverbank distinctions if high contact and low contact are the only distinctions that matter for the screening?

  RESPONSE 99:

  EPA believes that there is an important distinction between floodplain and riverbank soil, and it was necessary to evaluate these media separately in Phase

1. The primary differences between floodplain and riverbank soil are location and accessibility. Riverbank soil is located directly adjacent to the river and occurs in the form of banks along the river. Floodplain soil includes all of the soil from the riverbank to the lateral extent of the floodplain. This distinction may also be important in future remedial decisions.

It also appears that the entire 10-year floodplain was not included in this screening analysis (Ex. Fig 3-7 of Vol IIB).

RESPONSE 100:

This comment regarding the inclusion of the entire 10-year floodplain in the Phase 1 analysis is not clear. If the comment is referring to the southwestern portion of Figure 3-7, please refer to Figure 3-9, which evaluates this area. This occurs on other figures as well. Each figure focuses on the areas being evaluated (i.e., presents the data for those areas only).

- Page 2-3, lines 8-24: Should indicate what summary statistics or 95% UCLs are chosen when the data fit neither a normal nor lognormal distribution.

RESPONSE 101:

The UCLs for the Phase 1 direct contact assessment were calculated based on 1992 EPA guidance (EPA, 1992b), and not in the manner described for the Phase 2 direct contact assessment. For the Phase 1 direct contact assessment, all 95% UCLs were calculated using the Land H-statistic. Additional clarification will be provided in Volume I of the revised HHRA.

- Page 2-6, line 18: EPA's assumption discussed here should carry a reference.

RESPONSE 102:

EPA agrees with the Reviewer's comment. A reference to MDEP's Method I soil cleanup standards will be included in the revised HHRA.

Stephen T. Washburn

The general procedures used to screen out properties and areas from further evaluation of direct contact exposures appear to be appropriate. Specifically, a wide range of potential receptor populations have been evaluated, usually based on conservative combinations of exposure assumptions and inputs that would be expected to lead to an overstatement, rather than an understatement, of risks. However, the following elements of the Phase 2 Direct Contact Screening should be reconsidered:

- Certain larger areas warrant additional analysis to ensure that small subareas with higher levels of contamination are properly assessed and included in Phase 2 if appropriate. In Reaches 5 and 6, screening of PCB concentrations in floodplain soil was conducted for each tax parcel regardless of size (Volume I, p. 3-4). In Reaches 7 and 8, screening was conducted on exposure areas that encompass more that one tax parcel, while screening of

Reach 9 was conducted for the entire reach and Reaches 10 – 17 were screened for the entire stretch of the Housatonic River in Connecticut (Volume I, p. 3-5). If the maximum concentration in an exposure area were to exceed an SRBC, then the 95% UCL was compared to the SRBC. In some instances, however, an exposure area as defined in Phase 1 can be quite large (e.g., J4-3-13 [35 acres in floodplain]; 29-2 [102 acres in floodplain]; 19-1 [70 acres in floodplain], based on the *EPA Response to Questions from the HHRA Document Review Meeting*) and the 95% UCL is considerably smaller than the maximum detected concentration. This suggests that there may be subareas within a tax parcel or exposure area that are relatively large (e.g., at least several acres in size) and for which a conservative estimate of the exposure concentration may be significantly higher than the 95% UCL for the tax parcel as a whole and also higher than a relevant SRBC. This issue could be addressed in a sensitivity analysis in Phase 1, with additional subareas carried into Phase 2 as appropriate.

RESPONSE 103:

EPA believes that the Phase 1 assessment is a conservative screening evaluation that did not eliminate any areas that had high concentrations. EPA understands the concern regarding evaluating large areas and, in Phase 2, consideration was given to this concern by evaluating subareas within an EA. Further, in the revised HHRA, additional subareas will be identified and evaluated. Please refer to the responses to General Issues 7.A and 7.C.

- The SRBCs for different potential receptor populations are based on different target cancer risk levels (e.g., $5x10^{-6}$ for residents and recreational uses; $1.6x10^{-6}$ for the utility worker and $1.1x10^{-6}$ for the commercial groundskeeper). While I do not object to the use of a range of risk targets in the screening evaluation, Volume I of the HHRA should provide a clearer explanation of the reasons for the differences.

RESPONSE 104:

Please refer to the response to General Issue 6.A.

In particular, it appears that the use of a $5x10^{-6}$ for residents is based on the 2 mg/kg cleanup level previously agreed to by EPA, the State of Massachusetts, and GE for PCBs in residential properties nearer to the GE Pittsfield plant, and thus reflects a risk management decision that actions would not be taken in areas where PCB concentrations are below this level in residential or recreational parcels in the "Rest of River" site. Assuming that such a management decision has been made, I concur with the HHRA that carrying areas that present a risk lower than $5x10^{-6}$ for residents is unnecessary. However, in that case, it is not clear why a more stringent target is being used for the utility worker or commercial groundskeeper.

RESPONSE 105:

Please refer to the response to General Issue 6.A.

- The report should be clarified to emphasize that Phase 1 is intended to only to screen out properties and areas from further evaluation of exposures through direct contact, but that potential exposures through consumption of livestock and produce are evaluated for all current or reasonably foreseeable agricultural areas in Phase 2. While this is clear from Volume V, there was some confusion on the panel based on the text in Volume I.

RESPONSE 106:

The Phase 1 screening risk assessment focused only on direct contact with soil and sediment (ingestion and dermal contact), as stated in Section 3.1 of Volume I of the HHRA. The results of the Phase 1 analysis did not impact the evaluation of indirect exposures via agricultural products (e.g., milk, produce, poultry), which were conducted independently and are presented in Volume V of the HHRA. This will be clarified in the Executive Summary and Sections 1 and 3 of Volume I of the revised HHRA.

The breast milk pathway should be further addressed for PCBs and dioxins/furans. I recognize that this pathway is often excluded from quantitative evaluation in risk assessments due to a lack of recent EPA guidance and limitations in available data. However, given the tendency for PCBs and dioxins/furans to accumulate in fat and both public and regulatory concerns regarding effects of short-term exposure on infants, I believe that the breast milk pathway should be included in an uncertainty analysis. A method for quantifying exposures through the breast milk pathway is described by Smith (1987) [*Infant Exposure Assessment for Mother's Milk Dioxins and Furans Derived from Waste Incinerator Emissions*, Risk Analysis, Volume 7]. This comment also applies to the Phase 2 direct contact, fish and waterfowl, and agricultural exposure evaluations.

RESPONSE 107:

Please refer to the response to General Issue 3.A.

- Given the assumptions used to evaluate incidental ingestion and dermal contact exposures, and the results of air monitoring at the site, I agree with EPA that including inhalation of PCBs in either vapor or particulate-bound form is not necessary in the Phase 1 screening. However, to address public comment on this issue, it may be worthwhile to expand Volume I to discuss the basis for excluding inhalation in establishing the SRBCs. This is particularly important given the relatively large number of articles that have been published over the past several years regarding the importance of long-range atmospheric transport of PCBs.

RESPONSE 108:

EPA agrees with the Reviewer's comment, and will include an expanded discussion of this issue in the revised HHRA.

- The discussion of future land use in Phase 1 (Volume 1, p. 3-9) should explicitly refer to EPA's guidance on the consideration of future land use in the risk assessment process, including the 1995 OSWER Directive on Land Use Policy.

RESPONSE 109:

The revised HHRA will include a reference to this policy. Also, please refer to the response to General Issue 2.A.

It is also unclear from the HHRA why the primary focus of the Phase 1 screening evaluation was current land uses, as stated on p. 3-9. The text suggests, perhaps incorrectly, that the consideration of potential future land use was largely in Phase 2, after many properties had already been screened out based primarily on the basis of current land use. This raises concerns that a more complete evaluation of potential future land use in Phase 1 may have resulted in additional parcels being carried through to further evaluation in Phase 2.

RESPONSE 110:

Section 7 of Appendix A, Phase 1 Direct Contact Risk Assessment evaluates the impact of future land use changes on the screening results. EPA has attempted to accurately classify the current land uses while also considering the reasonably anticipated future land uses. This evaluation included visits to these areas, discussions with the local planning officials, and review of planning documents. When the land use at an area was in question, it was assumed that the most restrictive land use was occurring. An expanded discussion of future use will be included in the revised HHRA. Please refer to the responses to General Issues 2.A, 2.B, and 7.D.

B. PHASE 2 – DIRECT CONTACT EXPOSURE ASSESSMENT (VOLUME III)

GENERAL COMMENTS

Holly Hattemer-Frey

Although the Charge questions do not specifically address the selection of COPCs, my comments on Section 2, Hazard Identification, follow.

The Phase II soil/sediment screening process focused on PCBs, PCDDs/PCDFs, and Appendix IX compounds. Screening of chemicals was based on comparisons to EPA Region IX PRGs as well as site-specific and Massachusetts (MDEP) background data. Use of established PRGs is acceptable, but the text needs to clarify why Region IX PRGs were used versus PRGs from other EPA regions or site-specific SRBCs (e.g., PRGs may be more conservative than site-specific SRBCs).

RESPONSE 111:

EPA Region 1 Risk Update Number 5 (EPA, 1999b) recommends using the Region IX preliminary remedial goals (PRGs) to screen for chemicals of potential concern. As noted, the PRGs are more conservative than site-specific screening risk-based concentrations (SRBCs).

Also, in Phase II, PRGs based on exposure to multiple chemicals (instead of just PCBs) across multiple pathways (versus just direct contact with sediment and soil) would have been more representative and accurate. Had SRBCs been based on exposure to multiple chemicals across multiple pathways, additional chemicals may have been retained as COPCs.

RESPONSE 112:

Conservative screening based on a single medium is consistent with RAGS. The Phase 2 risk assessment evaluated direct contact exposure (incidental ingestion and dermal contact) to multiple chemicals as presented in Section 2.5 of Appendix B, Volume IIIA. Multiple chemicals were also evaluated for indirect contact (consumption) exposure pathways as described in Section 2.5.1 of Volume IV, Appendix C (Fish and Waterfowl) and Section 2.2.1 of Volume V, Appendix D (Agricultural Products).

Although the affect on risk estimates is likely to small given that dominance of PCBs at the site, the potential to underestimate risks should be discussed in greater detail.

RESPONSE 113:

EPA believes that all COPCs at the site have been identified and agrees that any effect on the risk estimates is small. Uncertainty with respect to identification of COPCs was discussed in Section 7.2.1 of Appendix B, Volume IIIA.

Table 2.2: The text needs to clarify why the PRG for naphthalene was used as a surrogate for four select PAHs. It would have been more conservative to use the PRG for BaP. If the PRG for BaP had been used, measured concentrations of acenapthylene, benzo(ghi)perylene, and 2-methylnapthalene would have exceeded their PRG and would not have been eliminated as COPCs at this point.

RESPONSE 114:

For non-carcinogenic PAHs, such as acenaphthylene, benzo(g,h,i)perylene, and 2-methylnaphthalene without a reference dose or concentration, it is EPA Region 1 policy to adopt the reference dose or concentration of a structurally similar PAH for hazard identification purposes (EPA, 1999b). Subsequent to the preparation and release of the HHRA, EPA revised the IRIS profile for 2-methylnaphthalene (published online on 22 December 2003). An RfD for 2-methylnaphthalene is now available, and will be used as a basis for a PRG in the revised HHRA. The data regarding the carcinogenicity of 2-methylnaphthalene are considered inadequate to assess human carcinogenic potential, and therefore no slope factor is published in IRIS.

Table 2-3: I recommend adding a statement to footnote b stating that samples were shown to be normally distributed; hence the arithmetic mean is reported.

RESPONSE 115:

Distributions were not determined for the data presented in Table 2-3. The arithmetic mean was shown as a measure of the central tendency of the data sets.

Table 2-4: I disagree with the elimination of aluminum and manganese as COPCs. Six of the seven samples exceeded the PRG for both chemicals. Given the small sample size (n=7) and the high exceedance rate, aluminum and manganese should be retained as COPCs. Since background concentrations were not provided for these two chemicals (since they were eliminated from the process), it is impossible to determine if measured levels exceed site-specific and MDEP background levels. Inclusion of aluminum and manganese as soil COPCs is likely to have minimal impact on risk estimates, however.

RESPONSE 116:

Please refer to the response to General Issue 5.B.

Section 2.5.2.2.3: I disagree with the deletion of chromium as a COPC for soil based on comparison with background concentrations. Mean chromium concentrations in site soils exceed both MDEP and site-specific background levels. Inclusion of chromium as a COPC is likely to have minimal impact on risk estimates, however.

RESPONSE 117:

Please refer to the response to General Issue 5.B.

I do agree with eliminating the five remaining PAHs since mean site-related concentrations were less than site and MDEP background levels. Table 2-13 & Section 2.5.3.2.3: I disagree with the deletion of chromium and thallium as COPCs for sediment based on comparison with background concentrations. Mean concentrations in site sediment exceed MDEP and site-specific background levels. Inclusion of chromium and thallium as sediment COPCs is likely to have minimal impact on risk estimates, however.

RESPONSE 118:

Please refer to the response to General Issue 5.B.

1. ***Were the following aspects of the direct-contact exposure assessment appropriate under the evaluation criteria?***

   - ***The exposure scenarios which were evaluated.***
   - ***The exposed populations which were selected for each scenario.***
   - ***The exposure areas identified based upon potential current and future use(s).***
   - ***The routes of exposure for each scenario.***

   Consider the following when addressing this question:

   – ***Current and reasonably anticipated future land uses, physical conditions, and accessibility;***

   – ***Locations, concentrations, and distribution of COPCs in the sediment, bank soil, and floodplain soil; and***

   – ***Ages of the selected exposed populations.***

COMMENTS

Holly Hattemer-Frey

There is definitely disagreement between GE, EPA, and the public about possible future use of the area. On the one hand, the claim that increased commercial agricultural activity is not likely because it's not financially viable seems reasonable. Conversely, it does seem reasonable that if the floodplain were not contaminated, more non-commercial, small-scale agricultural activity would probably occur.

RESPONSE 119:

Please refer to the responses to General Issues 2.A, 2.C, 2.D, and 2.E.

Similarly, on one hand, the RA argues that since 75% of the land is state owned, future land use in those areas won't change. Conversely, just because the land is state owned doesn't mean land use wouldn't vary. New trails and fishing areas could be opened up by the state to encourage higher use of the area, for example (especially if the area was not contaminated).

RESPONSE 120:

EPA agrees with the Reviewer's comment. The statement in the HHRA was meant to convey that the general land use is not expected to change and that the land would remain as Wildlife Management Area or State Forest with open access. Please refer to the response to General Issue 2.C.

The main issue at stake here is that the RA is supposed to evaluate potential risks under current *and reasonable future land use scenarios*. The RA does seem biased toward little or no change in the future relative to current land use.

RESPONSE 121:

Please refer to the responses to General Issues 2.A, 2.C, 2.D, and 2.E.

I recommend that at a minimum, local government planning information be consulted to verify EPA's current position or a broader definition of future land use be adopted (i.e., that the RA acknowledge that in the absence of contamination, more areas may be used for agricultural and recreational purposes in the future than are currently considered).

RESPONSE 122:

Substantial effort was put into consulting with local government planners and other resources regarding the consideration of future use in the HHRA. Please refer to the response to General Issue 2.A.

F. Owen Hoffman

- ***The exposure scenarios which were evaluated.***

The exposure scenarios appear appropriate for the assessment of direct contact with PCB's, although the procedure for estimating the exposure and risk to dioxin- like PCB congeners is in need of further scrutiny.

RESPONSE 123:

Please refer to the response to General Issue 5.A.

- ***The exposed populations which were selected for each scenario.***

The exposed populations appear appropriate, but the potential sizes of these populations should be discussed.

RESPONSE 124:

Please refer to the response to General Issue 1.B.

The averaging time and exposure durations associated with age categories used for non-cancer risk assessment may be too large for children.

RESPONSE 125:

Please refer to the response to General Issue 3.B.

- ***The exposure areas identified based upon potential current and future use(s).***

The exposure areas appear appropriate. The assumption of complete random access to an exposure area requires additional discussion. Individuals with preferred access to a subset of areas within a defined exposure area could receive exposures markedly different from that specified by the assumed EPC. The issue has been addressed in a qualitative discussion but not in a quantitative manner.

RESPONSE 126:

Please refer to the response to General Issues 7.A and 7.C.

- ***The routes of exposure for each scenario.***

The routes of exposure appear appropriate.

John C. Kissel

The direct contact scenarios considered generally appear appropriate and adequately inclusive.

Roger O. McClellan

It is difficult to evaluate the adequacy of the direct contact exposure assessment scenarios because the report does not provide adequate background information on the demographics of the Pittsfield, MA area including the Rest-of-River. The report would be substantially improved if population-based data were provided including historical and current information as well as projections for the future.

RESPONSE 127:

Please refer to the response to General Issue 1.A.

Some overall trends regarding land use would also have been useful.

RESPONSE 128:

Please refer to the responses to General Issues 2.A, 2.C, 2.D, and 2.E.

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

RESPONSE 129:

It is expected that a number of activities, such as launching canoes, fishing from shore, hunting waterfowl, swimming, wading, and others, can result in contact with sediment. EPA believes that the exposure resulting from each of these activities is similar. Based on this, EPA developed an exposure scenario that estimated exposure from all of these activities. This approach was followed in order to evaluate sediment exposure using a single scenario as opposed to developing a scenario for each activity that may result in exposure to sediment. In addition, evaluating sediment separately provides valuable information in a context that could be used for decisionmaking. The revised HHRA will provide a more detailed description and rationale for the sediment exposure pathway.

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

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

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

RESPONSE 130:

Please refer to the response to General Issue 5.B.

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

RESPONSE 131:

EPA agrees that permanent construction will not take place in the floodplain.

P. Barry Ryan

- ***The exposure scenarios which were evaluated.***

The exposure assessment models did a good job in assessing those scenarios likely to produce exposure among the actual population in the greater community of individuals throughout the full extent of the Rest of the River. Through meetings with individual members of the community as well as community groups, they established likely exposure scenarios including recreational use of the Rest of the River and its environs, certain commercial use, and the use of agricultural products gathered near the River or grown on or near the floodplain. Further, the exposure assessors have attempted to ascertain high-exposure individuals, selecting certain recreational activities likely to result in very high exposure to a small number of individuals as their reasonable maximum exposure. This is a conservative procedure and one that is likely to lead to excellent screening as well as quality estimates of reasonable maximum exposure. (NB The use of the term "screening" in this context is not to be confused with the Phase I screening process. Here "screening" means evaluation based on a relatively detailed assessment of risk but based on a modeling approach.) I must admit that, at first, I was taken aback by inclusion of a scenario for marathon canoeists. However, once I realized that they were exploring individuals likely to experience the highest level of exposure and that these individuals would serve to simulate exposures experienced by other high exposure individuals, I became more satisfied with the approach.

There is no claim that marathon canoeist represent a large fraction of the community but rather their exposures are likely to be at the very high end of all exposures experienced by those recreating on the River.

RESPONSE 132:

The revised HHRA will be expanded to include a discussion of the conceptual site model (CSM) and the strategy for the risk assessment. The text will include discussion of the observation made by the Reviewer that receptors such as the marathon canoer (which does occur at the site) were also intended to simulate exposures experienced by other high-exposure individuals.

- ***The exposed populations which were selected for each scenario.***

As discussed under the previous heading, I believe that the populations selected are appropriate and sufficiently conservative to act as an appropriate screening tool.

- ***The exposure areas identified based upon potential current and future use(s).***

The exposure areas identified are consistent with measured concentrations, i.e., the 1 mg/kg tPCB concentration profile. However, I am concerned about unusual events in the past (or future) that may cause inundation of the floodplain with sediment containing higher concentrations and the concomitant later use of these areas for recreation, agriculture, or future building sites. My concerns have yet to be assuaged either by material presented in the HHRA nor by any presentation. While this may be a particular problem with my point of view and my childhood memories of flooding in western and central Massachusetts, I would still like to have more justification. It is my assessment that the exposure areas identified based upon current and future use(s) are adequate but I would like to see assessments of flooding scenarios based on 50- or 100-year flood plains and concomitant movement of sediment from the river bed to adjacent floodplain area.

RESPONSE 133:

The General Electric/Rest of River site, which is the subject of the Rest of River study and the HHRA, includes the floodplain downstream of the confluence of the East and West Branches of the Housatonic River, as defined in the Consent Decree. The lateral extent of the area under investigation includes the floodplain extending to the 1-ppm isopleth, which is shown in the RFI (BBL and QEA, 2003) to be approximately equivalent to the 10-year floodplain. EPA has no basis or justification for extending its investigation outside the boundaries of the site, as defined by the Consent Decree. The 1-ppm isopleth was derived using data that reflect the dispersion of PCBs since the beginning of their use at the facility in the 1930s. The interim time period has included multiple large (including 100-year) storm events.

While current land use scenarios are adequately described and presented, the future uses of the land are not done so in a transparent manner. For example, is it reasonable to assume that the entire floodplain to the Massachusetts/Connecticut border will be maintained essentials as publicly-owned park land for the foreseeable future? If not, what effect does this have on the scenario assumptions?

RESPONSE 134:

Please refer to the responses to General Issues 2.A, 2.C, 2.D, and 2.E regarding anticipated future land use. Only the floodplain in Reaches 5 and 6 is composed of large tracts of publicly owned land. Appropriate potential future uses were evaluated in other reaches based upon discussion with local planning boards and other resources. If reevaluation of the reasonably anticipated future use results in more intensive soil exposure than the current use, that future use will also be evaluated. Please refer to the response to General Issue 7.D.

If the area were declared "cleaned" would there be a reemergence of small dairy farms along the Housatonic River?

RESPONSE 135:

Please refer to the response to General Issue 2.E.

If so, it is likely that the agricultural pathway (see below) would be affected, but what of the direct contact? There would be more farmers and agricultural workers. These scenarios become more important.

RESPONSE 136:

EPA agrees that if there were more dairy farms, there would be more farmers and other agricultural workers. Please refer to the response to General Issue 7.D regarding the evaluation of future uses in the direct contact risk assessment.

An important scenario for consideration that has not been addressed focuses on the land use if the Rest of the River were cleaned up. What would be the appropriate scenarios then? Some discussion of this option would be of use and may inform the discussion of the cleanup process.

RESPONSE 137:

EPA believes that the general categories of activities and uses evaluated in the HHRA would remain the same in the absence of contamination. However, the exposure frequency and other specific exposure parameters may change, resulting in more intense or frequent exposure. A more detailed description of current and future land uses will be included in the revised HHRA. Please refer to General Issue 2.

- ***The routes of exposure for each scenario.***

The routes of exposure- dermal contact, ingestion of small amounts of soil consistent with expected intake given EPA guidance, and ingestion of game, etc., are adequate. The pathways investigated appear to be those most likely to give rise to exposures and to give the most frequent exposures and exposures with the greatest magnitude and duration.

Lee R. Shull

- ***The exposure scenarios which were evaluated.***

- In general, the exposure scenarios evaluated are appropriate.
- Page 4-3, Section 4.2.3: It is not clear why a construction worker scenario was not considered or discussed in the CSM. I believe a construction worker should be included in the analysis, at least evaluated (and dismissed) in the CSM, which is usual practice. A construction worker who is not a building construction worker (e.g., someone who constructs buildings, which would not be constructed in the floodplain), but rather an earth worker (e.g., earth moving equipment operator) such as a road construction worker

should at least be identified in the CSM, and then dismissed, if appropriate, with supportive rationale.

RESPONSE 138:

EPA will include discussion of a construction worker in the conceptual site model (CSM) in the revised HHRA. However, EPA believes that a building or road construction worker exposure would be unlikely to occur in the floodplain given that most of the land within the floodplain is considered wetland, which would preclude those types of construction activities. At present, there are no maintained or paved roads in the 10-year floodplain. There are a few dirt roads and easements that were evaluated based on recreational and/or commercial/industrial exposure. EPA believes that the utility worker scenario conservatively covers worker exposure in the floodplain. Thus, a construction worker scenario will not be quantitatively evaluated.

- ***The exposed populations which were selected for each scenario.***

- In general and except for the following comments, the exposed populations evaluated for each scenario are appropriate.

- In the receptor matrix (Table 4-1) and in Section 4.2.3, three receptor groups are identified; the younger child, older child, and adult. The text in Section 4.3.5.1 (lines 13-15) then states that dose and risk estimates were generated for two groups; children (0-6) and adults (7-45). This difference needs to be clarified.

RESPONSE 139:

In accordance with EPA policy for carcinogenic risk (EPA, 1991a, RAGS B), residential doses were calculated for a combined child and adult receptor using an age-adjusted approach, which includes all three age groupings (please note that the child is actually 1 to 6, not 0 to 6 as noted in the comment). The revised HHRA will clarify this issue for both cancer and noncancer doses and risk.

Furthermore, an explanation should be provided why older children are lumped in with adults for the residential scenario and not for the recreational scenarios.

RESPONSE 140:

Residential exposure was age-adjusted because it was assumed that the exposure at the same location occurs when an individual is a young child, an older child, and an adult. Some of the recreational scenarios assume that the activity primarily occurs at a particular life stage. For example, only adults were considered to be marathon canoers and only older children to ride dirt bikes/ATVs.

- Page 4-10, Section 4.3.5.2.1, Table 4-1: Regarding the ATV/dirt and mountain bike riding, it is not clear why an adult receptor was not considered for this scenario. Adults over the age of 30 routinely engage in such activities on a regular basis. Lines 15-17 implies that the adult is addressed, which is not the case for the ATV/dirt and mountain bike rider.

RESPONSE 141:

EPA assumed that the frequency of ATV/dirt and mountain bike riding would be less for an adult than for an older child while other exposure parameters, with the exception of body weight, would be similar for both child and adult. Therefore, the adult exposure would be less than that of the child and was not quantitatively evaluated. This approach may be reconsidered in the revised HHRA based on Reviewers' comments.

- ***The exposure areas identified based upon potential current and future use(s).***

- The exposure areas identified for potential current and future use are appropriate.

- ***The routes of exposure for each scenario.***

- The routes of exposure for each exposure scenario are appropriate.

Stephen T. Washburn

The exposure scenarios, exposed receptor populations, exposure areas, and routes of potential exposures selected for the Phased 2 Direct Contact Exposure Evaluation generally appear to be appropriate, except as follows:

- The rationale for determining future land use assumptions for the direct contact evaluation is not clearly described either in Volume I or in Volume IIIA. For example, according to p. 4-26 of Volume I, "Not all properties were assessed for future residential uses, only those that had the characteristics of properties that have been converted to residential use in Massachusetts in recent years". I was not able to locate a discussion of what these characteristics are, or how they were assessed in the HHRA.

RESPONSE 142:

Please refer to the responses to General Issues 2.A, 2.C, and 2.D.

Furthermore, "industrial/commercial and agricultural exposures were assessed only for those areas currently designated for these uses" (p. 4-26). It is not clear from the information provided in the HHRA whether or not such an assumption is reasonable.

RESPONSE 143:

Please refer to the responses to General Issues 2.A, 2.C, 2.D, and 2.E.

I recommend that the future land use decisions be revisited and documented using the framework described in the 1995 OSWER Directive on Land Use Policy.

RESPONSE 144:

EPA agrees and will do so in the revised HHRA. Please refer to the responses to General Issues 2.A and 2.D.

- The selection of age ranges for evaluation should be supported by a discussion of what is considered to represent a chronic exposure, particularly for PCBs. EPA guidance under Superfund recommends a generic assumption that chronic exposures are those that are relatively continuous over a period of at least 7 years (USEPA Risk Assessment Guidance for Superfund, Part A, 1989). If that is considered to be appropriate for PCBs, dioxins/furans, and the other primary COPCs in the risk assessment, then the age ranges that have been selected appear to be appropriate.

  However, if exposures of only a few years are considered to be chronic for some of the primary COPCs, or if the subchronic toxicity is considered to be similar to the chronic toxicity, then EPA should consider breaking down the "young child" (age 1 through 6) receptor group into smaller subgroups to account for differences in body weight and behavior that may lead to higher risks for infants.

RESPONSE 145:

Please refer to the response to General Issue 3.B.

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

COMMENTS

Holly Hattemer-Frey

Elimination of the Housatonic River as a source of drinking water now and in the future is appropriate. Although incidental ingestion of and dermal contact with surface water could occur, these pathways were appropriately eliminated by comparison of maximum measured surface water concentrations with site-specific SRBCs.

All other complete exposure pathways were evaluated with the exception of the breast milk pathway. One reason given for not calculating potential exposures to infants from consumption of breast milk was lack of EPA guidance. However, methodologies for quantifying the breast milk pathway are available in EPA's (1988) Hazardous Waste Combustion Guidance. Unless EPA can provide new information as to why methodologies available in other EPA documents and the scientific literature are not appropriate, potential risks from consumption of breast milk should be quantified. While the contribution to overall risk from the breast milk pathway is likely to be small relative to other pathways, risks for the breast milk pathway should be evaluated to verify their contribution to overall risk.

RESPONSE 146:

Please refer to the response to General Issue 3.A.

F. Owen Hoffman

Yes, in general. For non-cancer risks, the relationship between annual intake and body weight should be addressed further. The highest ratio between intake and body weight is anticipated for the youngest age groups, which would be larger than what is currently assumed for an average extended over the ages of 1 to 6 years of age.

RESPONSE 147:

Please refer to the response to General Issue 3.B.

John C. Kissel

In the context of direct contact exposure, the pathways considered generally appear appropriate and adequately inclusive.

Roger O. McClellan

The most important exposure pathways were evaluated in the assessment.

As noted earlier the water pathway was evaluated by comparing measured concentrations with health protective concentrations and a decision reached that this pathway did not require a quantitative evaluation. I concur with this decision. I also concur with the decision to not do a quantitative evaluation of the air pathway.

P. Barry Ryan

The pathways under this direct contact exposure have been adequately characterized. However, it would be useful to examine secondary pathways influenced by the direct contact pathway. Most notable among these is ingestion of breast milk from mothers exposed through this pathway. Since PCBs are lipophilic, storage in adipose tissues for a significant amount of time is possible. Washout of stored PCBs during pregnancy and lactation has been documented in many studies. It would be of interest to explore this pathway for relevance in the population living near the Housatonic that might give rise to this secondary pathway.

RESPONSE 148:

Please refer to the response to General Issue 3.A.

Lee R. Shull

- In general, the most important exposure pathways have been identified and evaluated.

- The breast milk and transplacental pathways should be considered for inclusion in the residential population analysis. As was expressed at the public meeting November 18-20, potential health impacts associated with neonatal exposure to PCBs and dioxins/furans is among the greatest concerns of residents and medical personnel in the area. Risk assessment methods are available for such an analysis; EPA's *"Methodology for Assessing Health Risks Associated with Multiple Exposure Pathways to Combustor Emissions" (2000?).*

  RESPONSE 149:

  With respect to breast milk exposure, please refer to the response to General Issue 3.A. As discussed in the HHRA, EPA does not believe there is a basis with which to quantify risks from transplacental exposure. The HHRA summarized recent studies investigating effects associated with transplacental exposure in Volume I, Section 2.3.4. The discussion of the uncertainty associated with transplacental exposure will be expanded in the revised HHRA.

Stephen T. Washburn

Overall, the most important exposure pathways have been identified and evaluated. As discussed above in the context of the Phase 1 screening for direct contact, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis.

RESPONSE 150:

Please refer to the response to General Issue 3.A.

In addition, the discussion of site-specific data and used to eliminate inhalation as an exposure pathway of primary concern is very limited (p. 4-6, Volume IIIA), and I recommend that it be expanded to address expressed public concerns.

RESPONSE 151:

An expanded discussion of the air exposure pathway will be included in the revised HHRA.

3. Were the approaches and methods used to calculate and apply exposure point concentrations (EPCs) for the direct-contact exposure assessment appropriate under the evaluation criteria?

COMMENTS

Holly Hattemer-Frey

EPCs were defined as the 95% UCL or maximum value, whichever was lower, which is consistent with EPA guidance and appropriate.

A spatial weighting approach was used to calculate EPCs for Reaches 5 & 6. While I understand the purpose of the spatial weighting approach (to estimate concentrations over a large area where collecting samples from the entire area would be prohibitive), and I don't have a problem with the approach used, the discussion of the methodology used (Section 4.4.4.1, page 4-7 and Attachment 3 of the HHRA) is difficult to follow. Development of EPCs is a critical step in the RA process, since many subsequent calculations (for Reaches 5 & 6 only) rely on the accuracy and reliability of the spatial weighting results. The approach and assumptions used to generate EPC for Reaches 5 & 6 need to be much more transparent and verifiable.

RESPONSE 152:

Please refer to the response to General Issue 4.B.

Detailed information on the extent that spatial weighting affects EPCs (i.e., would EPCs probably be higher or lower without spatial weighting) should be discussed as well. For example, if spatial weighting hadn't been used, would the authors expect soil concentrations to be higher by a factor of 2 or 10?

RESPONSE 153:

Please refer to the response to General Issue 4.B.

I recommend the information provided to Panel members by EPA in response to a reviewer's questions be added to the text along with the example calculations provided.

RESPONSE 154:

Please refer to the response to General Issue 4.B.

The Panel was provided with the measured and interpolated data for five EAs selected by chance, so that Panel members could better evaluate the influence of IDW on EPCs. Dr. Ryan made an interesting observation that the maximum interpolated value exceeds the maximum measured value for EA32, which indicates that some of the interpolated data used to calculate the EPC for EA32 were taken from areas outside of EA32. While this approach seems odds, I'm not sure that it is wrong or significant. I had assumed that only values from within an EA would be used to calculate an EPC for that EA. If the number of interpolated values taken from outside an

EA is small relative to the total number of interpolated values used to calculate the EPC for that EA, the effect on risk estimates would be small. I suggest EPA elaborate on why interpolated values were taken from outside an EA to clarify this issue.

RESPONSE 155:

Please refer to the response to General Issue 4.B.

I was surprised by the extremely low percentage of measured to extrapolated samples. For each of the five EAs listed in the memo from EPA, measured data comprised <1% to 1% of the total values (measured and interpolated) used to calculate the EPC for that parcel. The RA just doesn't give any indication of this fact and should. I recommend that EPA note this in the report and comment on the statistical reliability of that ratio.

RESPONSE 156:

Please refer to the response to General Issue 4.B.

For example, when spatial weighting approaches are applied to other, large sites, is the ratio of measured to interpolated data similar, and is the IDW approach considered statistically reliable when the number of interpolated values is considerably larger than the number of measured values?

RESPONSE 157:

Please refer to the response to General Issue 4.B.

Finally, EPA calculated 95% UCLs for the measured data only and for interpolated data (for the five EAs mentioned above). For EA 40, the maximum measured value was used as the EPC, so a 95% UCL was not calculated. For the other four EAs, the 95% UCLs for measured and interpolated data varied by less than a factor of two. This suggests that the effect of spatial weighting on the calculation of 95% UCLs is probably small (within a factor of two) for most EAs. The EPC could be over- or underestimated, as EPA noted, depending on the sampling strategy used for different EAs. Clarification of this topic in the RA would be useful.

RESPONSE 158:

Please refer to the response to General Issue 4.B.

Since PCDD/PCDF and PCB congeners were only directly measured in 10% of site samples, regression analyses were used to estimate congener concentrations in the remaining samples. While I don't have a problem with the application of regression analyses per se, I found the discussion difficult to follow. Hence, it was difficult for me to evaluate the accuracy of the methods used. One example is the fact that the selection of regression models was based on the p value and sample size (when more than one regression equation had a p-value < 0.01). Why r^2 values were not considered is unclear. If a particular equation had a highly significant p-value but a relatively low r^2 value, it would have been selected under the methods used in the RA, but that equation may not be adequately predictive. A discussion of corresponding r^2 values and better justification for the equation selection process needs to be included.

RESPONSE 159:

Please refer to the response to General Issue 4.F.

Another potential problem associated with the use of regression equations is that the congener profiles were based on data collected in Reaches 5 & 6 only but applied to all downstream areas.

In other words, the current approach does not account for the fact that congener profiles downstream could be different than those observed in Reaches 5 & 6. There needs to be some discussion on how representative the data from Reaches 5 & 6 are to the rest of the site and what impact the assumption of no change in the congener profiles downstream may have on risk estimates. In other words, what is the likelihood that congener profiles could be substantially different downstream than those observed in Reaches 5 & 6? If congener profiles might be different, would the assumption of no change in congener profiles likely to over- or underestimate EPCs?

RESPONSE 160:

Because of this and other uncertainties, the risk from TEQ for Direct Contact will be addressed in the uncertainty section. Please refer to the response to General Issue 5.A.

In the calculation of EPCs for recreational activities, the authors apply a use-weighting factor to account for accessibility (which lowered EPCs), since the spatial weighting technique cannot account for accessibility. While this approach seems reasonable, the application of use weighting factors is very arbitrary and does not seem to accomplish its goal. I recommend that accessibility be accounted for by adjusting exposure frequencies or FI.

RESPONSE 161:

EPA understands and appreciates this comment, but does not believe that this approach is practicable, as the exposure frequencies were established for a scenario, and the accessibility of areas at the parcel-specific level varies greatly. The use-weighting methodology will be reevaluated and discussed in greater detail in the revised HHRA, as described in the response to General Issue 7.B.

In addition to the application of a use weighting factor, exposure frequency was also adjusted to represent the amount of time an individual spends in a given area performing a given activity. On the surface, this could appear to be two separate methods for accounting for the amount of time an individual would spend in a given area performing a given activity. Regardless of whether the authors decide to apply a use weighting factor or to adjust EF or FI, the method used to calculate EPCs for recreational exposures needs to be more fully explained to ensure that no "double counting" occurred (i.e., that EPCs were not lowered twice for the same reason).

RESPONSE 162:

Please refer to the responses to General Issues 7.B and 7.E.

Section 5.5: It would be useful to have a summary table of the EPCs used for each EA evaluated. I know these data are presented in Tables 5-2 through Tables 5-398, in Section 5 figures (in Appendix B), and in the text on a EA by EA basis, but it would be useful to have a table listing all of the EPCs for soil and sediment by EA, so the reader can easily see the variations in soil and sediment concentrations with location. Thus, I recommend adding the soil and sediment EPCs used to calculate HIs and risks to Table 5-1.

RESPONSE 163:

EPA agrees with the Reviewer's comment, and will include the exposure point concentrations (EPCs) in summary tables.

F. Owen Hoffman

The statistical procedures and spatial weighting methods used to determine the 95% UCL for the exposure point concentration (EPC) understate the overall uncertainty associated with determination of the true mean concentration for an exposure area. Uncertainty is due to limited and non-representative sampling and the use of spatial and accessibility weighting to interpolate estimated concentrations for areas without direct measurements. Uncertainty associated with interpolation is presently ignored in the HHRA determination of the EPC.

RESPONSE 164:

EPA guidance emphasizes methods that account for the statistical uncertainty from limited sampling. There are, of course, other sources of uncertainty such as laboratory measurement error and model uncertainty associated with the choice of the interpolation method. Please refer to the response to General Issue 4.B.

The present procedures for estimating an EPC for a given exposure area should be further evaluated to determine the extent to which the true mean concentration is under- or overestimated by the EPC and the likelihood that the estimated 95% UCL properly accounts for uncertainty in the estimate of the mean, without being an implausible over-estimate of the true mean.

RESPONSE 165:

It is not clear what evaluations beyond the simulations of coverage rates described in Attachment 4, Calculation of Exposure Point Concentrations (see especially pages 11-14) the Reviewer is requesting. EPA believes these simulations clearly convey the general properties of the computed EPCs for an array of distributions such as are encountered in the HHRA data sets. However, additional distribution shapes may be included in the revised HHRA if any are identified that would be particularly relevant to HHRA data sets.

Interpolation is used to project PCB concentrations as point estimates for a very large number of 3 sq. meter sub-areas that make up the overall exposure area. However, the uncertainty associated with spatial interpolation is not addressed. The projected PCB concentration for each sub-area is given as single value, not a range or a probability distribution of possibly true values.

RESPONSE 166:

The uncertainty associated with spatial interpolation would be model uncertainty. Please see response to the General Issue 4.B for a discussion of the plan to explore this uncertainty in the revised HHRA.

The authors of the HHRA discuss the fact that the original samples of PCB concentrations in sediment and soil are not obtained from a randomized design. They clearly recognize and express the concern that the sampled data must be representative of the true distribution of contamination within the exposure area before classical statistical procedures can be used reliably to test the underlying distributional shape of true values and to estimate the 95% UCL of the mean. Interpolation is employed to reduce the bias associated with a non-randomized sample design.

The procedure of inverse distance weighting is used to interpolate from the few locations where samples have been taken to the many sub-areas that are without a sample. The interpolated values are point estimates, without error. Thus, the 95% UCL for an exposure area EPC does not account for uncertainty due to interpolation. The use of statistical tests on interpolated point estimates to test for the shape of the underlying frequency distribution of true PCB concentrations is questionable, given the non-random nature of the original sample and uncertainty associated with spatial interpolation.

RESPONSE 167:

More detailed discussion of these uncertainties will be included in the revised HHRA. Please refer to the response to General Issue 4.B.

The uncertainty associated with spatial interpolation should be included in the analysis so that the 95% UCL will be inclusive of all identifiable sources of uncertainty, not just the frequency distribution of interpolated data and the degrees of freedom determined by the size of the original sample.

RESPONSE 168:

EPA agrees with the Reviewer's comment that the EPC computed from interpolated values does not account for uncertainty due to interpolation because the interpolated values are point estimates rather than distributions; however, as stated, the comment may be misleading. The EPC does incorporate the sampling uncertainty present in the original data, which is the primary concern of assessments conducted according to EPA guidance. The original data are point estimates too. The interpolation is a form of data transformation, much like a log transformation, of the original data. The uncertainty associated with such a transformation is not usually the subject of scrutiny in an uncertainty analysis. What the Reviewer is suggesting is that, because there are different possible interpolation schemes that could have been used, one might be interested in estimating the uncertainty that is associated with selecting the inverse distance weighting (IDW) scheme over the others. Please see the response to General Issue 4.B for a discussion of the plan to study this issue by conducting example calculations using a variety of other interpolation methods.

When re-evaluating the procedure used to obtain the EPC, the following questions should be addressed:

(a) What difference in the estimate of the 95% UCL would occur if Kriging were used for interpolation instead of inverse distance weighting?

RESPONSE 169:

Please refer to the response to General Issue 4.B.

(b) What difference in the estimate of the 95% UCL would occur if Kriging or inverse distance weighting were to be based on the logarithms of the original data as opposed to the untransformed values?

RESPONSE 170:

Please refer to the response to General Issue 4.B.

(c) What differences in results would occur if the 95% UCL were to be based on a full probabilistic uncertainty analysis composed of numerous alternative realizations of the true but unknown spatial distribution of PCB concentrations within the entire exposure area?

RESPONSE 171:

As explained in the response to General Issue 4.C, EPA guidance requires the use of the EPC as a point estimate. In addition, it is not a straightforward statistical problem to produce a distributional estimate for the interindividual distribution of long-term averages because it would require unavailable data or a model with many assumptions. In practice, because sample sizes are limited, the 95% UCL is expected to usually be larger than the bulk of values in such a distribution, and this affords risk assessors an appropriate estimate for the concentration term.

In the procedure proposed in (c) above, each alternative realization of the spatial distribution of concentrations would have a unique arithmetic mean (assuming randomized access to the exposure area by a potentially exposed person). Each realized mean concentration would be a representation of the true mean for the exposure area. The variation in mean concentrations would represent all quantifiable sources of uncertainty, including uncertainty due to limited sample size, imperfect sample representativeness, approximations associated with the mathematical models and weighting coefficients used for interpolation, as well as the chance that some subareas may have true concentrations that extend beyond the observed range defined by the minimum and maximum concentrations observed.

RESPONSE 172:

Although the suggested approach would be an informative exercise, EPA believes that such an approach would require the specification of uncertainties beyond those that are really quantifiable in the sense that they can be justified with empirical evidence. Moreover, EPA expects the contribution of uncertainties

> from the weighting coefficients and from the choice of the mathematical model (interpolation scheme) to the overall uncertainty of the results will be fairly small compared to the uncertainty due to sample size, which is the focus of concern in the HHRA assessment, as dictated by EPA guidance. See the response to General Issue 4.B for a discussion of the plans to assess the possible magnitude of these uncertainties.

The examples given on pages 22 to 28 of Attachment 4 to Volume 1 clearly show a wide variation in the 95% UCL when a restricted sample of size 30 is repeatedly taken at random from a data set of 1024 interpolated values. The authors of the HHRA seem to imply that the reliability of the approach used to obtain the 95% UCL from the mean and variance obtained from the entire 1024 interpolated subareas (with the degrees of freedom restricted to n=30) has been established through demonstration that agreement occurs with the average 95% UCL obtained from several thousand randomly repeated estimates of the 95% UCL (each derived from a simple random sample restricted to size n=30). I do not concur. Anticipated agreement between these two calculational approaches should be obvious, but such agreement does not establish the reliability of the result.

RESPONSE 173:

> The simulations mentioned by the Reviewer illustrating the agreement between the two calculational approaches were presented in the HHRA for the benefit of readers who might not consider the agreement to be obvious or mathematically necessary. These results show that the answers are the same whether analysts use the calculation shortcut or compute the UCL using the more elaborate resampling approach.
>
> As to the reliability of the UCL, it is impossible to ensure the computed UCL is larger than the true mean in every case, unless the method overestimates the true mean in every case. Please refer to the Volume I, Attachment 4, Calculation of Exposure Point Concentrations, especially Figures 5, 6, and 7.

The variation in the repeated estimates of the 95% UCL provides some information on the overall reliability of the EPC, but it still does not account for interpolation uncertainty. Additional work needs to be undertaken to address the extent to which the present scheme used for interpolation from a non-random and somewhat biased sampling design may result in a misrepresentation of the true heterogeneity of subarea concentrations within an exposure area and the extent to which there is an overall bias in the estimate of the exposure area mean and its 95% UCL.

RESPONSE 174:

> The spatial weighting is intended to transform a sample distribution based upon data into a distribution that is more representative of the actual distribution of the concentration of PCBs across an exposure area. See the response to General Issue 4.B for a discussion of the magnitude of model uncertainty that comes from choosing one spatial interpolation scheme from among the many possible such schemes. See also the response to General Issue 4.B for a discussion of how the question about non-random sampling affects the calculation of the 95% UCL will be evaluated in the revised HHRA.

The role of accessibility weighting in defining the EPC for each exposure scenario is also not entirely transparent. Intuitively, for areas that are "difficult to access" or "merely wadable," an accessibility weight of 0.5 seems high and biased towards overestimation of true exposure.

RESPONSE 175:

Please refer to the response to General Issue 7.B.

For Reach 7, the direct use of the non-random sample without interpolation to determine the 95% UCL on the mean for the EPC is most likely biased towards overestimation of the actual exposure received by an RME or CTE.

RESPONSE 176:

As shown in the response to General Issue 4.B, the EPC calculated from non-interpolated data can be either higher or lower than the EPC calculated with interpolated data.

The use of classical statistical tests to determine the underlying shape of the frequency distribution of contamination in soil and sediment based on samples that were not taken from a randomized design is questionable at best.

RESPONSE 177:

For soil in Reaches 5 and 6, the statistical tests were applied to data after they were spatially weighted. The transformed distribution is expected to be more representative of the actual distribution of concentrations across the exposure area than are the original measurements. In this case, 'representative' implies having a mean and shape that are similar enough to the underlying distribution that it will generate a UCL that would be appropriate if the underlying distribution had itself been accessible to analysts. See the response to General Issue 4.B for a discussion of EPA's plan to study the effect of non-randomness of sampling on the calculation of the UCL.

I recommend that EPA convene a separate panel of experts in uncertainty analysis of spatially distributed data to more thoroughly evaluate the adequacy of the procedures used for the estimation of the EPC before the present results are accepted for use in this HHRA.

RESPONSE 178:

EPA believes that with the additional evaluation of uncertainty in the revised HHRA and the comparison of alternative methods to calculate EPCs, a significant improvement in the understanding of the uncertainty associated with the direct contact risk assessment will be realized, and that a separate panel is not necessary. Please refer to the response to General Issue 4.B.

John C. Kissel

The methods used to calculate and apply soil EPCs are not entirely transparent although, to the extent that they can be understood, they do seem consistent with EPA guidance. The use of weighting factors related to exposure point accessibility seems arbitrary. The assumption that exposure is random within exposure sub-areas is also questionable. An individual could habitually contact soils that are more or less contaminated than the mean as a result of selective visitation within a parcel.

RESPONSE 179:

The use-weighting factors will be reevaluated and better described in the revised HHRA. Please refer to the responses to General Issues 4.A, 7.A, 7.B, and 7.C.

EPA guidance on this topic is fairly prescriptive, requiring sequential tests for normality and lognormality and then providing further options. Over a large site broken into many parcels, such as is the case here, the overall result can be questionable even though each individual decision is defensible.

RESPONSE 180:

Please refer to the response to General Issue 4.A.

Uncritical acceptance of the results of formal parametric statistical tests can easily lead to use of different methods for estimation of EPCs in adjacent parcels. It is reasonable to ask whether contaminant distributions really alternate from normal to lognormal to neither over short distances or whether that apparent result is simply an artifact of (non-random) sampling.

RESPONSE 181:

Although the Reviewer's point is well taken, the data distribution and method used to calculate EPCs were typically consistent on adjacent parcels. As summarized in the HHRA, Appendix B, Table 4-2, with one exception, the distributions in the individual EAs (and sub EAs) were determined to be inconsistent either with normal or lognormal distribution in Reaches 5 and 6. The EPCs were calculated using the Hall's bootstrap methodology for the majority of these EAs. The maximum detected concentration was used in the remaining EAs. In Reaches 7 and 8, the EPCs were based on the maximum detected concentration for 23 of 30 of the EAs.

It is also reasonable to ask whether a normal distribution is ever a good choice for environmental measurements given the possibility of negative (impossible) values. Use of a consistent methodology (e.g., assumption always and everywhere of lognormality) would produce a result easier to understand, more defensible (in my opinion), and less time consuming to obtain.

RESPONSE 182:

EPA does not agree that the underlying distribution of the data should be discarded for the sake of applying a consistent methodology if there is information regarding the distribution to suggest otherwise. Please refer to the response to General Issue 4.A.

Roger O. McClellan

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

RESPONSE 183:

EPA does not believe that the 95% UCL and the EPCs were overestimated. As summarized in the HHRA, Appendix B, Table 4-2, with one exception, the distributions in the individual EAs (and sub EAs) were determined to be inconsistent with normal or lognormal distribution in Reaches 5 and 6. The EPCs were calculated using the Hall's bootstrap methodology in the large majority of these EAs. The maximum detected concentration was used in the remaining EAs. In Reaches 7 and 8, the EPCs were based on the maximum concentration detected for 23 of 30 of the EAs, as shown in Table 4-3. Two EPCs were calculated based on Land's H-statistic, five using the t-statistic (normal distribution) and the remaining EAs using the Hall's bootstrap methodology.

One approach to remedying this problem would be to use Hall's Bootstrap procedure. This procedure uses a transformation to correct for bias and skewness of the data points.

RESPONSE 184:

Please refer to the response to General Issue 4.A.

Another alternative would be to treat several smaller parcels, with limited number of data points, as a composite EA. This would require a judgment to be made that the tax parcels were similar in geography and use potential.

RESPONSE 185:

EPA did use this approach in a number of cases, especially in Reaches 7 and 8, where data were more limited.

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

RESPONSE 186:

Floodplain EAs evaluated in Phase 2 range in area from less than an acre to over 100 acres, and more than half of the EAs encompass at least 5 acres. Therefore, EPA does not agree that exposure areas are too small nor that they should be expanded to include areas outside the 1-ppm isopleth. Conversely, because many of the exposure areas are large, EPA has noted in the HHRA that if the area over which random exposure occurs is smaller than the entire EA, risk may be underestimated if the exposure point concentration is greater for the smaller area than that calculated for the entire EA. This uncertainty will be further evaluated in the revised HHRA, as described in the response to General Issue 7.C.

Both of the difficulties discussed above likely result in risks being overstated to some degree.

RESPONSE 187:

Please refer to the previous two responses.

P. Barry Ryan

The principal problems I noted with the calculation of the EPCs from the use of spatial weighing and the generation of EPCs based upon the distributional characteristics of the observed data. Some background is needed to kick off the discussion.

Throughout the various reaches of the river, PCB concentrations were determined based on a sampling protocol that, while not completely transparent, was certainly not based on developing input for modeling. After sampling was completed, various regions, called Exposure Areas or EAs, were identified and characterized according to their likely use- recreational, residential, etc. Scenarios were then implemented as described above and in the document that resulted in use patterns for the individual EAs. It was then assumed that the EA would be visited randomly requiring an estimate of the mean exposure experienced on that EA. A 95% UCL for the mean was calculated using distributional assumptions where appropriate or bootstrapping methods where no distribution could be identified.

Problems occur because of a mismatch between the sampling done and the needs of the modeling used to develop the 95% UCL for the mean. Measurements were not made randomly. Often a purported hot spot was sampled or a transect made across an EA was done, etc. Determination of the mean concentration of an EA based on measured results would likely bias the expected concentrations, especially in the case of hot spot evaluation. Spatial weighting analysis was used to overcome this mismatch. Values were interpolated onto a 3m x 3m grid in each EA. We were told that the measured points for each EA were used and an inverse distance weighing was performed in which the nearest two points were used to determine the values on each grid point.

The interpolated data were then used to calculate the mean and standard deviation for the whole EA. These values were used to calculate the UCL for the mean, but the original number of measured data points was used in the standard formula where N, the number of points, was needed. The equation to produce the UCL is:

$$\overline{X}_{UCL} = \overline{X}_{\text{interpolated}} + t\frac{s_{\text{interpolated}}}{\sqrt{N_{measured}}}$$

where the subscript interpolated implies that the statistic is obtained from the interpolated data while the subscript measured denotes the measured data statistic. I have used the t statistic for the multiplier here, but in actuality the value or form would be determined by the distributional characteristics of the measured values in the EA. This is sort of an apples and oranges kind of analysis but one that, I believe gives a better assessment of the true mean and standard deviation and, perhaps, a better picture of the UCL for the mean. We were given an example in a presentation, but requested several more to compare the results.

Examination of these data revealed several problems. First, a 3m x 3m grid requires interpolation of about 450 points per acre. EAs ranged in size from under an acre to at least 50 acres, the latter requiring in excess of 20,000 interpolated points. In many cases, the number of measured points represented only a few percent of the number of points interpolated calling the accuracy of the points into question and increasing the uncertainty in these estimates substantially.

Further, in examining the data sent to us, I noted cases from which the extrapolated points exceeded the maximum value actually observed within the EA, contrary to what we were told and inconsistent with the assertion that only points contained within the EA were used in developing the grid for a given EA.

I am not certain about the effect of these observations on the EPCs calculated. I believe that the modeling is a good-faith effort to improve upon the results of the measurements in determining what the likely exposure is. Indeed, there are cases in which the EPC for the measured data is lower than that calculated through the spatial weighting procedure and cases for which it is higher. The description given in the public forum for the HHRA is, I believe, inconsistent with some of the results given to us at our request. The interpolation may have been done differently than described, e.g., all data were interpolated using the closest points (some of which may have been outside a specific EA) and then the EAs drawn around them.

Alternatively, errors may have been made in the calculations of the EPCs that were presented to us. We cannot know because the details have not been included.

At the very least, the presentation of this interpolation scheme - a scheme that is intrinsic to the overall risk process- must be more clearly articulated.

RESPONSE 188:

Please refer to the response to General Issue 4.B.

Further, a detailed calculation for a specific EA should be given and sufficient detail in the other EAs, including means and standard deviations for both measured and interpolated data. It is difficult to accept at face value the EPCs determined for each EA given inconsistencies found in the test cases and the lack of a scripted protocol for how they were developed.

RESPONSE 189:

Please refer to the response to General Issue 4.B.

There is an additional problem associated with “aging” of PCB mixtures. I am not certain of the likely magnitude of the effect, but the more water soluble, i.e., lower K_{ow}, PCB congeners are likely to move more quickly than the less soluble congeners. This may result in different mixtures as one proceeds further down the Rest of the River. What starts out as Arochlor 1260 on Reach 5 may look more like Arochlor 1254 at Wood’ Pond. Assumption of constant ratios of various congeners, and the concomitant TEQ associated with this may change. I would like to see a discussion of this and, if it is deemed so, dismissal if no problem exists.

RESPONSE 190:

Please refer to the response to General Issue 4.F.

Lee R. Shull

- In general and except for the following comments, EPC calculation methods are appropriate. Use of the 95% UCL or maximum whichever is lower is consistent with guidance and standard risk assessment practice.

- Page 4-15, lines 5-9: Please expand the explanation for how these “test runs” were done, or refer to a relevant section of the report(s) where the reader can find the information.

RESPONSE 191:

Please refer to the response to General Issue 4.B.

- Page 4-18, lines 24-page 4-19, line 6. Whereas all measured and interpolated data were used in the 95 UCL calculation, the value of “n” was restricted to measured data only. Please provide additional rationale or relevant citation(s) justifying/substantiating this approach to improve transparency.

RESPONSE 192:

The rationale was provided in Volume 1, Attachment 4, Calculation of Exposure Point Concentrations, p.20 ff. A reference to this rationale will be more clearly provided in the revised HHRA.

- Page 4-19, line 7: Suggest providing a brief technical description of ProUCL in an attachment. The purpose is to inform readers who may be unfamiliar with this program confidence that it is a “black box”, but that it is appropriate for performing statistical analyses. If there is EPA precedent for its use, this should be stated.

RESPONSE 193:

EPA will provide a technical description of ProUCL in the revised HHRA.

- Page 4-21, lines 9-13. Suggest expanding the discussion as to why the approach for deriving EPCs in Reaches 5 and 6 was not applied in Reach 7. It is not clear whether by not applying IDW to fill data gaps results in EPCs with greater uncertainty, meaning risk estimates will have greater uncertainty.

RESPONSE 194:

The IDW spatial weighting approach was not applied to floodplain areas downstream of the Reaches 5 and 6 (PSA) for two reasons. First and most important, data collection was not as intensive downstream of the PSA due to the markedly lower concentrations in the downstream floodplain of PCBs from the GE Pittsfield facility. In addition, as indicated in the text, detailed habitat mapping was performed only for the PSA; therefore, it was not possible to apply the same approach used in the PSA to downstream areas and impose the habitat integration of contaminant distribution. Therefore, EPA does not believe that the data set for the other reaches satisfied the technical considerations for using a spatial weighting approach.

- Page 4-22, lines14-16: Should again briefly describe the 8 areas, or, ideally reference a figure that shows the 8 areas.

RESPONSE 195:

EPA agrees with the Reviewer's comment, and will include a reference to the index figure in the revised HHRA.

- Note comments on Attachments 1, 2, 3 and 4 below, all of which relate to the derivation of EPC estimates in this HHRA.

Stephen T. Washburn

EPA should be recognized for using well-recognized and applicable geostatistical spatial weighting approaches for calculating EPCs for the Phase 2 Direct Contact Exposure Evaluation. These approaches allow for effective use of the existing soil datasets. However, the following elements of the development of EPCs should be reconsidered:

- EPA should emphasize that the data used as input to the Phase 2 spatial weighting approach was not randomly collected, but instead largely based on sampling biased toward areas that are believed to exhibit the highest PCB levels in soil. It appears that the spatial weighting approach will not assign concentrations exceeding the maximum detected concentration to any grid location. This limitation could be significant and lead to a possible underestimate of exposure point concentrations if EPA believes that there are soil areas in any EA where PCB concentrations might substantially exceed the maximum concentration detected in that EA. However, the biased sampling approach used by EPA would tend to mitigate such concerns.

RESPONSE 196:

Please refer to the response to General Issue 4.B.

- Certain larger areas may warrant consideration of additional analysis to ensure that small subareas with higher levels of contamination are properly assessed. As indicated in Volume IIIA, p. 4-13, in Phase 2 "exposure was assumed to occur randomly across an EA or subarea. However, a number of these EAs and subareas are large, and, if an individual's actual exposure occurs primarily to areas of higher contamination, risks may be underestimated". EPA should consider maximum concentrations relative to the 95% UCL concentrations to determine if conclusions regarding an EA would change if relatively small but still substantial (i.e., at least an acre in size) subareas were evaluated separately.

RESPONSE 197:

Please refer to the response to General Issue 7.C.

- The data used in the regression equation to relate PCBteq concentrations in soil to PCBtotal concentrations in soil appear to be adequate and relatively consistent. However, the HHRA should provide an explanation based on the environmental behavior of the various PCB congeners for the finding that the PCBteq content in soil is relatively higher in soils with lower PCBtotal concentrations in soil. For example, according to Table 4-16 in Volume I, a 100- fold increase in the PCBtotal concentration in soil (1 ppm to 100 ppm) results in less than a 20-fold increase in the PCBteq concentration.

RESPONSE 198:

Please refer to the response to General Issue 4.F.

4. Were the values used to represent the exposure and absorption parameters used in the direct-contact exposure assessment appropriate under the evaluation criteria, specifically:

- ***Exposure duration for each scenario;***
- ***Exposure frequency and area use factors for each scenario and exposure area;***
- ***Soil ingestion rates;***
- ***Exposure assumptions affecting dermal contact (e.g., soil adherence rates, skin surface areas assumed to contact soil or sediment); and***
- ***Oral and dermal absorption factors.***

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

COMMENTS

Holly Hattemer-Frey

The assumption that all exposures occur randomly across a tax parcel, EA, or subarea is troubling. I do agree that this approach is a logical starting point and is appropriate for areas where receptors are truly likely to traverse most or all of an exposure area (e.g., smaller areas less than five acres in size) or for areas where the EPCs do not differ significantly. However, exposures could be underestimated for areas where it is possible that an individual may restrict his/her activities to a smaller area where concentrations are statistic ally higher than the EPC for the entire EA.

RESPONSE 199:

EPA guidance specifies that random exposure be assumed. Please refer to the responses to General Issues 7.A and 7.C.

My attached Table 1 shows the size of areas evaluated as well as the maximum and 95% UCL concentrations for all tax parcels whose designated land use is recreational and whose size is more than five acres. Table 1 shows that some of the tax parcels are quite large and that within many of the parcels, PCB concentrations are variable (as exemplified by the large difference between the maximum and 95% UCL concentrations). For these areas, the assumption of random exposure across an area may not be appropriate. For these areas, exposures to smaller subareas where PCBs have accumulated to a greater extent should be quantified (assuming that these areas are accessible for recreational use now or in the future).

RESPONSE 200:

Please refer to the response to General Issue 7.C.

Section 4.5.3.1.2, page 4-33: Exposure duration values were based on how long an individual lived at one address versus lived in the Housatonic River Area. Using the former could result in an underestimation of risks to an individual who lived at different locations but within the Housatonic River Area. RME and CTE exposures could be underestimated by a factor of two. I recommend basing ED values on duration of residency versus length lived at one residence, although this change will have minor impact on risk estimates.

RESPONSE 201:

This comment refers to residential scenarios. EPA believes that the use of an exposure duration based on the length of time living at a single residence is adequately conservative. As noted in the HHRA, current residences that have actual or potential lawn areas contaminated with PCBs have been transferred to GE for further evaluation. This exposure scenario is based only on future development. EPA believes it unlikely that a resident will live at two or more residences in newly developed areas in the floodplain.

Section 4.5.3.3, page 4-38. I disagree with the assumption that ATV and mountain/dirt bike users are limited to the older child receptor, since adults frequently participate in this type of activity. I do agree, however, the risks to the older child would be higher than those for the adult, so calculation of the adult receptor is not required. I recommend rewriting the text to clarify these issues.

RESPONSE 202:

EPA assumed that the frequency of ATV/dirt and mountain bike riding would be less for an adult than for an older child while other exposure parameters, with the exception of body weight, would be similar for both child and adult. Therefore, the adult exposure would be less than that of the child and was not quantitatively evaluated. This approach will be reconsidered in the revised HHRA based on Reviewers' comments.

Page 4-42, lines 7-11: I believe the older child is just as likely to go canoeing or boating at the same frequency as an adult. I suggest adjusting exposure frequency values accordingly.

RESPONSE 203:

Please refer to the response to General Issue 7E.

Section 4.5.3.10.3, page 4-53, lines 21-24. Soil ingestion rates of 100 mg/day for the RME scenario and 50 mg/day for CTE scenario were used for the groundskeeper (individuals who mow lawns). These values are the same as those used for adult residential receptors. I believe that the soil ingestion rates for the groundskeeper should be consistent with those used for other contact intensive activities (e.g., farming and riding ATVs/mountain bikes), since mowing can stir up a large amount of dust.

RESPONSE 204:

As described in the HHRA, the groundskeeper's activities are assumed to include lawn mowing and some gardening. These activities are similar to that of the "outdoor worker" considered in the Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (EPA, 2001a). The recommended RME and CTE soil ingestion rates in this guidance are 100 mg/day and 50 mg/day, respectively.

Section 4.5.3.9.1, page 4-51, lines 15-19: I disagree with the EF used for agricultural receptors. It is likely that farmers would work in their fields many more days than just at planting and harvesting time. EF certainly needs to be modified to a much higher value (five days a week?) I agree with the use of an oral absorption factor of 100% for PCBs.

RESPONSE 205:

Please refer to the response to General Issue 7E.

The specific EPA document that recommends a dermal absorption rate of 14% for PCBs need to be cited (along with the Wester et al., 1993 study).

RESPONSE 206:

EPA will provide this clarification in the revised HHRA.

The text notes that the EF of 60 days/year was based on professional judgment that an individual would fish two times a week over a seven-month period. Survey data presented in Maine, Connelly, and ChemRisk studies seem to suggest an EF of 30-40 days/year. I recommend an EF of 30-40 days per year be used, since it is based on empirical data versus professional judgment.

RESPONSE 207:

Please refer to the response to General Issue 7.E.

There was much discussion on soil ingestion rates during Panel deliberations. The authors did use EPA standard default values, which is appropriate in an assessment of this type. If the authors review newer, peer reviewed studies and choose to lower the rate that would be acceptable as well. Since I have not reviewed the Staneck and Calabrese (1997, 2000) articles, I cannot comment on their accuracy.

RESPONSE 208:

Please refer to the response to General Issue 7.E.

It is appropriate to assume that 100% of soil ingested by recreational receptors comes from the floodplain (i.e., FI=1) if EF and ED accurately reflect the amount of time spent in the floodplain (versus outside of the floodplain).

Section 4.5.3.1, page 4-32, lines 11-12: As written, current language makes it sounds as if people over the age of 45 weren't considered in the RA. Suggest changing the text to state an exposure duration of 45 years was used.

RESPONSE 209:

EPA will provide clarification in the revised HHRA.

F. Owen Hoffman

- ***Exposure duration for each scenario.***

My concern here is with respect to the assumptions for children for estimation of the noncancer HI. It is evident that exposure durations and averaging times less than 1 to 6 years could lead to a higher ratio of intake to body weight than would be produced with the current set of exposure assumptions. This is especially true for children ages 0.5 to 2 years of age who are toddlers and likely to play near the soil surface during the summer months.

RESPONSE 210:

Please refer to the response to General Issue 3.B.

An additional analysis of the appropriateness of the baseline risk values used in Phase II would require a full quantitative uncertainty analysis to reveal the effect of compounded conservative assumptions on the overall result.

RESPONSE 211:

Please refer to the response to General Issue 7.F.

- ***Exposure frequency and area use factors for each scenario and exposure area.***

I will defer to my other colleagues on this issue. However, I do feel that quantitative uncertainty analysis would be useful as Phase II is a step beyond conservative screening, and should produce more realistic estimates of exposure and risk.

RESPONSE 212:

Please refer to the response to General Issue 7.F.

- ***Soil ingestion rates.***

Again it appears as if the baseline exposure assumptions are standard, but a quantitative uncertainty analysis will reveal the extent to which compounded conservative assumptions lead to extreme conclusions. A quantitative uncertainty analysis will also reveal which assumptions and inputs will dominate the overall expression of uncertainty in exposure.

RESPONSE 213:

Please refer to the response to General Issue 7.F.

Rather than treat inter- individual variability in the population as a stochastic process, I recommend approaching the RME exposure and the CTE as separate assessment endpoints or scenarios, each requiring their own unique set of assumptions.

RESPONSE 214:

Please refer to the response to General Issue 10.A.

Some panel members have mentioned recent studies by Calabrese and others to update assumptions used in the HHRA. I would also recommend a paper published in Health Physics Journal in 1998 by Dr. Steve Simon of the National Cancer Institute on the subject of soil ingestion rates (Simon S. Soil ingestion by humans: A review of history, data, and etiology with application to risk assessment of radioactively contaminated soils. Health Physics 74:6, 647-672. 1998).

RESPONSE 215:

Please refer to the response to General Issue 7.E.

- ***Exposure assumptions affecting dermal contact (e.g., soil adherence rates, skin surface areas assumed to contact soil or sediment).***

I defer to my other colleagues on this issue.

- ***Oral and dermal absorption factors.***

I defer to my other colleagues on this issue.

John C. Kissel

Generally exposure frequencies and durations appear reasonable or conservative. The selected exposure frequency for direct contact by farmers (10 days per year) is implausibly low.

RESPONSE 216:

Please refer to the response to General Issue 7.E.

EPA uses residential soil ingestion rates of 200 mg/day for children and 100 mg/day for adults. GE argues these rates are too high. Given that EPA's standard assessment practice does not consider the possibility of a geophagic child (and is therefore unlikely to be protective of such an individual) further reduction in soil ingestion rate estimates should only be considered on strong evidence. GE offers a letter by Calabrese in support of lowered values. Calabrese and his coworkers have a history of publishing multiple and inconsistent conclusions from the same datasets and of non transparent derivation of their estimates. Indeed, the existing EPA defaults are based on results published by Calabrese's group. As recently as 1995 (Environ Health Perspec 103:276-285) Stanek and Calabrese reported an estimate of 1200 mg/day for the 90th percentile annual average daily soil ingestion rate for children in the U.S. Child soil ingestion rate estimates attributable to Davis et al. (Arch Environ Health, 45(2):112-122, 1989) should be viewed as at least as valid as estimates generated by Calabrese et al. Estimated 95th percentiles from the Davis et al. data using silicon and aluminum as tracers exceed 200 mg/day. Reduction of the child RME value is therefore not justified.

RESPONSE 217:

Please refer to the response to General Issue 7.E.

The default dermal absorption value for PCBs (14%) used in the HHRA is based on results reported by Wester et al. (1993). The laboratory protocol employed by Wester et al. has multiple weaknesses including failure to record PCB-soil contact time prior to exposure, use of an inappropriate particle size, use of an animal model that precluded sacrifice and determination of mass balance, and use of a vertical animal posture that would permit soil sloughing. Nevertheless it is impossible to state with certainty whether the default value is conservative or non-conservative. Since the default has been in use for some time, it should, in the interest of consistency, continue to be used until such time as a more defensible factor is available. The methodology described in a recent paper by Mayes et al. (2003) repeats some of the mistakes of

Wester et al. and compounds them with additional design flaws. Most significantly, Mayes et al. applied soil in amounts that would represent many (probably 20 or more) layers. When results are expressed as percent absorbed, layering will lead to artificially low apparent absorption. Cautions regarding the effects of layering on dermal absorption can be found in EPA guidance dating back to 1992. Correction of the results reported by Mayes et al. leads to the conclusion that equivalent absorption from a monolayer would have been on the order of 80%. Hence downward adjustment of the EPA default on the basis of the Mayes et al. experiments is completely unwarranted.

RESPONSE 218:

The revised HHRA will continue to use a dermal absorption value for PCBs of 14% as documented in RAGS, Part E Guidance (EPA, 2001c).

Although it is taken directly from 1992 EPA guidance in which layering effects are discussed, the EPA default estimate of dermal bioavailability for dioxin (3%) cited in the ROR HHRA was not derived from experiments conducted at monolayer loading or corrected for layering. It is therefore inconsistent with EPA guidance even though it represents EPA guidance.

RESPONSE 219:

Both the 1992 EPA Dermal Exposure Assessment (EPA, 1992d) and the RAGS, Part E guidance discuss the monolayer concept but conclude that it is not sufficiently well understood to use as a basis for making adjustments to experimentally derived absorption values (see Section 3.2.2.4 of RAGS, Part E). The dermal absorption value of 3% for dioxin comes directly from empirical evidence. Therefore EPA does not agree that this dermal absorption value of 3% is inconsistent with Agency policy. The revised HHRA direct contact risk assessment will characterize risks associated with toxicity equivalence (TEQ) only in the uncertainty section, as discussed in the response to General Issue 5.A. The uncertainty regarding the dermal bioavailability of dioxin will be discussed in this context.

It should be noted that the dermal bioavailabilites cited above are 24 hour bioavailabilities. Use of a fixed dermal absorption factor expressed as a percent, although consistent with current EPA guidance, is poor practice as it ignores the time dependence of absorption (or effectively leads to the unlikely assumption that all dermal exposures last for 24 hours). Consideration of temporal dependence of dermal absorption is a refinement that has not yet been incorporated into EPA guidance related to soil contamination at Superfund sites.

Roger O. McClellan

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

RESPONSE 220:

Please refer to the response to General Issue 7E.

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

RESPONSE 221:

Please refer to the response to General Issue 7.E.

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

RESPONSE 222:

With respect to exposure duration, two other Reviewers commented that the ED was too short; and that it should also have included adults. As discussed in the response to General Issue 7.E, EPA will review exposure parameters as part of the process of HHRA revision.

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

RESPONSE 223:

Please refer to the response to General Issues 7.E and 8.D.

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

RESPONSE 224:

Please refer to the response to General Issue 8.A for information on the population density and biomass of fish in Reaches 5 and 6 of the Housatonic River.

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

River product? Indeed, it is difficult to envision the projected kill rate even if it included both non-migratory and migratory birds.

RESPONSE 225:

Please refer to the response to General Issue 9.C. for data on waterfowl productivity. For direct contact exposure, it is not necessary to bag birds, only to hunt them. EPA does not believe that hunters bag waterfowl on every trip. According to the Ducks Unlimited poll conducted in 2001, of 7,348 respondents, 27% spend greater than 50 days each year in the field.

Of course, it must be recognized that the residence time of migrating birds on the river makes it unlikely that they accumulate significant burdens of PCBs.

RESPONSE 226:

Residence time of migrating birds and their ability to accumulate significant burdens of PCBs does not influence risks to waterfowl hunters due to direct contact. For a discussion of the potential for consuming resident versus migratory waterfowl, please refer to the response to General Issue 9.C.

The upper-bound soil ingestion rates of 200 mg/day for young children and 100 mg/day for older children and adults are excessive. It is reasonable to project that recreational use per day will vary from perhaps an hour up to all day. The recent work of Stanek and Calabreze (2000) and Stanek et al (1997) appear to support values of 100 mg/day for young children and 50 mg/day for older children and adults.

RESPONSE 227:

Please refer to the response to General Issue 7.E. It should be noted that another Reviewer disagrees with this opinion and recommends that no change be made to these ingestion rates. EPA will continue to use the same ingestion rates in the revised HHRA, as recommended by EPA guidance.

Moreover, even the latter values would appear to be over-estimates when it is recognized that the individuals are likely to be in the Exposure Areas for only some modest portion of each day. For many exposure areas there will also be a high likelihood that individuals will spend substantial time in adjacent areas devoid of contamination. Indeed, EPA's (1989) own guidance has provision for taking accounting of time spent in contaminated versus non-contaminated areas.

RESPONSE 228:

Please refer to the response to General Issue 7.E. Most of the recreational scenarios in the HHRA assumed a CTE with a fraction ingested (FI) of 0.5.

- ***Exposure assumptions affecting dermal contact (e.g., soil adherence rates, skin surface areas assumed to contact soil or sediment).***

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

RESPONSE 229:

Please refer to the response to General Issue 7.E. It should be noted that another Reviewer disagrees with this opinion and recommends that no change be made to dermal absorption and other dermal parameters. EPA will continue to use the same dermal parameters in the revised HHRA, as recommended by EPA guidance.

- ***Oral and dermal absorption factors.***

The use of a dermal absorption factor of 0.14 does not appear warranted when a value derived from a study with Housatonic River soil is available. Mayes et al (2002) conducted such a study and reported a dermal absorption factor of 0.04.

RESPONSE 230:

It should be noted that another Reviewer disagrees with this opinion and recommends that no change be made to this absorption factor. EPA will continue to use the same absorption factor in the revised HHRA, as recommended by EPA guidance. Supporting information is included in Section 2.3.1.2 of Volume I of the HHRA.

When site-specific data are available such data should be used rather than defaulting to other generic data.

RESPONSE 231:

EPA prefers site-specific data when suitable data are available. EPA carefully reviewed the data provided in Mayes et al. (2002) and concluded that serious flaws in the study precluded its use. Please see the response to the previous comment.

P. Barry Ryan

- ***Oral and dermal absorption factors.***

In each of the above cases, the exposure assessors have chosen factors from the EPA Exposure Factors Handbook, commonly regarded as the best source of various factors associated with exposures through various environmental media. One may indeed quibble with individual selection, or even the choice of values selected by EPA, e.g., EPA often selects a default value based on very limited, or even no, data. One may suggest that experiments on rhesus monkeys using Housatonic River soil are most relevant here. However, as Dr. Kissel pointed out, the methods used may not have been the best. This is just one example of the sparseness of the data associated with dermal contact. A single experiment costing a large amount of money to do is all we have available for this parameter. Many other parameters have no data at all. The uncertainty introduced by using a value for such a parameter is not known. However, the estimates are the best available and are the best choices we have.

RESPONSE 232:

EPA agrees with the Reviewer's comment.

Lee R. Shull

- ***Exposure duration scenario.***

- In general and except for the following comments, the ED values used seem appropriate.

- In Section 4.2.3, the age ranges for each of the identified exposed populations are given (e.g., older child 7-18 years of age). The sources (references) of these age ranges should be given and a definitive statement should be made that the ranges are reasonable for this risk assessment.

RESPONSE 233:

EPA will provide clarification in the revised HHRA.

- Page 4-8, lines 12-15: Exposure duration for adults is defined as 7-45 years. This differs from EPA's default exposure duration (30 years). Rationale or a reference citation for this value should be provided.

RESPONSE 234:

In the HHRA, EPA used site-specific data to develop the residential exposure duration as presented in Section 4.5.3.1.2 of Appendix B, Volume IIIA. EPA believes that the available site-specific data is of adequate quality to use in place of default values. EPA will provide clarification to the justification in the revised HHRA.

- Page 4-48, lines 8-9 and Table 4-17: Seems like the CTE ED should be 19 years instead of 25 years, since a <12 yr old is not allowed to hunt (i.e., 31-12 = 19 yrs).

RESPONSE 235:

EPA believes the ED value used in the HHRA is correct. As presented in Section 4.5.3.7.2, a child is permitted to hunt in Massachusetts at age 12, making the older child waterfowl hunter ED 6 years (12 – 18 years). This value was subtracted from the mean number of years living in the Housatonic River area (31 years) to yield an adult ED of 25 years.

- ***Exposure frequency and area use factors for each scenario and exposure area.***

- In general and except for the following comments, the exposure frequency and area use factors seem appropriate.

- Section 4.4.1.1.1: Regarding area use weighting, the factors selected seem appropriate. However, given the overall impact of EF on the risk estimates, this section deserves more consideration in my opinion. GE presented information at the November 18-20, 2003 public meeting that described/documented the inaccessibility of some areas in Reaches 5 and 6. I strongly suggest this information be taken into consideration and that reevaluation of the area use factors be done.

  RESPONSE 236:

  Please refer to the response to General Issue 7.B.

  As a minimum, the GE information should be presented in the uncertainty section with some level of judgment about the impact of the values used on the risk estimates.

  RESPONSE 237:

  Please refer to the response to General Issue 7.F.

- Page 4-24, Section 4.5.1.1: Age adjustment of body weight is common practice in risk assessment. Rationale should be presented here as to why this practice was not done.

  RESPONSE 238:

  Body weights were included in the age-adjustment process as noted on Table 4-10. See also the response to General Issue 3.B.

- Page 4-32, Section 4.5.3.1.1: The EF for residential sites is typically 350 days/yr. The difference in the basis for the MDEP-referenced value of 150 days/yr and the 350 days/yr default (1998 Soil Screening Guidance [SSG] and 2002 SSG Supplement) should be provided.

  RESPONSE 239:

  The revised HHRA will provide the rationale for the difference from the soil screening guidance.

- Page 4-33, line 2: Please state whether MADPH, 1997 is a peer-reviewed study. If it is not, stronger statement should be added stating why the risk assessors believe can be relied upon in this HHRA.

  RESPONSE 240:

  The Housatonic River Area PCB Exposure Assessment Study (MDPH 1997) includes the results of the Exposure Prevalence Study as well as the results of blood tests for PCBs. The Exposure Prevalence Study included a household screening survey that identified patterns of potential exposure by different pathways. Peer review of the household screening questionnaire included input from the community, citizens groups, local and state agencies, and other experts. The results of the analyses of PCBs in blood were reviewed by a panel of experts on PCBs and health effects convened by MDPH.

- Page 4-35, line 11: Better rationale for the two EF values should be provided. If the basis was professional judgment, a statement of same should be included. For example, later in the report (page 4-38, lines 12-13), a clear statement is made regarding the EF basis. This approach should be applied throughout Section 4.

RESPONSE 241:

EPA will provide clarification in the revised HHRA. Please refer also to the response to General Issue 7.E.

- Page 4-42, lines 1-3: How can the mean be 18, and the 50th percentile 2, and the 75th percentile 7? Please clarify.

RESPONSE 242:

The above-mentioned statistics are correct and indicate a skewed data set.

- Page 4-49, Section 4.5.3.8.1: Would it be possible to provide some additional rationale for these EF values (i.e., some minimal information to support the professional judgment).

RESPONSE 243:

EPA will provide clarification in the revised HHRA. Please refer also to the response to General Issue 7.E.

- Page 4-51, Section 4.5.3.9.1: The EF for the farmer receptor of 10 days per year seems low. Many other management practices such as irrigation, tilling, side dressing/ fertilization, inspection, etc. occur for which direct soil contact occurs in addition to harvesting and planting.

RESPONSE 244:

Please refer to the response to General Issue 7.E.

- Page 4-54, Section 4.5.3.11.1: The utility worker EF of 5 days/yr seems low. Is the assumption of 5 days/yr for a single area, or all areas where PCB contamination exists?

RESPONSE 245:

Please refer to the response to General Issue 7.E.

- ***Soil ingestion rates.***

- In general and except for the following comments, soil ingestion rates are appropriate.

- Page 4-33, Section 4.5.3.1.3: Rationale for applying 0.5 of the 100 mg/day as the CTE ingestion rate should be provided.

  RESPONSE 246:

  Please refer to the response to General Issue 7.E.

- Page 4-55, Section 4.5.3.11.3: It doesn't seem accurate to assume an RME ingestion rate of 330 mg/day soil ingestion for a utility worker compared to 200 mg/day for a farmer. Either the utility worker is too high or the farmer is too low.

  RESPONSE 247:

  Please refer to the response to General Issue 7.E.

- ***Exposure assumptions affecting dermal contact (e.g., soil adherence rates, skin surface areas assumed to contact soil or sediment).***

- In general and except for the following few items, the exposure assumptions related to dermal contact are appropriate.

- There appears to be some inconsistency in the selection of some exposure parameters across similar, if not identical, exposure scenarios. For example, the skin surface areas for the marathon canoeist and recreational boater are different, but no rationale is given for the difference. Consistency across similar exposure scenarios would be preferred, or additional discussion to provide justification for the difference would meet the evaluation criteria.

  RESPONSE 248:

  Please refer to the response to General Issue 7.E. Assumptions regarding the intensity of exposure were among the characteristics used to distinguish between recreational and marathon canoers. Marathon canoers were assumed to have less intense, but more frequent exposures. This will be clarified in the revised HHRA.

- Page 4-25, line 29: Reference is made to two concerns by the EPA of the GE dermal absorption study in rhesus monkeys. Clarification is needed as to whether these "concerns" are reflected in a formal peer review conducted by either EPA or GE, or whether they are concerns of the authors of this risk assessment.

RESPONSE 249:

This will be clarified in the revised HHRA. As pointed out in the HHRA, Volume I, page 2-21, the EPA Superfund Dermal Workgroup and MDEP reviewed the Mayes et al. 2002 study and submitted written comments regarding the limitations of the study. The concerns, as expressed in the written comments, were summarized in the HHRA.

- Page 4-31, Section 4.5.2.4.2: Additional discussion of the available adherence factors (AFs) would improve clarity, specifically a discussion of rationale as to why the AFs selected are believed representative of Housatonic River soil and sediment.

RESPONSE 250:

Please refer to the response to General Issue 7.E.

- Page 4-48, line 25. Use of reed gatherer AFs for soil exposures seems overly conservative. A "moist soil" value, if available, would be more appropriate.

RESPONSE 251:

Please refer to the response to General Issue 7.E.

- ***Oral and dermal absorption factors.***

- The dermal absorption factors are appropriate for this risk assessment.

Stephen T. Washburn

In general, the combinations of exposure factors used in the Phase 2 Direct Contact Assessment appear to be conservative (i.e., more likely to overstate than understate exposures). In fact, in some cases, the combinations appear to lead to inappropriately high estimates of exposure.

RESPONSE 252:

Please refer to the response to General Issue 7.F.

According to EPA's Policy for Risk Characterization at the U.S. Environmental Protection Agency (March, 1995), "If only limited information on the distribution of the exposure or dose factors is available, the assessor should approach estimating the high end by identifying the most sensitive variables and using high end values for a subset of these variables, leaving others at their central values." It is not clear that this guidance has been followed in estimating the RME for direct contact exposures.

RESPONSE 253:

EPA believes the exposure parameters selected for the RME calculation were consistent with this guidance. Dermal contact exposures, for example, were based on central tendency body surface areas and body weights. However, as discussed in the response to General Issue 7.E, the exposure parameters will be reviewed as part of the HHRA revision. The revised HHRA will also quantify the uncertainty associated with combining exposure parameters for each of the receptors, as described in the response to General Issue 7.F.

While the individual exposure parameters (e.g., soil ingestion rate, fraction of contaminated soil ingested, exposure frequency, exposure duration) do not necessarily seem unreasonable when taken individually, when combined they can produce a scenario that does seem highly unlikely, at least for many of the EAs. For example, under the RME general recreation scenario, it is assumed that an individual may contact the floodplain in a single EA over 6,300 days over the course of a lifetime, that 100% of the soil ingested on each of those days comes from that EA, and that the individual displays behavior that corresponds to "high end" incidental soil ingestion on each day. To address this issue, specific recommendations include the following:

- Since Dr. Edward Calabrese is a primary source of the data used in developing the ingestion rates selected for the HHRA, EPA should revise its RME and CTE soil ingestion rates to reflect those recommended by Dr. Calabrese in his January 23 2003 letter included as Exhibit E.1 of the GE/AMEC/BBL comments on the HHRA [i.e., for young children, 20 mg/day (CTE) and 100 mg/day (RME); for adults, 10 mg/day (CTE) and 50 mg/day (RME), unless a technical rationale for rejecting those updated estimates is identified and documented. The updated soil ingestion rates recommended by Dr. Calabrese are similar to those also recommended by the Agency for Toxic Substances and Disease Registry (ATSDR) [i.e., 50 to 100 mg/day for non-pica children, and 50 mg/day for adults] in its Public Health Assessment Guidance Manual (ATSDR 1992), to represent conservative estimates of typical behavior.

  RESPONSE 254:

  EPA does not agree (as also expressed by another Reviewer) with the revised values attributed to Calabrese, 2003. Please refer to the response to General Issue 7.E.

- Combine the high-end soil ingestion rate with more likely values of fraction ingested (FI) for incidental soil ingestion and fraction contacted (FC) for dermal contact with soil, under both RME and CT scenarios. Currently, the HHRA assumes an FI value of 1.0 for both the RME and CT residential scenarios, and FI RME and CT values of 1.0 and 0.5, respectively, for the all non-residential scenarios. In addition, the HHRA appears to explicitly assume an FC value of 1.0 for all direct contact scenarios. These FI and FC assumptions are highly conservative when combined with the soil ingestion and dermal contact assumptions, which relate to the total amount of soil ingested or contacted each day, regardless of source. Alternatively, the high-end FI and FC assumptions could be combined with soil ingestion and dermal contact rates that are more representative of central tendency estimates.

RESPONSE 255:

The revised HHRA will quantify the uncertainty associated with combining exposure parameters for each of the receptors, as described in the response to General Issue 7.F.

- Avoid combining the RME exposure frequency with the RME exposure duration. For example, for the angler, the RME exposure frequency is assumed to be 60 days per year, corresponding to 2 days a week for a 7- month period. Such a frequency may not be unreasonable for a period of several years. However, when combined with an RME exposure duration of 60 years, then the result is an estimated 3,600 days spent by an angler at the same EA, and 100% of the soil ingested on each of those days comes from that EA.

RESPONSE 256:

Please refer to the response to General Issue 7.E for a discussion of exposure parameters that will be reexamined as part of the HHRA revision. The revised HHRA will also quantify the uncertainty associated with combining exposure parameters for each of the receptors, as described in the response to General Issue 7.F.

- Adjust the use-weighting factors and exposure frequencies to better reflect the likelihood that recreationalists would routinely contact areas. The assignment of use-weighting factors in the direct contact assessment reflects considerable judgment, and based on the discussion in the HHRA, the factors for "difficult to access" and "wadable" categories seem high relative to the "walkable" category (Volume I, p. 4-9).

RESPONSE 257:

Please refer to the response to General Issue 7.B.

In addition, the HHRA assumes an RME general recreational exposure frequency of 30 days/year along with an exposure duration of 70 years (or a total of 2,100 days of exposure) even for areas that are "characterized by having inundated wetlands and dense vegetation, and are remotely located" (p. 4- 35, Volume I). Based on observations during a site visit, and the material presented in the HHRA, large portions of the floodplain would be expected to be contacted very rarely, if at all. These observations are consistent with the results of a Floodplain User Survey discussed during the Peer Review Panel public meeting held in November, 2003.

RESPONSE 258:

Please refer to the responses to General Issues 7.E and 7.F.

On the other hand, it should be noted that the following Phase 2 assumptions may lead to underestimates of potential exposures through direct contact:

- Exposure frequency for the farmer: 10 days per year seems low for both CT and RME scenarios.

  RESPONSE 259:

  Please refer to the response to General Issue 7.E.

- Soil ingestion rates for the commercial groundskeeper: The soil ingestion rate for the commercial groundskeeper is assumed to be the same as for the adult resident. Depending on the specific activities of the groundskeeper, this may be an underestimate, particularly if the updated soil ingestion rates recommended by Dr. Calabrese are adopted for the HHRA.

  RESPONSE 260:

  Please refer to the response to General Issue 7.E.

5. Is the approach used to estimate a Reasonable Maximum Exposure (RME) and a Central Tendency Exposure (CTE) for the direct-contact exposure assessment appropriate under the evaluation criteria?

COMMENTS

Holly Hattemer-Frey

Yes, overall, the approach is reasonable and consistent with EPA guidance. There is some question about the approach used to calculate RME EPCs, with respect to application of the bootstrapping technique. While I agree that bootstrapping is commonly used, it may not be as robust (and possibly conservative) as the t-statistic and Land's method. Considering that 78 out of 90 EPCs for Reaches 5&6 (zero out of 30 for Reaches 7&8), were derived using bootstrapping, the authors need to discuss the influence bootstrapping may have on EPC calculations. Specifically, is bootstrapping expected to over- or underestimate EPCs and by what factor? One way to provide a perspective on this issue would be to use to calculate 95% UCLs assuming the data are normally and lognormally distributed (using the t-statistic and Land's method), and the comparing these UCLs to the value derived using bootstrapping.

RESPONSE 261:

Please refer to the response to General Issue 4.B.

F. Owen Hoffman

The assumptions used for the deterministic estimate of baseline risk appear reasonable and consistent with EPA guidance. Results, however, that show merely a factor of two difference between the RME and CTE exposure are counterintuitive. I would expect a much wider margin of difference.

RESPONSE 262:

The difference between RME and CTE is substantially higher than 2 and often more than 10 for all exposure scenarios with the exception of residential exposure for children. Also, please refer to the response to General Issue 7.E.

Again, evaluation of the effect of compounded conservative assumptions on the final results should be addressed using a quantitative uncertainty analysis, which has only been performed for the ingestion of fish and waterfowl.

RESPONSE 263:

Please refer to the response to General Issue 7.F.

John C. Kissel

EPA guidance for estimation of RMEs is subject to interpretation. Some unstated number of exposure factors are to be incorporated at upper percentiles while others are held at central tendencies. This leaves ample room for production of disparate estimates of the RME by investigators using the same data. With this caveat, the general approach taken appears reasonably consistent with EPA guidance.

Roger O. McClellan

The approach taken to estimating the risks to the Reasonable Maximum Exposure (RME) individuals are ultra-conservative. In my opinion, they represent Extreme Maximum Exposure individuals unlikely to be representative of any individuals in the future. It is a misnomer to designate them as Reasonable Maximum Exposure.

RESPONSE 264:

The HHRA was intended to be fully consistent with EPA guidance and policy, including the following:

"For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at the site. Under this approach, some intake variables may not be at their individual maximum values but when in combination with other variables will result in estimates of the RME. " (EPA, 1989, RAGS A, p. 6-21.)

"Contact rate reflects the amount of contaminated medium contacted per unit time or event. If statistical data are available for a contact rate, use the 95th percentile value for this variable." (RAGS A, p. 6-22)."

"Exposure frequency and duration are used to estimate the total time of exposure. These terms are determined on a site-specific basis. If statistical data are available, use the 95th percentile value for exposure time." (RAGS A, p. 6-22).

The point estimate risk assessment utilized upper-bound (usually 95th percentile), but not maximum values for assessing contact rate and exposure duration to the RME. EPA does not consider any of the parameter values used in the exposure assessment to be implausible.

The extreme estimates of exposure result from the layering of conservative to ultraconservative assumptions and parameters one after another to yield calculated extreme value estimates. These assumptions and parameters have been discussed elsewhere but in the interest of completeness, I will recapitulate them here:

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

RESPONSE 265:

The floodplain EAs evaluated in Phase 2 range in area from less than an acre to over 100 acres, and more than half of the EAs encompass at least 5 acres. Therefore, EPA does not agree that exposure areas are too small nor that they should be expanded to include areas outside the 1-ppm isopleth. Conversely, because many of the exposure areas are large, EPA has noted in the HHRA that if the area over which random exposure occurs is smaller than the entire EA, risk may be underestimated if the exposure point concentration is greater for the smaller area than that calculated for the entire EA. This uncertainty will be further evaluated in the revised HHRA.

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

RESPONSE 266:

Soil EPCs are estimates of the central tendency of the observed distributions, not upper-bound estimates. This is the difference between a 95% upper confidence limit of the mean and a 95th percentile of the full distribution.

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

RESPONSE 267:

Please refer to the response to General Issue 7.E.

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

RESPONSE 268:

Please refer to the response to General Issue 7.E.

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

RESPONSE 269:

Please refer to the response to General Issue 7.E.

P. Barry Ryan

I expressed concerns in my initial comments regarding the use of the UCL for the mean in expressing measures of CTE and RME. I do not believe that these questions have been adequately addressed.

However, the scenarios used in selecting maximally exposed individuals do appear conservative enough for me to be more confident in the overall approach.

See the discussion of the interpolation methods above.

In many cases, we do not have the data that would allow us to respond to this question effectively. We are given the procedures that are used if, for example, the distribution of measured values was deemed lognormal or had no distributional characteristics that could be gleaned. However, we are not given the measured data locations and locations of the grid points so that it is impossible to reproduce the results given. Those that were supplied to us later in summary form call into question the procedures used to generate the "working data" and do not generate confidence in the EPCs and CTEs calculated.

RESPONSE 270:

Please refer to the responses to General Issues 4.A and 4.B.

Lee R. Shull

The approach used to estimate RME and CTE are considered appropriate.

Stephen T. Washburn

See comments above.

6. Were the uncertainties adequately characterized and expressed?

COMMENTS

Holly Hattemer-Frey

Uncertainties were evaluated (for the most part) qualitatively (versus applying a formal quantitative analysis, such as a Monte Carlo simulation). The Uncertainty Analysis provides limited information as to whether a source of uncertainty is likely to over- or underestimate risks. I suggest the authors include a summary table including each and every source of uncertainty associated with the Phase 1 assessment, whether the source is likely to over- or underestimate risks, and quantify (where possible) the extent to which the source is likely to over- or underestimate risk.

RESPONSE 271:

Please refer to the response to General Issue 7.F.

Then, major sources of uncertainty should be discussed in more detail as well. I note three issues below that warrant further evaluation/discussion. This approach should be repeated for all subsequent analysis (Phase II, Fish and Wildlife, Agricultural).

RESPONSE 272:

Please refer to the response to General Issue 7.F.

Random Exposure Within an Exposure Area

The issue of assuming random exposure within a parcel is troublesome. The text admits that if individuals preferentially occupy one part of a parcel over another, exposures could be higher or lower than estimated. For the larger parcels with varying PCB concentrations, the potential to underestimate risks seems large enough that a more quantitative reporting of to what extent risks could be underestimated is warranted (or recalculation of potential exposures in smaller areas).

RESPONSE 273:

Please refer to the responses to General Issues 7.A and 7.C.

Current Versus Future Exposures

Section 7.2.2.5 states that only properties currently used for residential or agricultural purposes were evaluated. Thus, risks to potential future receptors who could reasonably use specific areas for residential or agricultural purposes in the future were not quantified. This approach is inconsistent with EPA policy and may underestimate risks if these areas experience different land uses in the future.

RESPONSE 274:

The future residential scenario included properties that are currently not developed as such but have a reasonable potential for residential development as described in Section 4.3.5.1. Please refer to the responses to General Issues 2.A, 2.C, 2.D, 2.E, and 7.D.

I recommend that possible exposures to individuals who could live on one of the "several locations that are not currently developed but could be used for housing in the future" be quantified.

RESPONSE 275:

Please refer to the responses to General Issues 2.A, 2.C, 2.D, and 7.D.

The same applies for those areas that are not currently used for agricultural purposes but could be in the future.

RESPONSE 276:

Please refer to the responses to General Issues 2.E and 7.D.

Uncertainty Associated with the Toxicity Assessment

Potential cancer risks were appropriately quantified using the approved dioxin cancer slope factor (CSF) of 1.5×10^5 $(mg/kg\text{-}day)^{-1}$. Since EPA is reevaluating the potential cancer effects of dioxin-like compounds and may revise the CSF for dioxin, I recommend that cancer effects be quantified (versus just stating that risks would increase by a factor of six) using the revised EPA CSF of 1×10^6 $(mg/kg\text{-}day)^{-1}$ for all pathways and receptors and results presented in the Uncertainty Analysis.

RESPONSE 277:

Please refer to the response to General Issue 12.C.

The quantification of potential noncancer effects from exposure to dioxin-like compounds remains controversial. While EPA has not formally established an RfD for dioxin-like compounds, there is a growing body of literature suggesting that dioxin-like compounds may cause noncancer effects in humans. At a minimum, I recommend that potential noncancer effects be discussed in the toxicity assessment.

RESPONSE 278:

Please refer to the response to General Issue 12.C.

Although the "informal" RfD of 1.0 pg/kg-day for dioxin has not been approved by EPA, it has been used in other EPA assessments, thus giving use of the informal value some legitimacy. If the authors choose to provide a perspective on potential noncancer effects from exposure to dioxin-like compounds, the results should be included as part of the Uncertainty Analysis, not the formal RA.

RESPONSE 279:

Please refer to the response to General Issue 12.C.

F. Owen Hoffman

No. The uncertainty analysis section for the Phase II Direct Contact Exposure Assessment is inadequate. All factors that could lead to an over- or under-estimate of exposure and risk should be identified and discussed. The extent to which over-or estimation may occur should be quantified, at least in a general sense (i.e., less than a factor of 2, a factor of 2 to 5, on the order of a factor of 10, or greater than a factor of 10).

RESPONSE 280:

Please refer to the response to General Issue 7.F.

Preferably, a more formal quantitative uncertainty analysis should be performed. In so doing, I would recommend treating the RME and CTE as distinctly different scenarios of exposure. Probability distributions would be used that represent states of knowledge (given available evidence) about uncertain assumptions for estimating RME and CTE exposures and risks.

RESPONSE 281:

Please refer to the response to General Issue 7.F.

There is no mention of the degree to which uncertainty in the toxicity coefficients could lead to strongly biased results for either the RME or CTE.

RESPONSE 282:

Please refer to the response to General Issue 12.B.

There is also a need for a quantitative uncertainty analysis associated with the use of TEQ's to estimate the cancer risk from the presence of dioxin-like PCB congeners and the use of regression analysis used to infer the quantitative presence of these congeners.

RESPONSE 283:

Please refer to the responses to General Issues 4.F and 7.F.

A quantitative uncertainty analysis would facilitate identification of results that contain a strong bias towards over-or under-estimation of exposure and risk. A quantitative uncertainty analysis would also disclose the relative importance of all assumptions affecting the estimate of exposure and risk and where improvements in the state of knowledge would be effective in reducing uncertainty and bias.

There needs to be more discussion about the potential for substantial bias associated with the assumption of random access to relatively large exposure areas, especially when true access for real persons may be non-random and restricted to a subsection of the overall exposure area.

RESPONSE 284:

Please refer to the responses to General Issues 7.A and 7.C.

John C. Kissel

Uncertainties are discussed in qualitative terms, but the Direct Contact Exposure Assessment is a deterministic analysis. The numerical results simply do not express uncertainty. (I do not agree that estimation of two values, the RME and CTE, which are of essentially unknown statistical character, constitutes uncertainty analysis.)

RESPONSE 285:

EPA understands the concerns of the Reviewer that the RME and CTE do not constitute an uncertainty analysis. The revised HHRA will include probabilistic methods to evaluate the uncertainty about these risk estimates. Please refer to the response to General Issue 7.F.

Roger O. McClellan

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

RESPONSE 286:

Please refer to the response to General Issue 7.F.

P. Barry Ryan

The uncertainties in these approaches were addressed by examining the lowest and highest values determined in the deterministic approaches. While certainly spanning some type of range, I do not believe that it adequately represents the full uncertainty of the procedures and certainly does not address the uncertainty as defined by Ferson as variability and "incertitude" associated with a Monte Carlo assessment. Further, there is little placement of these uncertainties on any kind of likelihood scale. Much more presentation is needed on the uncertainties in these estimates. Are they a factor of two, which is certainly acceptable, or several orders of magnitude, which is not likely to be acceptable? A much more through discussion of these important concepts is warranted.

RESPONSE 287:

Please refer to the response to General Issue 7.F.

Lee R. Shull

- The qualitative uncertainty analysis presented is incomplete and inadequate. Not all factors that could impact risk estimates, either over- or under-estimates, are identified and evaluated. For many of the sources, the document states "risk may be either over- or under-estimated." In my view, the risk assessor should, if at all possible, use his/her judgment, experience, etc to put forward a position whether risks are either under- or over-estimated. If risks could go either way, reasons for same should be provided.

  RESPONSE 288:

  Please refer to the response to General Issue 7.F.

- In several places, confusing terminology is used. For example, on page 7-2, lines 22-24, the following statement is made: "Therefore, exposure to surface water was eliminated from further consideration and quantification, which would lead to an insignificant underestimate of risk." Does this mean there may be an underestimate of risk, but it is considered insignificant?

  RESPONSE 289:

  PCBs were detected in surface water, thus exposure could occur. However, as noted by EPA in Section 2.5.4, the measured concentrations are well below site-specific risk-based screening concentrations; therefore, the risk posed by this exposure pathway would be below the EPA risk range.

  In this case, since the conclusion was made based on scientific evidence in the exposure assessment that no PCB concentrations exist in water, this means there is no exposure. If the assessors believes scenarios exist whereby exposure and some level of risk associated with water could occur, these scenarios should, as a minimum, be identified and discussed qualitatively.

  RESPONSE 290:

  Please refer to the previous response.

- Page 7-1, line 16: Suggest adding "…overview of sources of uncertainties…"

  RESPONSE 291:

  The wording will be clarified in the revised HHRA.

- Page 7-3, lines 20-23: Suggest stating mean concentrations are likely to be overestimated.

  RESPONSE 292:

  The wording will be clarified in the revised HHRA.

- Page 7-4, line 19: Should comment whether current land uses are likely to over- and/or under-estimate risks.

This section of the HHRA discusses that the risks would be underestimated if the land use changed to residential. More detailed discussion of uncertainty will be provided in the revised HHRA.

- Page 7-7, line 7: Suggest adding the words "….risk compared to the central tendency CSF."

  RESPONSE 293:

  This section will be revised and clarified.

- Page 7-7, Section 7.2.3.1: This section is sorely lacking. One of the greatest sources of uncertainty in human health risk assessment is in the areas of animal- to-human extrapolation, and high-to-low dose extrapolation. This section contains no mention of these factors, as well as no mention of human (e.g., epidemiology) information that helps understand the degree to which strict reliance on animal data impacts risk estimates. I strongly suggest the addition of this information to this section, with an assessment by the risk assessor as to whether these sources of uncertainty present an over- , no impact, and/or under-estimation of the risk estimates presented in these documents.

  RESPONSE 294:

  Please refer to the response to General Issue 12.B.

- Page 7-8, lines 6-7: It is my understanding that the TEFs are based primarily on CYP1A1 induction, which is a relative indicator of Ah binding in the liver. Please clarify.

  RESPONSE 295:

  The development of TEFs and the uncertainty associated with their use was discussed in the HHRA Volume I, Sections 2.2.2 and 2.2.3. The section referred to in this comment, Volume IIIA, Section 7.2.3.2, will be revised to reflect these points.

- Page 7-8, section 7.2.3.3: This entire section should be eliminated from the document. In particular, I do not believe it is not appropriate to discuss EPA's proposed draft TCDD cancer slope factor (CSF) of 1E+06 $(mg/kg\text{-}d)^{-1}$. The EPA's Science Advisory Board (SAB) has provided comments to EPA on this issue, yet the EPA has not yet released a revised document for public or peer review. The derivation of this CSF is a highly controversial issue due to EPA's failure to clearly describe and document its derivation, and because it appears to be based largely on epidemiological studies for which there are substantial confounding factors and spurious associations.

  RESPONSE 296:

  Please refer to the responses to General Issues 5.A and 12.C.

  Furthermore, the uncertainty discussion specifically fails to make reference to other alternative CSFs for TCDD published in the peer-reviewed literature and by other federal regulatory agencies, specifically those published by the FDA (1992) and Keenan et al. (1991).

RESPONSE 297:

Please refer to the responses to General Issues 5.A and 12.C.

In the absence of a final consensus in the scientific and regulatory communities on the potential human carcinogenicity of TCDD, it is speculative and presumptuous to even discuss EPA's draft CSF for TCDD in this risk assessment.

RESPONSE 298:

Please refer to the response to General Issue 12.C.

Should EPA decide to keep this discussion in the uncertainty section, I recommend that the full range of possible TCDD CSFs published since the Pathology Working Group reported its findings of the 1990 re-evaluation of the Kociba et al. (1978) rat liver pathology slides (Sauer 1990; Keenan et al. 1991; Goodman and Sauer 1992) be included also.

RESPONSE 299:

Please refer to the response to General Issue 12.C.

- A high quality HHRA should present relevant information that helps the risk manager to place the estimated risks in proper perspective. Information provided in GE's presentation at the November 18-20, 2003 public meeting could be used to accomplish this objective.

RESPONSE 300:

The revised HHRA will include expanded risk characterization and uncertainty sections as well as additional information regarding the site. Please refer to the responses to General Issues 1.C, 1.D, 7.F, 11.C, 12.B, 12.C, and 13.B.

The findings in two studies described at this meeting – the MDPH Exposure Assessment Study, 1997 and the ATSDR/MDPH Cancer Incidence Study, 2002 – provides excellent information to which the risk estimates can be compared.

RESPONSE 301:

Please refer to the responses to General Issues 1.C and 1.D.

Without placing risk estimates in proper perspective, including identifying data gaps where they exist, can be result in misleading risk managers during the decision making process.

RESPONSE 302:

The revised HHRA will include expanded risk characterization and uncertainty sections as well as additional information regarding the site. Please refer to the responses to General Issues 1.C, 1.D, 7.F, 11.C, 12.B, 12.C, and 13.B.

Stephen T. Washburn

Given the comments above, and the results of the HHRA for the direct contact scenarios, it is recommended that EPA provide a more complete and, to the extent feasible, quantitative analysis of uncertainties.

RESPONSE 303:

EPA agrees. Please refer to the response to General Issue 7.F.

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

COMMENTS

Holly Hattemer-Frey

Yes, except for the comments made previously.

F. Owen Hoffman

Yes, for the deterministic estimate that leads to a baseline risk, but not from the standpoint of revealing the overall effect of compounded conservative assumptions. Therefore, I recommend that the Phase II direct contact scenario be subjected to a formal quantitative uncertainty analysis.

RESPONSE 304:

Please refer to the response to General Issue 7.F.

John C. Kissel

The overall approach is generally consistent with EPA guidance and practice. Some shortcomings of the prior screening process (see discussion above) may have resulted in premature elimination of exposure areas that should have been retained. Any such failures would have simply been carried through the direct contact assessment.

RESPONSE 305:

Conservative exposure assumptions were made by EPA to reduce the potential for false negatives. Three tax parcels (one low-contact residential and two recreational) in Reaches 5 and 6 would have been eliminated from consideration based on the PCB concentrations on the parcels in the Phase 1 screening, but were retained for the Phase 2 analysis because of elevated PCB concentrations on nearby or adjacent properties. These areas included parcels H6-4-13, J3-2-6, and 19-2.

There were no samples collected from tax parcel J6-2-3, a low-contact residential area in Reach 5, because of the lack of area in the floodplain. However, given its proximity to the confluence and the highly contaminated sediment and properties nearby, this property was evaluated in the Phase 2 evaluation. Further, utility easement 3 in Reach 5 was eliminated from consideration in Phase 1 based on commercial/industrial use. However, this easement is also used for recreational purposes; therefore, it was included in the Phase 2 evaluation.

These examples are presented in greater detail in Sections 3 and 4 of Appendix A, Volume IIA, and illustrate EPA's commitment to eliminating the potential for false negatives.

Roger O. McClellan

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

RESPONSE 306:

Please refer to the responses to General Issues 7.E and 7.F. In addition, the revised HHRA will include expanded risk characterization and uncertainty sections that will put the risks in perspective. Please refer to the responses to General Issues 1.C, 1.D, 12.B, 12.C, and 13.B.

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

RESPONSE 307:

Please refer to the response to General Issue 7.E.

P. Barry Ryan

Generally, the estimates of risk from direct contact are adequate for estimating baseline risk subject to the cautions given in the above comments. However, the implementation of the methods described and the uncertainties in such estimates are not well described. This precludes answering the question. While the methods appear well-conceived, the implementation questions give one pause. Further, we have little in the way of discussion of the precision or accuracy of such estimates. Hence, it becomes difficult to assess the "reasonableness" of the baseline risk.

RESPONSE 308:

Please refer to the response to General Issue 7.F.

Lee R. Shull

- In general, the assessment does provide the information in the four areas stated on page ES-1. Although the Phase 2 report lacks a clear statement of objectives, if these four items are taken as "objectives", I believe the assessment generally meets the overall purpose of providing this information, in particular the first item: " a characterization of the potential human health risks under baseline conditions (i.e., no action) for current and future uses." Also, for the most part, EPA's risk characterization criteria of transparency, clarity, consistency and reasonableness, and the additional "objectivity" criterion are met, with the exception of the uncertainty analysis (Section 7). In my opinion, the greatest deficiencies are in the area of lack of transparency and clarity.

  RESPONSE 309:

  Please refer to the response to General Issue 7.F.

  Other key deficiencies exist in some parts of the assessment that could result in significant over-estimations of risk. As a minimum, the assessment should address these deficiencies, especially the uncertainty analysis, to ensure the results of the risk assessment are appropriate and are placed in proper perspective for risk management decision making.

  RESPONSE 310:

  Please refer to the responses to General Issues No. 7.E, 7.F, and 13.B.

- Because of the central role played by the Consent Decree in the performance of this HHRA, a similar comment as was made on the Phase 1 screening assessment is relevant to the Phase 2 assessment. A brief summary as to how the Consent Decree dictates procedures, methods, etc as related specifically to the Phase 2 Direct Contact assessment should be identified and briefly summarized in Section 2. This addition would improve transparency. Again, this summary should consist of more than simply a reference to the Consent Decree (Appendix J).

  RESPONSE 311:

  The revised HHRA will clarify the role of the Consent Decree in the strategy and methodology of the risk assessment.

Stephen T. Washburn

With the exception of the comments listed above, the overall approach used to evaluate baseline risk in the HHRA appears reasonable.

ADDITIONAL REVIEWER COMMENTS

Lee R. Shull

- Page ES-1, line 18-19 (also Page 1-1, lines 23-25): The 1 ppm isopleth and its equivalency to the 10-year floodplain is such an important component of this risk assessment that it warrants more discussion, even in the Executive Summary. Alternatively, a reference to a section(s) of the report where the underlying rationale and essential information for this approach is given should be provided.

  RESPONSE 312:

  The revised HHRA will enhance this description in the executive summary.

- Page ES-5, lines 5-6: The role of the two agencies (EPA and MDEP) should be either elaborated here, or a reference to a description provided in a place elsewhere in the documents should be cited here.

  RESPONSE 313:

  The EPA methodologies, policies, and guidances for conducting risk assessments are applicable to the HHRA. Although the MDEP policies and guidances do not strictly apply, specific information from the Massachusetts Contingency Plan (MCP) is used where appropriate. For example, information on background concentrations of contaminants in soil was cited in the HHRA. It should be noted that the Consent Decree establishes the Performance Standard for residential properties relying upon the MDEP 2-ppm standard (MDEP, 1994).

- Page ES-5, line 21: An explanation of the PSA should be included, or a reference to a definition provided elsewhere in the documents should be cited here.

  RESPONSE 314:

  Clarification will be provided in the revised HHRA.

- Page ES-6, line 8: Given the significance of SRBCs in this risk assessment, it is important to add some additional description of their basis in the Executive Summary (e.g., reference to toxicity criteria used, citing key references, methods used in derivation).

  RESPONSE 315:

  Clarification will be provided in the revised HHRA.

- Page ES-9, lines 1-3: I believe a construction worker should be included in the analysis. This is not a building construction worker (e.g., someone who constructs buildings, which would not be constructed in the floodplain), but rather an earth worker such as a road construction worker. I see nothing in the HHRA that indicates such work would not be done. This is different than a utility worker who may be involved in short-term activity (e.g., trenching). If EPA believes an earth work type of construction worker is not significantly different than a utility worker in regards to the exposure assumptions, then documentation/rationale should be provided.

  RESPONSE 316:

  EPA will include a construction worker in the CSM. However, EPA believes that a building or road construction worker exposure would be unlikely to occur in the floodplain given the potential for flood events and the fact that much of the land within the floodplain is considered wetlands, which would preclude construction activities. There are currently no maintained or paved roads in the floodplain. There are a few dirt roads and easements that were evaluated based on recreational and/or commercial/industrial exposure. EPA believes that the utility worker scenario conservatively covers worker exposure in the floodplain. Thus, a construction worker scenario will not be evaluated.

- Page ES-20, line 9: Additional information should be provided here on the rationale for 10% of all soil and sediment samples to be analyzed for PCB congeners, dioxins, and furans. Because of its significance to the risk assessment, rather than reference the SIWP, the rationale should be provided/described in sufficient detail here.

  RESPONSE 317:

  The revised HHRA will provide additional detail regarding data quality objectives.

- Page 1-2, lines 7-8: The issue of cumulative risk (e.g., summing risks for multiple exposure pathways) should be addressed here. I know EPA has a good explanation for not developing cumulative risk scenarios, and this would be a good place in the Phase 2 Direct Contact HHRA to provide this rationale.

  RESPONSE 318:

  Please refer to the response to General Issue 14.

- Page 1-3, lines 16-19: It would be helpful to readers to better understand land use trends in the flood plain area (i.e., what land uses are diminishing and disappearing and what land uses seem to be increasing or emerging). A better profile of what the land uses in the area are likely to be over the next 30-50 years would be helpful.

  RESPONSE 319:

  Please refer to the responses to General Issues 2.A, 2.C, 2.D, and 2.E.

- Page 1-5, lines 12-20: It would be helpful to readers to explain here the rationale for not applying the Phase 1 screening, as is the usual case, to COPC selection instead of using it only to narrow the study area to be assessed in Phase 2.

  RESPONSE 320:

  EPA will provide additional discussion to clarify this issue in the revised HHRA.

- Page 1-5, lines 24-26: Rationale for including pesticides as COPCs in the fish and waterfowl consumption risk assessment and not in other assessments should be provided here. This explanation should include whether the assessors do or do not consider the GE facility as a source of these pesticides.

  RESPONSE 321:

  Please refer to the response to General Issue 5.C.

- Page 2-2, line 15: Suggest adding a brief statement of rationale for how the analyte list was originally selected should be given here.

  RESPONSE 322:

  The rationale for selection of the analyte list was provided in the SIWP. EPA will provide a specific reference in the revised HHRA.

- Page 2-2, lines 25-27: Suggest adding to the end of this sentence the words "…and to do a quality human health risk assessment."

  RESPONSE 323:

  EPA believes it is inherent in its mission to conduct a "quality" risk assessment, and that such an assessment was conducted.

- Page 2-3, Section 2.3: This section should be expanded and more explanation of DQO provided, or, alternatively, reference made to another section of one of the other reports where the information is given. In particular, a discussion of DQO as related to human health risk assessment and confirmation that the data soil and sediment data were evaluated in accordance with EPA's DQO requirements for risk assessment (EPA, 1992).

  RESPONSE 324:

  The revised HHRA will expand the discussion of data usability, including the rationale for distinguishing between whether the data were of sufficient quality (i.e., met the DQOs) to be used in the HHRA.

- Page 2-3, line 34-page 2-4, lines 1-2: As stated above, this discussion should be expanded, or a document referenced that presents the methods and results of the DQO evaluation in which EPA data are documented as having met all DQOs pursuant to EPA DQO guidance.

RESPONSE 325:

The revised HHRA will expand the discussion of data usability, including the evaluation of the quality of the data to determine if they were of sufficient quality (i.e., met the DQOs) to be used in the HHRA.

- Page 2-4, line 8: Should begin this section by explaining briefly what is meant by "data reduction" and why it is done as a standard practice in risk assessment.

RESPONSE 326:

A brief description will be provided in the revised HHRA.

- Page 2-5, lines 10-12. This sentence implies that other chemicals were screened out (eliminated) in the Phase 1, which is not the case. Please clarify that only "areas" were screened in the Phase 1.

RESPONSE 327:

EPA will provide clarification in the revised HHRA.

- Page 2-5, line 20: What constitutes the PSA should be defined, or reference made to a section of the report that does define the PSA.

RESPONSE 328:

EPA will provide clarification in the revised HHRA.

- Page 2-5, lines 27-29: The discussion presented here on how background concentrations were addressed seems inconsistent with Section 2.5.2.2. Also, it would be helpful perhaps if some discussion about why EPA's 2002a guidance on dealing with background concentrations is not applied in this HHRA.

RESPONSE 329:

EPA will provide clarification in the revised HHRA and reference the use of the EPA 2001a guidance dealing with background concentrations in the revised HHRA.

- Page 2-8, line 7: This sentence is confusing. What is meant by "the initial step"?

RESPONSE 330:

The initial step refers to the three initial criteria used in the screening analysis: the frequency of detection, the frequency of exceedance of the PRG, and the degree of exceedance of the PRG. Please refer to the response to General Issue 5.C.

Also, does "evaluated" mean comparison to background concentrations? Please clarify.

RESPONSE 331:

Yes. Please refer to the response to General Issue 5.C.

- Page 2-8, line 21-23: Rationale for 0-1 ft depth for background samples should be provided.

  RESPONSE 332:

  EPA will provide clarification in the revised HHRA.

  Also, are residential PRGs as shown in Table 2-5 used consistently for background comparisons?

  RESPONSE 333:

  EPA compared the background concentrations to the PRGs for information purposes only. The intent of this comparison was to determine a quantitative evaluation of the background levels in relation to site-related concentrations.

- Page 2-9, lines 10-13: Rationale for not applying standard statistical methods in determining whether concentrations are or are not significantly different from background should be presented.

  RESPONSE 334:

  This rationale will be clarified in the HHRA.

  Also, the basis for applying a ratio of 5 for determining whether site and background concentrations differ should be given.

  RESPONSE 335:

  Page 2-9, line 13, "The remaining chemicals had ratios less than 5" describes the results of comparisons, not a criterion for determining whether site and background concentrations are different. Section 2.5.2.2.3 (page 2-10) describes the rationale for deciding whether or not chemicals are considered similar to background.

- Page 2-9, Section 2.5.2.2.2: Should provide some explanation on where the MDEP samples were collected, so that the reader has some basis for evaluating relevancy of these data.

  RESPONSE 336:

  EPA will provide clarification in the revised HHRA.

- Page 2-10, lines 18-19: The statement that PAHs above background are not site related because they are not widespread in distribution should be eliminated unless better supportive rationale/information can be provided. For example, if there is no historical information related to GE operations that would suggest GE as a PAH source, such additional statements should be added here.

RESPONSE 337:

EPA will add further discussion of the elimination of these COPCs in the revised HHRA.

- Page 2-10, Section 2.5.3 and Table 2-8: In keeping with the development of SRBCs for other purposes in this risk assessment, rationale as to why SRBCs for evaluating sediments could not have been developed also.

RESPONSE 338:

EPA will provide further explanation of this approach in the revised HHRA.

Lack of sediment PRGs is not an acceptable basis for not developing SRBCs (as was done in the Phase 1 assessment), unless solid scientific reasons can be given. If EPA chooses to retain the soil PRGs as screening criteria for sediments, then more justification should be given regarding the appropriateness of using soil PRGs for this purpose.

RESPONSE 339:

EPA will provide this justification in the revised HHRA.

- Page 3-4, lines 7-8: The basis for the statement that the 1996 PCB cancer re-assessment "remains consistent with the 1999 Revised Carcinogen Guidelines" should be provided. If EPA or some other body has issued a written statement that this is true, an appropriate reference should be provided. Also, EPA (2003b) should be referenced on line 8.

RESPONSE 340:

These references will be clarified in the revised HHRA.

- Page 3-4, lines 8-9: Reference to EPA (2003b) should be included.

RESPONSE 341:

The applicable reference will be provided in the revised HHRA.

- Page 4-8, line 20: Please clarify what is meant by "reasonable potential" (page 4-8, line 20) versus "realistic potential" (page 4-9, line 1).

RESPONSE 342:

EPA will provide clarification in the revised HHRA.

- Page 4-8, line 26: Define more specifically what are these restrictions. If they are zoning restrictions, EPA as a rule does not consider zoning as a basis for not addressing a future hypothetical land use.

RESPONSE 343:

Please refer to the response to General Issue, No. 2.A.

- Page 4-11, line 16: Please clarify what is meant by a "high quality fishery" (i.e., why is it described as a high quality fisher?).

RESPONSE 344:

The high-quality fishery is meant to convey that there are fish in the area that anglers seek. Please refer to the Response to General Issue 8.A for information regarding numbers and species of fish in subreaches within Reach 5 as well as Reach 6 (Woods Pond).

- Page 4-13, lines 5-7: This statement should be repeated in (or moved entirely to) the uncertainty section (Section 7).

RESPONSE 345:

The statement regards random exposure which is discussed in Sub-section 4.2.2.1 of the Uncertainty Analysis (Section 7).

- Except for Section 6.2, the rest of Section 6 presents a good overall summary of calculated risks for each of the EAs, exposure scenarios and receptors.
- Section 6.2: Suggest moving most of the information in this section into Section 5 (risk characterization). A summary of the information should be presented in Section 6.

RESPONSE 346:

The revised HHRA will include a number of changes. This suggestion will be taken into consideration.

Because the information presented is very difficult to grasp, also strongly suggest developing a graphic or diagram of some sort to clearly convey the dioxin TEQ process, and how site data are used to derive "predicted" and "expected" dioxin TEQ concentrations. The equation presented on page 6-3 is helpful, but doesn't go far enough.

RESPONSE 347:

The revised HHRA will not include an adjustment for excess TEQ. Please refer to the response to General Issue 5.A.

Also, should add a column in the table on page 6-3 showing the "expected TEQ" concentration. To better illustrate the process, suggest showing an example calculation of the recreation exposure scenario example through to completion (data in Table 6-2).

RESPONSE 348:

The revised HHRA will not include this adjustment. Please refer to the response to General Issue 5.A.

- Page 6-2, lines 15-22: Need further explanation of "expected" vs. "predicted." Also, for consistency, an equation showing calculation of adjusted TEQ (as is done for calculating expected TEQ) is suggested.

RESPONSE 349:

The revised HHRA will not include this adjustment. Please refer to the response to General Issue 5.A.

C. PHASE 2 - FISH AND WATERFOWL EXPOSURE ASSESSMENT (VOLUME IV)

GENERAL COMMENTS

Holly Hattemer-Frey

This volume is the most organized and well-written. Presentation is clear, thorough, and easy to comprehend.

The issue of potential risks to individuals who may participate in subsistence fishing needs to be evaluated in more detail. There is clearly contention among members of the public that some local Indians do participate in subsistence fishing and risks to these individuals have not be quantified. EPA needs to provide evidence supporting a claim of no subsistence fishing or quantify risks to these individuals.

RESPONSE 350:

Please refer to the response to General Issue 3.C.

Just because waterfowl were not sampled directly in Connecticut does not mean that risks for consumption of waterfowl by Connecticut residents can't and shouldn't be calculated. In the absence of actual sitespecific data, the HHRA should adopt a conservative method for quantitatively evaluating human exposure to waterfowl by Connecticut residents. The most conservative approach would be to assume that waterfowl in Connecticut are contaminated at the same level as waterfowl in MA. Or since tPCB concentrations decrease with increasing distance from the source, tPCB concentrations in Connecticut waterfowl could be adjusted to reflect this decline and risks quantified.

RESPONSE 351:

Please refer to the response to General Issue 9.E.

Section 3.2.4.2, page 3-10, lines 3-14. It is not clear how the expected TEQ concentration was calculated using the data listed in Table 3-3. Table 3-3 provides a listing of the data and results but does not provide a sample calculation (as the text states). Please provide a sample calculation.

RESPONSE 352:

Please refer to the response to General Issue 5.A.

Also, line 10 states that expected the TEQ concentration was subtracted from the predicted TEQ concentration. Please clarify which value in Table 3-3 is the predicted value? It would be useful to provide information on the number of waterfowl that actually reside in the affected area, so that consumption rates and exposure frequencies assumed in the HHRA can be balanced against reasonable hunting practices.

RESPONSE 353:

Please refer to the responses to General Issues 5.A and 9.C.

Sections 4.3.4.1 and 4.3.4.2 are redundant and should be combined.

RESPONSE 354:

The text will be edited in the revised HHRA to make it less redundant.

Fig 5-1: The incorrect figure is included. Fig 5-1 lists cancer risks associated with consumption of agricultural produce, not fish consumption.

RESPONSE 355:

The Reviewer is correct. The revised HHRA will have the correct figure. The CD version of the HHRA report had the correct figure.

Page 8-2, lines 27-30 & Table 8-1: The text states that data presented in Table 8-1 show a steady decline in cancer risk estimates from Reaches 5 & 6 downstream to Lakes Lillinonah and Zoar. While this is true, it would be helpful if the text clarified to what extent the reduction in cancer risk could be attributable to the fact the only bass and trout were sampled in lower reaches (versus just declining concentrations in general as one progresses further away from the source).

RESPONSE 356:

The revised HHRA will include additional text describing the summary figure, including the impact of the different data sets available for fish tissue in Massachusetts and Connecticut.

F. Owen Hoffman

Additional specific comments within Volume IV, Appendix C:

Pg. 4-30, Table 4-10: Why is the averaging time for non-cancer health effects taken to be 54 years for an adult and 6 years for a child? I would expect one year to be sufficient for estimating the non-carcinogenic effects of PCB's.

RESPONSE 357:

The noncancer evaluation is based on chronic exposure, which was assumed to be 6 years for a child and 54 years for an adult. Toxicity values for shorter exposure durations (subchronic exposures) are not available.

For non-carcinogenic effects, the dose rate is more important than cumulative dose as is the case for carcinogens.

RESPONSE 358:

EPA agrees with the Reviewer. Estimates of the average daily dose of a contaminant, as a result of chronic exposure (see response above), are compared to the reference dose for noncancer effects. With respect to the estimated risk of cancer incidence, a greater exposure during a lifetime results in a greater cancer risk.

Pg. 4-34, Table 4-11: For the estimate of health risk, the central tendency estimate is more appropriately the arithmetic mean than the median for either an individual or a potentially exposed population.

RESPONSE 359:

Table 4-11 is simply a presentation of data from Ebert et al., 1993. The CTE fish consumption ingestion rate used in the HHRA was based on the arithmetic mean (page 4-4, Table 4-17).

Pg. 4-40 to 4-41: What is the justification for not using the 95th percentile ingestion rate for the assessment of non-cancer health effects? In any given year, it is likely that an angler could consume more fish than a value averaged over a prolonged time of residency, (say 50 to 60 years).

RESPONSE 360:

Please refer to the response to General Issue 8.A. As stated in a previous response, the noncancer evaluation is based on chronic exposures.

Page 4-42: I believe the ingestion rates of fish for ages 3 to 5 are biased high for the selected target group of children ages 1 to 6. I do not expect the average ingestion rate for children in this age group to be only a factor of 0.5 of that of adults.

RESPONSE 361:

Please refer to the response to General Issue 8.A.

Page 4-50, the assumption that all fish consumed are fish caught from the Housatonic River at the location of interest by the CTE is extremely pessimistic, especially for exposure durations that extend for 20 to 60 or more years.

RESPONSE 362:

Please refer to the response to General Issue 8.B.

Page 4-58, Table 4-28: Although the exposure duration for non-cancer health effects may be as long as that for cancer, the critical time of exposure could be as short as a single year. The for non-cancer health effects, the exposure rate is often more important than is the cumulative exposure over time and for young children the highest ratio between intake and body weight will occur in the first few years of life.

RESPONSE 363:

Please refer to the response to General Issue 3.B.

Pages 4-60 through 4-69, Tables 4-30 through 4-39: The ratio between the CTE and RME doses for non-cancer exposures appears too narrow to meet my sense of face validity. I would expect a difference much greater than a factor of 2, approaching a factor of almost 10 or greater. This difference is perhaps due to the assumption that both the RME and the CTE catch and consume all of their fish from a given location within the Housatonic River and that fishing occurs in a uniform manner throughout the year, with no difference occurring between the summer months (when most creel surveys are conducted) and the winter months. I believe the estimates for the RME are about right, but the CTE estimates are biased high.

RESPONSE 364:

As discussed in the responses to General Issues 8.A and 8.B, for the CTE, the revised HHRA will be based on a decreased fish consumption rate and a decreased fraction ingested (FI). Combined, these changes will yield a ratio of reasonable maximum exposure (RME) to central tendency exposure (CTE) of at least 7, with a larger ratio if differences in exposure duration and cooking loss were factored in. However, the Reviewer is incorrect that the HHRA makes an assumption that fishing occurs in a uniform manner throughout the year. The HHRA makes no such assumption. An annual average rate of consumption is used in the calculation, but the actual consumption may take place unevenly throughout the year. The consumption rate is based upon the Maine Angler Survey, which evaluated fishing from all seasons.

Page 4-78, Tables 4-46 and 4-47: Again I believe that a bias is introduced with the direct application of the data on poultry consumption for children ages 3 to 5 as a surrogate for the age group 1 to 6. I anticipate that the age groups of 1 to 3 would be much less than the average for the age group 3 to 5.

RESPONSE 365:

As described in the response to General Issue 3.B, chronic exposure for a young child (ages 1 to 6) was evaluated in the HHRA. Because toxicity values for shorter exposure durations (subchronic) are not available, the revised HHRA will retain the young child (ages 1 to 6) as the child receptor. The bias introduced by consideration of a younger age group disappears when the larger age group is considered. The uncertainty section for all exposure pathways will be expanded to discuss this potential underestimation of exposure and risk to the very young child.

I also anticipate that the dietary survey is not appropriately age averaged. I anticipate more participants in the 4 to 5 year old range than in the 3 to 4 year old range. If the non-cancer Hazard Index is averaged over 1 year instead of 6 years, the intake to body weight for a one to 2 year old is expected to be much higher than the value of 1.1 g/kg-d given for the age group 3 to 5 years.

RESPONSE 366:

Please refer to the response to General Issue 3.B. The dietary survey from which the data were taken was the USDA Continuing Survey of Food Intakes by Individuals for the years 1989-91. Using a stratified sampling technique, individuals of all ages living in selected households in the 48 conterminous states and Washington, DC, were surveyed. Over 15,000 individuals provided food intake data (EPA, 1997). EPA has no reason to believe that there were more individuals in the 3- to 4-year-old range than the 4- to 5-year-old range.

Page 4-79: Why is the meal size for the consumption of poultry less than that for fish (i.e., 110 g per meal as compared with 227 g per meal)?

RESPONSE 367:

Please refer to the response to General Issue 9.B.

Page 4-81, Tables 4-48 and 4-49: the exposure duration and averaging times for noncancer health effects seem very long. This would be appropriate if the non-cancer health impacts are the result of the cumulative lifetime exposure to PCB's as opposed to the maximum annual exposure rate. Although, for the assessment of the non-cancer HI, the averaging time and exposure duration cancel, the ratio of intake-to-body weight will differ markedly for children of ages 1 to 3 than for children ages 3 to 6. The differences in the ratio of body weight to-intake will be even more pronounced for children ages 1 to 3 than for adults. The ratio of body weight-to- intake will directly affect the magnitude of the Hazard Index.

RESPONSE 368:

Please refer to the response to General Issue 3.B.

Page 5-3, Figure 5-1, and Page 5-5, Figure 5-2: There are too many variables displayed and subsumed within the colored bars. At the very least, the risks and HI's for the RME should be kept separate from the CTE. Figure 5-1 shows the importance of carefully investigating the affect of conservatism associated with the use of one half the detection limit for dioxin- like congeners of PCB's and the assignment of specific TEQ's for each congener. Variation due to River Reach should be separated from variation due to the RME and CTE.

RESPONSE 369:

Please refer to the response to General Issue 13.B.

Pages 5-7 through 5-31, Tables 5-2 through 5-21: show in each table the value used as the Exposure Point Concentration. For example, it is apparent in Table 4-7 on page 4-25 that the EPC for Smallmouth Bass-West Cornwall/Bulls Bridge is more than one half that of Brown Trout-West Cornwall, yet the cancer risks and HI for Brown Trout are less than those calculated at the same location for Smallmouth Bass. This seems counterintuitive, until one remembers that different ingestion rates are assumed for Smallmouth Bass than for trout. This should be pointed out in a footnote to the tables.

RESPONSE 370:

The revised HHRA will include a footnote as recommended.

ADDITIONAL COMMENTS ON VOLUME IV, APPENDIX C, CHAPTER 6 OF THE HHRA:

1. Page 6-1: the CTE should approximate the mean, not the median of the population of recreational anglers.

   RESPONSE 371:

   The text characterizing where the CTE falls on the distribution will be clarified in the revised HHRA.

2. Page 6-11: the HHRA states that the exposure point concentration (EPC) should be evaluated with a probability bounds analysis by substituting an interval for the point estimate. The interval "must be bounded below by a value that is known to be as low as the EPC could possibly be and above by a value that is known to be as high as the EPC could possibly be." But, in actuality the bounds are the sample mean and the EPC, whereby the EPC is the upper 95% confidence limit of the mean. The lower confidence limit on the mean is not used. This leads to an upward bias in the overall estimate of exposure and risk to the RME and CTE.

   RESPONSE 372:

   Please refer to the response to General Issue 4.D.

3. Pages 6-28 through 6-92, Figs. 6-17 through 6-103: all figures should be replotted using a logarithmic scale since the results span several orders of magnitude. The point estimates of the RME and CTE risk values in Chapter 5 should be included for comparison.

   RESPONSE 373:

   EPA agrees that the presentation of results can be improved, and this suggestion will be addressed in the revised HHRA.

4. Pages 6-60 through 6-91, Tables 6-6 through 6-13: the depiction of the RME as belonging to a subgroup potentially spanning the 90th to the 99th percentile of the population is useful. Additionally useful would be information about the potential size of the population of anglers being simulated.

   For example, if the population of recreational anglers were to approach 10,000 persons, the upper 90th percentile of the distribution would underestimate exposures and risks for the top 1000 individuals and the 99th percentile would underestimate exposure and risks for the top 100 persons.

RESPONSE 374:

Please refer to the response to General Issue 1.B.

For this reason, I believe it best to target the analysis on the RME and CTE as separate entities and not attempt to simulate inter- individual variability as a stochastic process. There are defined reasons (by number of fish meals and length of residency in the region) that can explain the major sources of individual variability of exposure. Variability need not be treated as a purely stochastic process. For the sake of transparency and ease of analysis, I would replace the one-dimensional Monte Carlo analysis of aleatoric variability with a one-dimensional analysis of epistemic uncertainty targeted at reference persons representing the attributes of the CTE and RME.

RESPONSE 375:

Please refer to the response to General Issue 10.A.

Because the HHRA probabilistic analysis is supposed to investigate the uncertainty in true exposures and risk, I recommend that the probabilistic risk analysis include the uncertainty in the PCB and TEQ concentrations in fish and the uncertainty in the toxicity factors (i.e., the cancer slope factor for PCB's and Dioxin, the Toxicity Equivalent Factors for dioxin- like PCB's, and the RfD for PCB's consumed in fish).

RESPONSE 376:

Regarding uncertainty in the concentration term, please refer to the response to General Issue 4.C. Regarding uncertainty in toxicity factors, please refer to the response to General Issue 12.B.

The uncertainty in EPA toxicity coefficients may need to be undertaken as an effort that is external to this particular assessment for the Housatonic River. Nevertheless, I feel that such information would be of value to risk managers, especially given the magnitude, cost, and potential disruption to sensitive habitats created by remediation efforts.

RESPONSE 377:

Please refer to the response to General Issue 12.B.

5. General comments on Chapter 6:

I believe it best to perform a probabilistic uncertainty analysis on the CTE and the RME separately and to include the uncertainty in the mean concentration of PCB's and dioxin-like congeners in fish and waterfowl and the uncertainty in the EPA toxicity coefficients for cancer and non-cancer health effects.

RESPONSE 378:

Regarding separate analyses on the CTE and RME, please refer to the response to General Issue 10.A. Regarding uncertainty in the concentration term, please refer to the response to General Issue 4.C. Regarding uncertainty in toxicity factors, please refer to the response to General Issue 12.B.

If EPA insists on using Monte Carlo techniques to simulate variability and exposure within the general population of recreational anglers using the questionable assumption that all inter- individual variability is stochastic, then I would prefer the use of two dimensional (second order) Monte Carlo simulation over the present probability bounds analysis to address epistemic uncertainty. Second order Monte Carlo analysis is well established in the general risk assessment community. The inner loop simulates the unknown frequency distribution, the outer loop generates alternative realizations of this unknown distribution based on all quantities for which there is lack of knowledge. In this case, I would prefer for the size of the simulated population be specified and that the upper 99.9th percentile of the distribution be quantified.

RESPONSE 379:

The revised HHRA will include a comparison (for one site, path, receptor, and model) between a second-order Monte Carlo simulation and the current assessment consisting of the one-dimensional Monte Carlo simulation and probability bounds analysis.

1. Were the approaches and methods used to calculate EPCs for the fish and waterfowl consumption scenarios appropriate under the evaluation criteria?

COMMENTS

Holly Hattemer-Frey

The comment about the application of bootstrapping techniques to calculate EPCs made previously applies to the fish data as well.

RESPONSE 380:

Please refer to the response to General Issue 4.A.

Section 2.2.2.3 describes how total cancer risks were lowered slightly to account for the amount of dioxin-like PCBs in the CSF for PCBs. The text further states (page 2-11, lines 5-6, for example) that uncertainty associated with calculation of the expected TEQ could over- or underestimate cancer risk from exposure to PCBs. Since 1) the authors admit that there are no reports in the open literature (or EPA documents presumably) that address methods for avoiding double counting, and 2) Dr. Keenan presented a compelling argument that the CSF already accounts for the presence of dioxin-like PCBs, I recommend that this approach be eliminated. If the authors do keep the adjustment in the report, they need to quantify to what extent risks may be over- or underestimated using this approach (versus just qualitatively discussing this point). See additional comments on this topic made under "E. Phase II – Integrated Risk Evaluation."

RESPONSE 381:

Please refer to the response to General Issue 5.A.

For Reaches 5 & 6, fish data used were "skinned and trimmed fillets." Use of these data may underestimate risks for individuals who cook and consume fish with the skin on. Did any of the three studies cited in Table 4-12 provide insight into whether individuals prepare and consume fish with the skin on? If not, the cooking loss data for PCBs presented in Tables 4-18 and 4-19 for skin-on and skin-off fillets might provide a basis for estimating the concentration of PCBs in fish with skin on. Table 4-19 shows that loss of PCBs during cooking is higher for skin-on fillets versus skin-off fillets, which suggests that the concentration of PCBs in fish consumed by anglers would be higher than that measured in "skinned and trimmed fillets."

RESPONSE 382:

The Maine Angler Survey provides data regarding preparation (but not consumption) of fish fillets with and without skin. These data will be discussed in the revised HHRA. Please refer to the response to General Issue 8.C for additional discussion regarding cooking loss.

It is appropriate to combine the four fish species into two discernable groups, to calculate one EPC for fish, and to use those EPCs to calculate doses for a general angler. This approach, however, does not account for the angler who may consume only one group of fish (bass/bullhead or sunfish/perch). Since the concentrations in these two groups of fish were statistically different, risks to individuals who consume fish from one group only could be over- or underestimated. I suggest calculating risks to individuals who may consume only one group of fish to resolve this issue.

RESPONSE 383:

As part of the uncertainty analysis, the HHRA presented the EPCs associated with individual fish species for the locations evaluated in Massachusetts (Appendix C, Table 7-2). As pointed out in the text, there is approximately a two-fold difference in concentration and thus in risk between the bass/bullhead and sunfish/perch groups of fish. The revised HHRA will include this information and take the calculation through to the risk estimate.

Furthermore, the analysis does not take into account the fact that some individuals may fish repeatedly in the same small area (i.e., a favorite spot), particularly when evaluating data for Reaches 5&6, which cover a relatively large area. The text should discuss how fish concentrations vary within EAs and the potential to underestimate risks if individuals fish in one area versus randomly within and EA (as was assumed). I would prefer to see actual quantification of risks to individuals who consume fish from one area only, especially for areas within Reaches 5 & 6.

RESPONSE 384:

Additional discussion will be added to the revised HHRA to address this comment.

To account for the fact that some of the waterfowl that could be consumed from the study area are migratory, the EPC was modified. I recommend that FI be adjusted versus the EPC as a more technically-correct approach. FI should be set equal to the percentage of waterfowl in the area that are resident (non-migratory) birds.

RESPONSE 385:

The waterfowl EPC was not modified to account for migration. The consumption rate is consistent with the consumption of only resident waterfowl. Please refer to the response to General Issue 9.C.

F. Owen Hoffman

Yes, for the purposes of a deterministic baseline risk assessment. The uncertainty analysis should include some probability that the RME and CTE catch freshwater fish in other locations besides the Housatonic River.

RESPONSE 386:

Please refer to the response to General Issue 8.B.

There is also a need to evaluate the potential for the present concentrations to be reduced with time due to the continuous process of sedimentation with uncontaminated materials covering old contaminated sediment leading to reductions in future PCB concentrations in fish and waterfowl.

RESPONSE 387:

As discussed in the response to General Issue 4.D, no temporal trend in concentrations in sediment has been identified. Thus, basing the risk assessment on current concentrations is the most appropriate, data-driven approach.

John C. Kissel

Methods used to calculate EPCs appear to be generally reasonable and consistent with EPA guidance. Missing data for some fish species in some reaches and waterfowl in Connecticut are weaknesses.

RESPONSE 388:

The revised HHRA will add a discussion regarding the lack of data for some fish species in the uncertainty section. Please refer to the response to General Issue 9.E for discussion regarding waterfowl in Connecticut.

Roger O. McClellan

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

RESPONSE 389:

Please refer to the response to General Issue 9.C.

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

RESPONSE 390:

EPA believes the size of the data sets for fish and waterfowl tissue were adequate. Data distributions were determined using EPA software (ProUCL, 2002e) applying statistical tests that were appropriate for the sample size (see page 4-17, lines 19 through 28). The Land H-statistic was used only to calculate the 95% UCL for distributions that met the criteria for lognormal distributions. Otherwise, a bootstrap method was used.

A major issue of concern for the waterfowl exposure relates to the killing and eating of local or native birds versus migratory birds. In my opinion, as noted above, the productivity of the river very likely does not provide sufficient ducks for harvesting to match to the input parameters in the modeling. In order to satisfy even realistic estimates of ducks harvested (numbers that are likely much smaller than used in the assessment), it is necessary to assume that a substantial portion of the ducks harvested are migratory fowl. These migratory fowl will have a very low content of PCBs from the Housatonic River flood plain because of their short residence time. Most assuredly, the migratory fowl will not have PCB levels equivalent to those found in the resident birds.

RESPONSE 391:

Please refer to the response to General Issue 9.C.

P. Barry Ryan

I believe that the approaches and methods used in this aspect of the risk assessment were adequate under the evaluation criteria. One may question the degree to which migratory waterfowl influence the exposure and the productivity of the fisheries in the area. Does one expect a dilution of the waterfowl effect by the presence of off-site waterfowl in the area during hunting season? If so, has this been accounted for?

RESPONSE 392:

Please refer to the response to General Issue 9.C.

Could the Housatonic support a large-scale fishery? What is the overall productivity? These are important questions for future use.

RESPONSE 393:

Please refer to the response to General Issue 8.A.

Lee R. Shull

In general and except for the following comments, the approaches and methods used to calculate EPCs for fish and waterfowl consumption are considered appropriate.

This section describes the fish and waterfowl tissue data available for use in this HHRA. Mention is made of other data that are available, but were not considered for use in the assessment. All available data should be described and subjected to the data usability evaluation, or clear explanation as to why not.

RESPONSE 394:

All data available for use in the fish and waterfowl risk assessment were described in Appendix C, Table 2-1, with the exception of the waterfowl and fish tissue samples collected from the reference areas. These data will be included and discussed in the revised HHRA. The table title will be clarified in the revised HHRA. In addition, Section 2.2, Available Data (pages 2-1 through 2-10) described the available data sources in text. Section 2.3, Data Usability and Validation (pages 2-10 through 2-27) described in detail how all data sets were subjected to the data usability evaluation and how data from the sources deemed usable were selected to produce the most relevant data set from which to evaluate risks from fish and waterfowl consumption.

Three criteria for selecting fish tissue data for use are identified. It is unclear as to whether these criteria were applied for an initial compilation of data, or if these criteria were applied to determine data usability in Section 2.3. These criteria include: 1) species typical of those consumed by humans, 2) tissue type representative of those consumed by humans, and 3) consistency with data quality objectives.

RESPONSE 395:

These criteria were applied to the data sets considered usable.

It is unclear as to whether temporal trends were considered in the selection of fish and waterfowl tissue data for risk assessment, since this was not listed as a criterion, and is not discussed in Section 2. However, it appears from comparison of Table 2-1 (Sources of Data Used in the Fish and Waterfowl Risk Assessment) with the data sets described in Section 3 (Data Usability and Validation) that fish tissue data collected before 1984 were not considered for use in the HHRA.

The selection of applicable and usable data for HHRA purposes should follow a systematic and transparent process.

RESPONSE 396:

The selection of data for use in the risk assessment followed a systematic process presented in Section 2.3, Data Usability and Validation (pages 2-10 through 2-27). Data usability was ranked based on six data evaluation criteria described in *Guidance for Data Usability in Risk Assessment* (EPA, 1992c). This ranking system, including how the date of collection was incorporated into the process and the individual data source scores, is described on pages 2-15 through 2-17, with a detailed discussion of the process provided in Attachment C.2. There were no temporal trends observed in the evaluation of all data in Massachusetts; however, there is a temporal trend in the data collected in Connecticut with a decrease in concentrations over the past until recently, when concentrations appear to have reached a plateau. This will be discussed in the revised HHRA.

Page 1-1, lines 23-25: Should refer to some other document or source regarding the discussion on the floodplain extending to the 1 ppm isopleth and its correspondence to the 10-year floodplain.

RESPONSE 397:

The 1-ppm isopleth is the definition of the lateral extent of the Rest of River in the Consent Decree. The approximate correspondence of the 1-ppm isopleth to the 10-year floodplain is based on information provided in the RFI (BBL, 1996, and BBL and QEA, 2003). A reference to these reports will be added to the revised HHRA.

Page 1-19, lines 9-10: Further discussion of the probability bounds analysis is needed, or reference to another section of the report where this additional discussion can be found.

RESPONSE 398:

A reference to Attachment 5 of Volume I, The Probability Bounds Analysis, will be added to this section in the revised HHRA.

In Section 2.2.1.1, it is stated that Total PCB (tPCB) concentrations for EPA Supplemental Investigation Data were calculated from PCB congener concentrations, but in Section 2.2 (Recent GE Data), tPCBs were analyzed as Aroclors. If tPCBs, as described in Section 2.2.1.1, was calculated as the sum of the PCB congeners, it is important to understand which congeners were specifically included in the summation. Section 2.3.1 indicates that 120 congeners were quantified in the EPA Supplemental Investigation data set, but it is unclear whether all 120 congeners were summed to estimate tPCB concentrations. If tPCB referred to in Section 2.2 are actually Aroclor data (or the sum of Aroclor concentrations), then the data should be described as such.

RESPONSE 399:

The calculation of tPCB concentrations will be clarified in the revised HHRA.

Throughout the risk assessments, the term "total PCB" and "tPCB" should be defined more definitively. Since the laboratory animal toxicity studies of Aroclor mixtures reflect toxicity associated with very specific and well-defined mixtures (e.g., Aroclor 1254), the uncertainty associated with the application of these toxicity data to PCB data represented by different analytical methods should be described in detail, including the implications of the assumptions used to combine data from different sources.

RESPONSE 400:

The revised HHRA will include clear definitions of and distinctions between Aroclors and tPCBs in the introductory sections of each of the documents. The discussion of the uncertainty associated with the application of commercial Aroclor data to environmental mixtures was provided in Volume 1, Section 2 of the HHRA. EPA does not agree with the Reviewer's comment that commercial Aroclor mixtures are that well defined with respect to congener concentrations. Although the chlorination percentages and the pattern of homolog groups in different commercial mixtures of PCBs, including Aroclors, are generally known, there are batch-to-batch differences in homolog patterns, congener concentrations, and impurities such as polychlorinated dibenzofurans (Erickson, 2001). Please refer to the response to General Issue 12.B for additional information regarding the uncertainty of PCB toxicity factors.

To that end, the specific PCB analytical methods used for each data set used in the risk assessment and the methods and rationale for combining data should be described in detail.

RESPONSE 401:

Additional information on analytical methods will be provided in the revised HHRA.

Data usability was determined by assignment of a "score" to each data set based on criteria presented in Table 2-6, and the scores for each data set are presented in Table 2-7. However, there is no indication of the individual criteria scores for each data set, and therefore, it is not possible to ascertain the basis for selecting specific data sets as usable for risk assessment.

RESPONSE 402:

This information will be provided in the revised HHRA.

In Section 2.3 (Usability and Validation), there is no discussion of Data Validation for any data set, nor is there any detailed discussion of data quality with respect to field duplicate samples, laboratory quality control samples, or estimated and rejected data.

RESPONSE 403:

The purpose of the data quality review (as presented in Section 2.3) was to identify the data appropriate for use in the fish and waterfowl consumption risk assessment. A reference to the Quality Assurance Project Plan (QAPP), as well as a discussion of duplicate samples and analytical variability, will be provided in the revised HHRA. The final data qualifiers assigned by the data validator were noted in Attachment C.3, Raw Data.

Tables 2-2, 2-4, and 2-5 summarize EPA Supplemental Investigation Data, Recent GE Data, and Historical Data for fish tissues. These data include fillet (skin-on and skin-off), composite, whole body, offal, and ovaries data. These tables should indicate which data were used in the quantitative risk assessment.

RESPONSE 404:

The tables will be revised to indicate the data that were used in the quantitative assessment in the revised HHRA.

Page 2-1, line 25: Again, an explanation should be provided as to why other edible body parts were not sampled (see comment in ES-5, line 7 above).

RESPONSE 405:

Please refer to the response to General Issue 9.A.

Table 2-1: Of the data sources described in this Table, those determined to be usable for risk assessment include "EPA data, recent GE data, and the data from Coles, 1996." (see Section 2.3). The discussion of these data is not balanced. There is an extensive discussion of the EPA Supplemental Investigation Data, a brief discussion of the Recent GE Data, and no discussion of the Coles (1996) data. Furthermore, there is no explanation as to why the Coles (1996) data were included in the risk assessment, but the Smith and Coles (1997) data, the MADEP data, and the State of Connecticut data were excluded.

RESPONSE 406:

Discussions regarding the available data were limited by the information available to EPA. In the case of historical data sets, little or no information regarding the sampling and analysis program and regarding data quality objectives were available, hence the disparity in the breadth of discussions provided. Data sources and specific samples were eliminated from the available data, as presented in Section 2.3, Data Usability and Validation (pages 2-10 through 2-27). Lastly, as indicated in Section 2.3.4.1.4, Fish Sample Data Set, page 2-25, lines 17 through 18, the Coles 1996 data were not included in the fish data set.

Page 2-4, lines 19-20: Should reference a section where the tPCB concentrations were calculated from congener concentrations are explained.

RESPONSE 407:

Total PCB concentrations were calculated by the laboratory and provided to EPA. Text will be added to the revised HHRA to clarify.

Page 2-6, lines 1-8: When referring to tissue concentration data, please clarify whether all concentrations are lipid normalized, or expressed on some other basis.

RESPONSE 408:

The concentrations were not lipid normalized; this will be clarified in the revised HHRA.

Page 2-7, line 1: Before (pg 2-6, line 18), the statement is made that waterfowl are yearround inhabitants of the area. Here, reference is made to migration. Please clarify whether the birds of interest migratory or non-migratory.

RESPONSE 409:

The text on page 2-6, line 18, refers to Canada geese which are year-round inhabitants of the Housatonic River Area. The text on page 2-7 refers to ducks, which do migrate, but some are reared in Reaches 5/6 prior to migration. Waterfowl consumption exposure includes both geese and ducks.

Page 2-7, lines 9-10: Again, no thigh or gizzard analyses were conducted. Is it assumed that concentrations in breast represent thigh as well?

RESPONSE 410:

As stated in the text, analytical tests were conducted on breast tissue and liver tissue. Please refer to the response to General Issue 9.A for a discussion of breast versus thigh tissue.

Page 2-7, line 20: Please clarify how/whether fish data were used in the revised RCRA permitting process. Further explanation here warranted.

RESPONSE 411:

It is unclear what the Reviewer is asking for. Although the fish consumption advisories are the responsibility of the States, there is a provision in the revised RCRA permit which involves EPA in assuring that appropriate signage regarding the advisories is maintained in the areas of concern. In addition, the modeling study that is being conducted will make use of the fish data in model calibration, validation, and comparisons to the projections of future baseline conditions. Lastly, as required in the revised RCRA permit, an evaluation of the biota data was included in the revised RFI (BBL and QEA, 2003).

Page 2-11 to 14, Tables 2-5. Given the fish analyses go back as far as 1977, the RA should contain more information verifying that all the data are usable for RA purposes…

RESPONSE 412:

Section 2.3, Data Usability and Validation (pages 2-10 through 2-27), describes in detail how all data sets were subjected to the data usability evaluation and how data from the sources deemed usable were selected to produce the most relevant data set from which to evaluate risks from fish and waterfowl consumption.

DQO process. Please clarify the makeup of the DQO team, and whether a separate DQO report was issued.

RESPONSE 413:

The revised HHRA will provide additional information on the DQO process and results along with citations to relevant documents.

Page 2-15, lines 4-5; 11-13: This DQO statement is very brief. Please clarify whether there is a separate DQO report. A reference to Attachment C.2 should be added.

RESPONSE 414:

The revised HHRA will provide additional information on the DQO process and results along with citations to relevant documents.

Page 2-23, line 9: Ice fishing has not been addressed in this HHRA. Please add information on the relative frequency of winter ice fishing compared to other times of the fishing season.

RESPONSE 415:

The occurrence of ice fishing will be described further in the revised HHRA. Ice fishing is frequently observed at impoundments in the winter. Ice fishing was addressed implicitly in the calculation of risks from eating fish (other than trout), because the consumption rate was an annualized value and was based upon the Maine Angler Survey, which evaluated consumption from fishing year-round.

Page 2-25, line 18: Please be specific as to what criteria are be referred to here.

RESPONSE 416:

This will be clarified in the revised HHRA.

Page 2-27, line 4: Should comment on other edible tissues (see comment under ES-5, line 7 above).

RESPONSE 417:

Please refer to the response to General Issue 9.A.

Page 2-29, line 10: The reference of this USGS study done for EPA should be provided.

RESPONSE 418:

This reference will be added to the revised HHRA.

Page 2-31, line 1-2: Should comment/discuss the applicability of these RBCs and the basis of their derivation. Reference table 2-12, which provides some basis. Should explain that their use in this HRA is in accordance with their intent.

RESPONSE 419:

Additional information will be provided in the revised HHRA to address these comments.

Page 2-35, table 2-12: Please provide the basis for the 54 g/day fish ingestion rate, which seems very high.

RESPONSE 420:

Table 2-12 lists the parameters used by EPA Region 3 to calculate fish risk-based calculations. They were used in the HHRA only to provide a conservative screening concentration to select COPCs other than PCBs and TEQ.

Page 2-41, lines 24: Combining perch and sunfish was done in Reach 5/6, but not in Rising Pond. An explanation of why this was not done in Rising Pond is warranted.

RESPONSE 421:

Statistical comparisons of the data showed significantly different distributions of PCB concentrations in fillets of perch and sunfish from Rising Pond. This was described in Volume C, Subsection 2.5.2.2, Rising Pond, page 2-41.

Stephen T. Washburn

The following recommendations are made regarding the calculation of EPCs for these scenarios:

- The approaches used in the HHRA to calculate the 95% UCL should be reviewed. The use of Land's H-statistic to calculate 95% UCL values for lognormal distributions is typically reliable for substantial datasets that are truly lognormal, but can provide unreliable results if the dataset is small or deviates from lognormality. It is recommended that EPA confirm the 95% UCL values using bootstrap methods, such as Efron's BCa (bias-corrected and accelerated) nonparametric bootstrap (Efron, B. and R. J. Tibshirani. 1998. An Introduction to the Bootstrap. Chapman & Hall/CRC, Boca Raton). For an empirical distribution that is approximately normal, the bootstrap confidence interval will be essentially the same as the normal confidence interval. For an empirical distribution that is not normal, however, the bootstrap prediction interval will be more accurate than a confidence interval calculated assuming a normal (or even lognormal) distribution, according to EPA guidance, “The Lognormal Distribution in Environmental Applications” (EPA 1997).

RESPONSE 422:

Please refer to the response to General Issue 4.A. In addition, EPA guidance was followed for calculating 95% UCLs. Data distributions were determined using EPA software (ProUCL, 2002e) (see page 4-17, lines 19 through 25).

- The HHRA does not include an evaluation of risks posed by consumption of waterfowl in Connecticut, due to a lack of data for calculating EPCs in the tissue of waterfowl along the Housatonic in that state. Given public concern regarding the consumptions of waterfowl, and the relatively high risks estimated in the HHRA for this scenario in Massachusetts, it is recommended that EPA include at least a semi-quantitative assessment for Connecticut in a sensitivity analysis based on relative concentrations of PCBs in soils and other media to which the waterfowl may be exposed.

RESPONSE 423:

Please refer to the response to General Issue 9.E.

- It is implicitly assumed that PCB concentrations in fish and waterfowl will remain constant over the time period considered in the HHRA (i.e., up to 60 years). The HHRA should present data from the Remedial Investigation or other site studies to provide a basis for understanding to what extent this represents a significant conservative assumption, given phenomena that may act to change PCB concentrations in water, sediment, and fish tissue.

RESPONSE 424:

An evaluation of the data for trends was presented in the revised RFI (BBL and QEA, 2003). Further discussion will be added to the revised HHRA. Please refer to the response to General Issue 4.E.

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

COMMENTS

Holly Hattemer-Frey

Tables 4-42 and 4-43: It is not clear why different consumption rates (g/day) were used to calculate non-cancer and cancer doses from consumption of waterfowl. Table 4-42 list an adult RME consumption rate of 5 g/day, while Table 4-43 lists an adult RME consumption rate of 20 g/day. CTE consumption rates for adults and children are consistent between the two tables.

RESPONSE 425:

The discrepancy is a presentation error that will be corrected in the revised HHRA. This error was not carried through in the calculations.

Noncancer doses reported in Table 4-51 are not consistent with the ingestion rates of 20 and 10 g/day listed in Table 4-43, so I suspect the RME consumption rates listed in Table 4-43 are erroneous.

RESPONSE 426:

Table 4-43 has a presentation error that will be corrected in the revised HHRA. This error was not carried through in the calculations.

The authors appropriately elected to use fish ingestion rates from the Maine Angler Survey. Given the information presented by Ms. Ebert, however, it seems clear that the ingestion rates selected by EPA were incorrect (too high). The consumption rate of 32 g/day used in the RA was based on a sensitivity analysis. Using the empirical data reported by Ebert et al., a 95th percentile fish ingestion rate of 12 to 16 g/day would be more appropriate.

RESPONSE 427:

Please refer to the response to General Issue 8.A.

I agree that assuming an individual consumes one fish meal a day from the Housatonic River, 365 days a year, for 60 years seems overly conservative. On page 4-31, lines 6-8, the report notes that according to the MDPH survey, 32% of residents claimed to consume freshwater fish one to four times a month, 26% one to two times a week, and 1% at least three times a week. This survey information should be used to adopt an upper-bound number of meals likely to be consumed by adults (e.g., an EF of two to three fish meals per week from the Housatonic River seems more reasonable).

RESPONSE 428:

Please refer to the response to General Issue 8.A.

The waterfowl scenario assumes individuals consume only breast tissue with skin on. The RA needs to clarify that this approach may underestimate risk for individuals who may consume other parts of the bird (e.g., legs and other dark meat).

RESPONSE 429:

Please refer to the response to General Issue 9.A.

A summary table on the concentration of PCBs in ducks taken from a reference area was provided to the Panel and PCB levels in reference ducks varied by three orders of magnitude. It would be prudent to statistically evaluate if PCB levels in waterfowl taken from the affected area are statistically higher than PCB levels in ducks taken from the reference area.

RESPONSE 430:

A summary of reference area waterfowl concentrations and appropriate statistical comparisons with site waterfowl concentrations will be provided in the revised HHRA.

F. Owen Hoffman

I believe the assumption for meal size for waterfowl ingestion is biased low. I see no logical reason why a meal size for fish consumption should be twice as large as a meal size for waterfowl. The apparent lower meal size for consumption of waterfowl is obtained from cited literature on dietary surveys on the consumption of poultry. The apparent discrepancy in the literature may be an artifact of the experimental design of the poultry dietary surveys. I question whether there are true differences in meal sizes for individuals likely to eat a meal of freshwater fish versus a meal of waterfowl. It seems intuitively reasonable that a generic meal size of about 8 oz. or 227 grams should be used for both and that meal size and body weight be correlated.

RESPONSE 431:

Please refer to the response to General Issue 9.B.

The meal sizes assumed for children ages 1 to 6 years of age appear high for the consumption of game fish. This may be due to the use of published dietary survey data for ages 3 to 5 years of age as a surrogate for the average daily consumption for the age group of ages 1 to 6 yrs. On the other hand, if non-cancer risks are relevant to an exposure duration of one to two years, then the highest ratio of intake to body weight would occur for the younger age groups of children (ages 1 to 2) even though the assumed daily dietary intake of fish for children of this age may be much less than assumed at present.

RESPONSE 432:

Please refer to the responses to General Issues 3.B and 8.A. The discussion regarding the derivation and selection of fish consumption rates for children will be expanded in the revised HHRA.

Some consideration should be given to the probability that the RME, and especially the CTE, catch freshwater fish from locations other than the Housatonic River. The assumption that 100% of freshwater game fish ingested are fish obtained from the Housatonic River appears extreme when other freshwater bodies are in the near vicinity.

Nevertheless, I would be reluctant to recommend a very high weight to the likelihood that some fraction of the total number of freshwater fish in the diet is from fish caught from other locations (as the HHRA should be focused on risks potentially caused by exposure to the ingestion of fish caught primarily from the Housatonic River). A weight of 15% to 20% could be given to the ingestion of fish from other locations for the RME who resides continuously in the area for 70 years. A weight of up to 30% to 50% could be attributed to the CTE, but not more, especially considering that the CTE also is given an exposure duration that is substantially less than the

RME. A range of plausible weights for the possibility that fish are caught from water bodies other than the Housatonic River could be considered within the quantitative uncertainty analysis.

RESPONSE 433:

Please refer to the response to General Issue 8.B.

John C. Kissel

The discrepancy between the assumed sizes of fish (8 oz) and waterfowl (4 oz) meals requires justification.

RESPONSE 434:

Please refer to the response to General Issue 9.B.

EPA appears to have misinterpreted the consumption rates from Ebert's 1993 Maine angler study.

RESPONSE 435:

Please refer to the response to General Issue 8.A.

Roger O. McClellan

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

RESPONSE 436:

Please refer to the response to General Issue 8.A for information on productivity of fish and to the response to General Issue 9.C for productivity of waterfowl. It should be noted that the objective of evaluating the risks from fish and waterfowl consumption is to determine the risk in the absence of an institutional control (advisory).

Several assumptions embedded in the assessment are open to question:

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

RESPONSE 437:

Please refer to the response to General Issue 8.A.

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

RESPONSE 438:

Please refer to the response to General Issue 8.B.

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

RESPONSE 439:

Please refer to the responses to General Issues 9.C and 9.D.

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

RESPONSE 440:

The HHRA considered cooking loss for both fish and waterfowl. Upon evaluation of the existing data regarding cooking loss, the loss for the RME was set to zero. The reasons for these decisions were described in the HHRA. Please refer to the response to General Issue 8.C for a discussion of the modifications to the treatment of cooking loss in fish to be made in the revised HHRA.

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

RESPONSE 441:

Please refer to the response to General Issue 8.D.

P. Barry Ryan

Questions were raised concerning use of the Maine "all-waters" fishing survey in assessing likely exposure. While these data may not be specifically relevant, and indeed their use in this assessment was criticized by the author of the study report, I think that they are the most relevant data available. Their use is in keeping with the generally conservative approach taken in the risk assessment.

RESPONSE 442:

Please refer to the response to General Issue 8.A.

Lee R. Shull

In general and except for the following comments, exposure assumptions and parameters used in this HHRA are appropriate.

Figure 1-5: It is not clear why an air/inhalation exposure pathway is identified as a complete pathway associated with the 'fish and waterfowl consumption' pathway on the CSM. As far as I can tell, it is not addressed with further (i.e., no qualitative discussion as to why it is eliminated from quantitative analysis.

RESPONSE 443:

Figure 1-5 presents the conceptual site model for the entire risk assessment and thus includes all complete and incomplete exposure pathways. It highlights the fish and waterfowl consumption exposure pathways since Appendix C specifically addresses these two pathways. The revised HHRA, Volume I will have an additional section that describes the air data from the site and the basis for the elimination of the inhalation pathway.

Page 4-2, lines 17-18: The basis for the potentially exposed population being anglers who consume at least one meal per year from the Housatonic River should be explained.

RESPONSE 444:

The revised HHRA will provide further rationale for the definition of the potentially exposed population.

Page 4-3, lines 24-25: The basis for the potentially exposed population being hunters who consume at least one meal per year of waterfowl from the Housatonic River should be provided, along with relevant discussion.

RESPONSE 445:

The revised HHRA will provide further rationale for the definition of the potentially exposed population.

Page 4-16, lines 6-8: EPA's conclusion regarding the lack of subsistence fishing should be explained in more detail or a study referenced.

RESPONSE 446:

Please refer to the response to General Issue 3.C.

Page 4-16, lines 11-13: The basis (reference?) of this statement that fetuses and young children are particularly sensitive to PCB adverse effects should be provided.

RESPONSE 447:

A reference will be added to this statement in the revised HHRA.

Page 4-22, Table 4-4: This table should reference page 4-31 where an explanation is given re. exposure prevalence study vs volunteer study.

RESPONSE 448:

The revised HHRA will include a footnote with this table referencing the definitions provided in the text.

Page 4-31, lines 1-2: It is not clear how the prevalence data were used in the HHRA.

RESPONSE 449:

The prevalence data were included in the comprehensive description of the available data. They were not used in the derivation of the fish consumption rate; however, they do support the consumption rate selected based on data from the Maine Angler Survey. Please refer to the response to General Issue 8.A regarding revisions to the discussion of the fish consumption ingestion rate in the revised HHRA.

Page 40 (Parameter Selection). The adult fish consumption rates used are taken from the Maine Angler Survey, which is clearly the most robust angler study available for the northeast. The 90th percentile and arithmetic mean adult consumption rates were selected to represent the RME and CTE rates, respectively, which seems reasonable. However, the study reported rates for "all waters" and for "streams/rivers", and the higher "all waters" rates were selected for use in the risk assessment. The 90th percentile rates are 32 and 15 g/day for "all waters" and "streams/rivers", respectively. The arithmetic mean rates are 14 and 8.9 g/day for "all waters" and "streams/rivers", respectively. Note that for trout, the "streams/rivers" rates were used. The rationale for selecting "all waters" fish consumption rate data should be described, including the difference between "all waters" (does this include marine waters?) and "streams/rivers".

RESPONSE 450:

Please refer to the response to General Issue 8.A.

Page 4-41, lines 10-17: Please clarify why the 90th percentile is applied instead of the 95th. Should provide additional rationale. Also, it is not whether the 90th vs 95th is based on professional judgment or some other basis.

RESPONSE 451:

Please refer to the response to General Issue 8.A.

Page 4-41 (Child Consumption Rate): The child fish consumption rates were estimated as approximately one-half of the adult rates. This assumption seems to be arbitrary given that there is no information provided to support the assumption. Given that the hypothetical child weighs 4.7 times less than the hypothetical adult (15 kg versus 70 kg), the differences in body weight alone do not support the assumption that a child consumes one-half the amount of fish as an adult. However, differences in dietary requirements and consumption rates for other foods may provide basis for a more reliable estimate of a child fish consumption rate.

RESPONSE 452:

Please refer to the response to General Issue 8.A.

Page 4-44 (Cooking Loss): Cooking loss for the RME scenario was assumed to be zero "based on data from several studies showing no cooking loss, and that individuals may consume the drippings/pan sauce." The studies showing no cooking loss are not cited. Furthermore, it does not seem logical that there would not be some cooking loss. Explanation as to why some studies showed cooking loss and others did not should be provided. Also, clarification as to whether detection limits in those studies that did not detect cooking loss were sufficiently low. The statement that "individuals may consume the drippings/pan sauce" seems to be based more on speculation than on actual facts. Note that CTE cooking loss percentages ranged from 21 to 24% for Massachusetts and Connecticut, respectively, based on cooking preferences.

RESPONSE 453:

Please refer to the response to General Issue 8.C.

Page 4-50, lines 12-13: Please clarify why no cooking loss was assumed for other COPCs, especially one like DDT.

RESPONSE 454:

Total PCBs and TEQ are the primary COPCs, and concentrations of other COPCs were very low. Therefore, literature searches were not conducted to determine cooking loss for the other COPCs. The assumption of no cooking loss (or some cooking loss) for other COPCs would not result in an appreciable difference in the risk estimates.

Page 5-50: (Fraction Ingested). The fraction of fish ingested from the Housatonic River was assumed to be 100% based on Ebert et al. (1996). However, as noted in the risk assessment, Ebert et al. reported that only 1.5% of 1,515 respondents to the Connecticut Housatonic River Creel Survey caught all their fish on the Housatonic River, and only 9.9% of these individuals indicated that at least 95% of their fishing trips were on the Housatonic River. They noted that the assumption is reasonable since the survey was conducted while the fish consumption advisory was in place.

RESPONSE 455:

Please refer to the response to General Issue 8.B.

Table 4-22: Recommend showing a calculation in a footnote for the preference weighting…its not immediately clear from the table.

RESPONSE 456:

The revised HHRA will include a footnote as recommended.

Stephen T. Washburn

Similar to comments above regarding the direct contact scenario, it does not appear that the combination of exposure assumptions and parameters used in estimating the RME for the fish and waterfowl consumption scenarios is consistent with EPA's Policy for Risk Characterization at the U.S. Environmental Protection Agency (March, 1995). While the individual exposure parameters do not necessarily seem unreasonable when taken individually, when combined they can produce a scenario that does seem highly unlikely.

RESPONSE 457:

Please refer to the response to General Issue 13.A.

To address this issue, specific recommendation include the following:

- EPA does a good job in the HHRA of summarizing relevant fish consumption rate data from the scientific literature. However, the selection of fish consumption rates for use in the HHRA appears to be overly conservative, based on a review of the Ebert et al. (1993) study selected as the foundation for the calculations. In particular, the assumption of basing the consumption estimate on a "no-sharing anglers only" scenario should be reviewed. The 90th percentile for the "nosharing" anglers (32 grams/day) is used as the RME consumption rate in the HHRA, despite data from Ebert et al. (1993) suggesting that a great majority of anglers in that study reported sharing recreationally-caught fish. The 90th percentile of the distribution for all anglers (including those who do not share) is approximately 15 grams/day. Thus, a more reasonable RME estimate for the HHRA would be 15 grams/day, especially since it is conservatively assumed that all of the recreationally-caught fish are taken from the Housatonic. This consumption rate of 15 grams/day is similar to the default value recommended by EPA for the development of ambient water quality criteria (EPA 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health).

RESPONSE 458:

Please refer to the response to General Issue 8.A.

- The exposure durations assumed for both fish and waterfowl consumption are not adequately supported, and may lead to significant overestimates of potential exposure when combined with the assumed consumption rates. Exposure durations of 23 years and 60 years, respectively, are used in the HHRA to estimate the CTE and RME for both fish and waterfowl consumption. These durations are based on an MDPH study, from answers to questions regarding the length of time that freshwater fish is consumed (p. 4-56; Volume 4; Appendix C). However, it is not clear that these values actually reflect the lengths of time that an individual would be expected to consume freshwater fish from the Housatonic, as opposed to other sources (such as stores and restaurants).

RESPONSE 459:

Please refer to the response to General Issue 8.D.

3. *Was the basis for the selection of point estimate RME and CTE exposure parameter values appropriate under the evaluation criteria, and were they clearly described and referenced?*

COMMENTS

F. Owen Hoffman

Yes, with the exception of issues already raised above.

To achieve a higher level of transparency, evaluation of fish concentration data for baseline risk EPC's need to be more explicit. It would therefore be useful to preserve information about EPC in results tables about exposures and risks for various river reaches.

RESPONSE 460:

An additional column will be added to each risk characterization table in order to provide the EPC used to obtain the reported cancer risk or hazard quotient.

Additional explanation would be useful as how EPC concentrations reflect the likelihood of harvesting migratory birds and birds taken from locations away from the Housatonic River.

RESPONSE 461:

Please refer to the response to General Issue 9.C.

John C. Kissel

Exposure factor selections were adequately documented. See two comments above.

Roger O. McClellan

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

RESPONSE 462:

Please refer to the responses to General Issues 8.A, 8.B, 8.C, 8.D, 9A, 9B, 9.C, 9.D, and 13.A.

P. Barry Ryan

While EPA guidance suggests the use of the 95th UCL of the mean as the measure of central tendency, I find this selection insufficiently conservative when data are plentiful. Certainly one may argue that the greater the number of data, the better predicted the mean may be and thus the shrinking of the 95th UCL is appropriate. Nevertheless, I still would argue for a more conservative approach, perhaps looking at the 95th UCL of the 75th percentile, or some such, for a screening value. It is my assessment that the RME and CTE exposure parameter values are appropriate and follow EPA guidance. However, I offer the caveat expressed earlier regarding potential low bias in using the UCL for the mean rather than a UCL on a higher percentage point.

RESPONSE 463:

The HHRA assessment assumes individual receptors experience many exposures over time, thus an estimate of the mean that represents long-term averages is appropriate. EPA guidance prescribes the use of the smaller of the 95% upper confidence limit (UCL) on the mean and the maximum concentration observed in such situations.

Lee R. Shull

In general, I believe the RME and CTE exposure parameter values are appropriate for purposes of this HHRA.

An explanation as to why it is reasonable to combine the 90th percentile fish consumption rate with the 95th percentile exposure duration for fish consumption should be provided.

RESPONSE 464:

Please refer to the response to General Issue 13.A.

Stephen T. Washburn

The selection of RME and CTE exposure parameter values were generally described very clearly and were adequately referenced. See comments above regarding selection of the point estimate values for use in the HHRA.

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

COMMENTS

Holly Hattemer-Frey

Since probabilistic risk assessment (PRA) is not my area of expertise, I have only a few comments to make here. I leave the detailed review of the PRA to my colleagues. I strongly disagree with using point estimates for fish concentrations in the PRA. Fish concentrations were allowed to vary from the mean to the 95% UCL value only instead of using the entire range of measured data. What is the value of having so much measured data if it isn't used in the PRA? Regardless of the methodology dictated in EPA's Uncertainty Guidance, I recommend that fish concentrations be allowed to vary over the range of measured data in the PRA.

RESPONSE 465:

Please refer to the response to General Issue 4.C.

Secondly, I concede that it EPA guidance recommends not including uncertainty associated with the toxicity constants in the PRA, and I understand the logic. On the one hand, the uncertainty associated with the toxicity values can overwhelm uncertainty associated with other parameters. On the other hand, there IS a great deal of uncertainty associated with the toxicity data, and that source of uncertainty should be accounted for in some way. I recommend performing the PRA both ways (one run with toxicity constant held steady, another run with toxicity constants allowed to vary over a reasonable range).

RESPONSE 466:

Allowing toxicity values to vary over some range in a probabilistic assessment would not lead to protective estimates of the effect of uncertainty about toxicity. As the Reviewer noted, EPA guidance is clear on how the toxicity values are to be used in probabilistic assessments (EPA, 2001b). Please refer to the response to General Issue 12.B.

F. Owen Hoffman

The approaches were extensively described, but the appropriateness of the approaches used is questionable for a number of reasons.

The HHRA uncertainty analysis assumes that all inter- individual variability in exposure is due to natural stochasticity and erroneously states that such variability is irreducible. Uncertainty due to inter-individual variability can be reduced substantially by conditioning the assessment on the life-styles and other attributes of the target populations of interest (such as the average member of a population of casual recreational fishermen versus a representative member of a much smaller group of avid consumers of river fish, who are likely to utilize the river over extended periods of time).

Probabilistic approaches were restricted in the HHRA to the simulation of stochastic variability (aleatory uncertainty) of exposure within a relatively undefined population mixed with casual and avid recreational anglers.

RESPONSE 467:

Please refer to the response to General Issue 10.A.

Epistemic uncertainty was analyzed using a non-probabilistic approach known as Probability Bounds Analysis (PBA).

Despite claims to the contrary in the HHRA, PBA is not well established and is rarely ever used in human health risk assessment.

RESPONSE 468:

As mentioned in the HHRA (Volume I, Attachment 5, pages 2-3, and Volume IV, Appendix C, Section 6, page 6-10), there are several papers and books in the scientific literature that establish the usefulness of probability bounds analysis (PBA) for risk assessments. References to several more relevant papers from the literature will be added in the revised HHRA. PBA is useful because it allows analysts to bound probabilistic outcomes without forcing them to make untenable assumptions about precise input distributions or inter-variable dependence functions. As mentioned in the response to General Issue 10.C, the numeric results of PBA are similar to those obtained by the Reviewer's own reanalysis.

This reviewer found the description of the PBA approach extremely difficult to comprehend upon both first and subsequent readings. It took considerable effort to become familiar with the mathematical procedures and their limitations. The substitution of PBA in the Housatonic Rest of River HHRA for probabilistic methods appears to be have been a deliberate decision influenced by individuals who, because their conviction as frequentists, are averse to the use of Bayesian probability to represent the state of knowledge about true but uncertain quantities.

RESPONSE 469:

Please refer to the response to General Issue 10.B.

Contrary to what is stated in the HHRA concerning the advantages of PBA over Monte Carlo methods, probabilistic uncertainty analyses are:

- established and accepted procedures for addressing epistemic uncertainty,
- easier to implement and more transparent than PBA,
- provide probabilistic uncertainty information on the computed exposure and risk which is a quantitative representation of the analyst's state of knowledge,

- the resulting 90 or 95% credibility intervals for the RME and CTE are more suitable for decision making than the extreme limits produced by the PBA.

The discussion given in the HHRA (pages 1 through 69 of Attachment 5 to Volume 1) to justify the advantages of the probability bounds analysis over probabilistic uncertainty analysis reflects mostly points of view of the authors. They are not statements of scientific fact, nor are these statements widely endorsed by the majority of practitioners of probabilistic uncertainty analysis (Kaplan and Garrick 1981, Bogen and Spear 1987, IAEA 1989, Morgan and Henrion 1990, Hoffman and Hammonds 1994, MacIntosh 1994, NRC 1994, Burmaster and Rhodes 1996, Frey and Rhodes 1996, NCRP 1996, NCRP 1997, Pate-Cornell 1996, Frey 1998, Frey and Rhodes 1998, Cullen and Frey 1999, EPA 1999, Hoffman and Kaplan 1999. A fuller list of references is found at the end of this document.).

RESPONSE 470:

EPA acknowledges that Monte Carlo methods are well established and appropriate for risk assessments. Monte Carlo simulations were applied in the HHRA to explore the effect of variability on risk estimates in the fish and waterfowl assessments. PBA has some advantages over Monte Carlo methods that recommend its use in risk assessments, namely, the ability to conveniently model uncertainty about distribution shape, intervariable dependence (as opposed to mere linear correlation), and model uncertainty. Recognizing the usefulness of PBA does not mean that Monte Carlo does not also have some advantages. A combination of Monte Carlo simulation to obtain a best estimate of the distributions of exposures and risks arising from variability, and a PBA to explore the effect of uncertainty about the input distributions from the Monte Carlo analyses was used in the HHRA to take advantage of the strengths of both methods. As to the use of Monte Carlo to represent subjective epistemic uncertainty, please refer to the response to General Issue 10.B.

The local sensitivity information obtained from the PBA is inadequate to guide decisions as to where to improve the state of knowledge in order to effectively reduce epistemic uncertainty of the computed risk. This inadequacy is not just because of the local nature of the PBA sensitivity analysis that requires "pinching" of a p-box for an input variable at a specified percentile of the frequency distribution, but also because the PBA approach fails to address differences in the state of knowledge within the limits of its extreme values.

RESPONSE 471:

It is not clear why the Reviewer believes the sensitivity analyses from PBA are inadequate. PBA does not address the internal structure within a p-box, but it can quantify how much the uncertainty of a p-box can decrease with the acquisition of new information, and this is sufficient to estimate the sensitivities needed for planning future efforts to improve the state of knowledge; however, that is not an objective of the application of this technique in the HHRA.

The Reviewer may misunderstand how pinching occurs in the sensitivity analyses. The p-boxes are entirely replaced by precise distributions (or points), not pinched at particular percentile or probability levels. In principle, one could pinch a p-box by reducing uncertainty by a given proportion that could be varied from a modest reduction to the complete pinching that is currently used.

The upper bounds produced by the PBA at the upper percentiles of the frequency distribution of exposure are implausible extremes for a population of recreational anglers. The results at the upper end of the distribution of angler exposures are more indicative of subsistence fishermen, the existence of which has not been demonstrated to date.

RESPONSE 472:

The upper tails of the input probability distributions and p-boxes are based on analyses of available literature, EPA default values, and site-specific data. Please refer to the response to General Issue 3.C. As to the issue of the PBA leading to implausibly high risk estimates, please refer to the response to General Issue 10.C.

The sensitivity of the risk estimates to uncertainty in the toxicity coefficients is not accounted for in the HHRA uncertainty analysis. The present HHRA uncertainty analysis has been restricted to the assumptions that determine individual exposure.

The uncertainty in the cancer slope factor and RfD is not addressed, as a matter of EPA policy. This is an area where EPA policy and guidance should be reconsidered and improved.

I recommend that the HHRA uncertainty analysis be extended to include the uncertainty in the toxicity coefficients of the risk assessment. These coefficients are often the dominant source of uncertainty, once the attributes of exposure duration and exposure frequency have been defined for individuals who are representative of RME and CTE exposures.

RESPONSE 473:

Please refer to the response to General Issue 12.B.

John C. Kissel

In general I find the probabilistic approaches unsatisfactory. This is due in part to the fact that I find mixed deterministic/probabilistic approaches to be confusing (especially to the general public). EPA justifies using both deterministic and probabilistic methods by citing guidance regarding tiered approaches. While this justification may be valid, the general organization of the tiers is poor. They do not logically flow from one to the next but are intermingled.

RESPONSE 474:

EPA guidance (RAGS Volume 3 Part A Chapter 2) suggests proceeding from a tier one assessment (point estimate) to a tier two (probabilistic) assessment when the results of the tier one assessment might be further clarified for decisionmakers by the quantitative treatment of variability or uncertainty in the inputs. The HHRA adheres to this guidance. The tiers are not “intermingled,” although multiple analytical tools are used in tiers two and three, a practice also in keeping with guidance (please see, for example, RAGS Volume 3 Part A Chapter 2 Section 2.3.5).

Moreover, the rationale for applying some form of probabilistic assessment only to the Fish and Waterfowl Exposure Assessment is not adequately developed. If it is the view of the authors of the ROR HHRA that fish and waterfowl pathways are the most significant and therefore deserving of the most sophisticated treatment, then that position should be revealed through an appropriate report structure (i.e., comparable initial assessments of all pathways providing evidence of quantitative differences followed by more sophisticated treatment of the most critical pathways). It is entirely possible that such an approach would have justified differential treatment of the fish and waterfowl pathways, but the case has not been adequately made. Using probabilistic methods within just one section in the middle of the overall report and then applying multiple techniques within that one section renders the reader's job more difficult.

RESPONSE 475:

The revised HHRA will expand the application of probabilistic techniques to direct contact and agriculture product consumption pathways. Please refer to the responses to General Issues 7.E and 11.

Roger O. McClellan

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

RESPONSE 476:

Probability bounds analysis is used in conjunction with the Monte Carlo approach to provide a general and comprehensive form of sensitivity analysis to the Monte Carlo results. Specifically, probability bounds analysis quantifies the reliability of the Monte Carlo results under uncertainty about the shape of the probability distributions used as inputs and assumptions about the intervariable dependencies.

P. Barry Ryan

The standard Monte Carlo procedures used in this assessment are consistent with EPA guidance on the subject. However, the use of the "probability bounds" procedure as described in the October meeting is new and has not, to my knowledge, been subject to EPA scrutiny and guidance. Despite this concern, it would appear that this new technique is at least as applicable as the more standard Monte Carlo techniques and fits within the framework of EPA's need for probabilistic assessments. Further, it offers some new features that make it of interest to the general risk assessment community in addition to its application here. It may, for example, present a more realistic picture of the influence of "uncertain" variables on the calculated risk distribution. However, the bounds so projected may be so wide as to reduce their utility in assessment the uncertainties for risk. They do represent, in some sense, what one would get from an infinite number of 2D Monte Carlo assessments, but we may be more interested in approaches that give some idea of what the most likely uncertainty bounds are. A reasonable approach might be to perform both standard 2D methods and probability bounds estimates and present both. In this way, the reader may develop a better appreciation for the effects of these uncertainties. However, there are still uncertainties not accounted for in parameters that have few data to support them.

RESPONSE 477:

In principle, if uncertainty associated with the input variables was very large, the resulting bounds would have been very wide and perhaps useless for decisionmaking. In the calculations underlying the HHRA, however, this appears not to have been the case. Use of such analyses for decisionmaking would arise, for instance, if the bounds included all possible results ranging from clearly no risk to clearly high risk. Only in rare cases in the HHRA do the bounds straddle the risk range or risk threshold. Indeed, these bounding analyses provide confidence about the risk estimates.

In the interest of adding clarity to the document, the revised HHRA will include a comparison (for one site, path, receptor, and model) between a second-order Monte Carlo simulation and the one-dimensional Monte Carlo simulation and probability bounds analysis.

Lee R. Shull

In general and except for the comments below, the probabilistic approaches used are clearly described and appropriate.

Knowing that probabilistic risk assessment is difficult for even practitioners to grasp, I suggest an expanded discussion on some of the basics, specifically a clearer discussion on how the results of the probabilistic analysis and Monte Carlo simulations are used in risk management decision making. For example, in the introduction to Section 6, it would be helpful to readers not familiar with probabilistic analyses to have an explanation as to what is meant by a probabilistic uncertainty analysis versus a probabilistic risk assessment (PRA). These terms are intermingled throughout, and are identical, but how the results are used in decision making differs. The explanatory information that is presented in Section 6 is excellent, but it doesn't go far enough. More examples to illustrate and convey PRA concepts would be helpful.

RESPONSE 478:

Risk management and decisionmaking are beyond the scope of the HHRA; however, some discussion supporting interpretation of results from the Monte Carlo and probability bounds analyses will be added to the revised HHRA. The revised HHRA will be reviewed to ensure consistent use of phrases such as "probabilistic uncertainty analysis" and "a probabilistic risk assessment (PRA)." Also, better referencing to Attachment 5 in Volume I will be included in Section 6 of Appendix C. This attachment contains additional explanatory material about the relationship between the probabilistic methods used in the assessment.

This section presents many figures, which contain a substantial amount of information. However, the text does not adequately explain how all this information is used in the risk assessment, and in risk-based decision making. Perhaps a figure similar to Figure 8-1 should be placed in this section to help educate readers.

RESPONSE 479:

Risk management and decisionmaking are beyond the scope of the HHRA; however, the revised HHRA will contain additional explanatory material. A sample figure with appropriate explanation or reference to Figure 8-1 will be included.

The rates of fish ingestion used in the probabilistic risk assessment are based on the exposure frequency (meals per year) and ingestion rate (grams per meal). For ingestion rate, separate CTEs are used for the adult and child; however, both the child and adult scenarios use the same exposure frequency. Thus, the result of a child consuming up to 2.9 meals per day is equivalent to a maximum fish ingestion rate of 331 g/day. This does not make sense.

RESPONSE 480:

The child ingestion rate is half of the adult ingestion rate in the probabilistic models. The exposure frequency distribution will be revisited in the revised HHRA. Please refer to the response to General Issue 8.A. The revised HHRA will also employ appropriate deconvolution algorithms to derive a plausible pair of distributions for both exposure frequency and intake rate from the distribution based on the Maine Angler Survey data. These distributions will be used in the Monte Carlo microexposure-event simulation. (No fish meal size is needed for the direct probabilistic models because the ingestion rate variable was derived from the Maine Angler Survey directly in terms of average grams per day.)

Page 6-1, lines 19-24. Again, this place in the document would seem to be a good place to state with appropriate citation that EPA's default percentile is the 95th percentile.

RESPONSE 481:

Additional citations to relevant EPA guidance will be included in the revised HHRA.

Page 6-12, lines 20-23. These two sentence are an example of the use of two terms (probability distribution, Monte Carlo input variable) that may mean the same. The result is confusion. Consistency of use of terms is very important, especially in a PRA because of the inherent complexity.

RESPONSE 482:

Consistent use of terminology will be used in the revised HHRA to address such possible confusion.

Page 6-15, lines 1-3. This statement is poorly worded and thus confusing. Please clarify what is meant by "…accounting for sampling uncertainty by using the EPC in place of the sample mean in probabilistic risk analyses."

RESPONSE 483:

This statement will be reworded and clarified in the revised HHRA. Also, please refer to the response to General Issue 4.C for an explanation of what sampling uncertainty is handled.

The same comment applies to page 6-49, lines 17-18.

RESPONSE 484:

This will be clarified in the revised HHRA.

Page 6-17, lines 11-16. This would be a good place to explain how "exceedance probability" is used in this risk assessment (i.e., in terms that a risk manager can understand). Perhaps using an example to explain would be helpful.

RESPONSE 485:

This will be clarified in the revised HHRA and an example will be provided.

Page 6-36, lines 4-7: Again, this would be a good place to explain in practical terms how the information is used in the risk assessment…to assist with transparency and clarity.

RESPONSE 486:

The portion of the document referenced by the Reviewer is a presentation of results. The revised HHRA will provide additional text in the introductory and other sections of the probabilistic sections of the report regarding the interpretation and utility of the results of the probabilistic assessment.

Stephen T. Washburn

The probabilistic approaches were adequately described, and such approaches are appropriate as a sensitivity analysis in the context of the fish and waterfowl scenarios.

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

COMMENTS

F. Owen Hoffman

The data sources for probability distributions were clearly described, but these data are not necessarily appropriate for defining stochastic variability of exposure without careful evaluation of the limitations of the data. The extent to which the various data sets are directly relevant for defining stochastic variability of exposure within a defined population has not been considered.

RESPONSE 487:

Regarding the definition of the target population, please refer to the responses to General Issues 1.A and 10.A.

The Reviewer is suggesting that one cannot assume that the distributional data collected from disparate sources are compatible in a stochastic model. For instance, it may not be reasonable to assume that a data distribution collected for anglers in Maine will apply to anglers along the Housatonic River. Likewise, the distribution of body weights for avid anglers might be different in some important way from that for people who fish occasionally or rarely. Using data from different sources requires the assumption that they are compatible; such criticisms are always possible for a probabilistic assessment. These issues can be addressed either by stratifying the assessment into multiple, separate scenarios, or by modeling the epistemic uncertainty about the distributions, including dependencies among the inputs, via some kind of comprehensive sensitivity analysis.

The first approach cannot completely answer the criticism until the assessment devolves to an individual-based model (which generally requires data that are not available). The second approach accounts for possible mistakes in the specification of the input distributions and possible correlations or even nonlinear dependencies among the inputs; this approach is used in the probability bounds analysis.

It is evident that only minor amounts of epistemic uncertainty are assumed for exposure frequency while, for cancer risk, almost all the uncertainty is assumed to be associated with exposure duration, with a heavy weight assigned to minimum and maximum values. No probability distributions were assigned to represent sources of epistemic uncertainty.

RESPONSE 488:

EPA does not agree with the Reviewer's characterization of the analyses in the HHRA. The impact of epistemic uncertainty on risk results is not revealed by such visual inspection of p-bounds output, but must be assessed by sensitivity studies. As shown in Table 6-14 of Volume IV, Appendix C, Section 6 of the HHRA, the sensitivities of the risk distribution to uncertainty in exposure duration and exposure frequency are about the same. In fact, the impact of epistemic uncertainty associated with meal size is greater than that from either of these variables. Thus, it is not the case that "for cancer risk, almost all the uncertainty is assumed to be associated with exposure duration."

The probabilistic analyses did not assign "heavy weight" to the minimum and maximum values. In fact, there are no weights assigned in the analyses; only constraints are placed on the values. Please refer to the response to General Issue 10.D for further discussion on this idea.

No distributions are assigned to describe variability in the EPC for fish and waterfowl. Yet, the mean concentration in fish will be different for each person sampling a finite number of fish from the river. The uncertainty in the EPC is defined by a range of values arbitrarily restricted to the sample mean and the deterministic EPC. The uncertainty in the mean PCB concentration should be greater for an individual who consumes few fish from the river than for one who consumes many.

RESPONSE 489:

As discussed in the response to General Issue 4.C, EPA guidance does not endorse the use of a distribution of the uncertainty associated with the EPC in the Monte Carlo simulation. Given that the assessment is for chronic exposures, even individuals who consume relatively few fish meals will eventually consume many over their entire lifetime. Therefore, a prediction interval that accounts for few exposure events would be very close to the confidence intervals that were used in the assessment. The intervals used in the probability bounds analyses are reasonable characterizations of the epistemic uncertainty arising from limited sampling of the underlying concentrations distribution, as discussed in the response to General Issue 4.D.

The application of data on fish consumption rates obtained from a relatively short-term dietary survey of sport anglers in Maine (from Ebert et al., 1993) to the population of recreational anglers who would use the Housatonic River is assumed to have only a 10% uncertainty in the estimates of the mean and spread of the distribution.

RESPONSE 490:

The exposure frequency distribution will be revisited in the revised HHRA. Please refer to the response to General Issue 8.A.

No credit is given to the claim that some fish and waterfowl would be harvested by avid and casual recreational anglers from areas outside of the Housatonic River.

RESPONSE 491:

The incorporation of an input to the probabilistic models accounting for uncertainty in the fraction of fish ingested from the Housatonic River will be considered in the revised HHRA. Please refer to the responses to General Issues 8.B and 9.D.

The p-boxes used for the PBA, however, assume that some individuals consume fish from the Housatonic River daily for the entire duration of their residence history, which is not a plausible assumption for recreational anglers. This assumption probably overstates the intake from representative members of subpopulations considered sustenance fishermen. However, there appears to be no recent record of the Housatonic River used by such persons.

RESPONSE 492:

The exposure frequency distribution will be revisited in the revised HHRA. Please refer to the response to General Issue 8.A.

The distribution of body weight is used to address stochastic variability but not epistemic uncertainty. The fact that cited information on short term observations of the variability of human body weights in a general population may only approximately describe the true variability of lifetime exposure among recreational anglers is not considered as a source of uncertainty. At a given percentile of the true frequency distribution of exposure, body weight is ignored as a factor that contributes to epistemic uncertainty.

RESPONSE 493:

Further characterization of the epistemic uncertainty in the body weight distribution will be considered in the revised HHRA.

The substitution of PBA for more established probabilistic approaches to address epistemic uncertainty is a major shortcoming of the quantitative uncertainty analysis in this HHRA.

RESPONSE 494:

Please refer to the responses to General Issues 10.A and 10.B.

John C. Kissel

Generally adequate information was provided to understand what assumptions were used. Why point estimates were used for fish concentrations and ingestion rates in an ostensibly probabilistic analysis is not clear. Mixed analyses produce hybrid results that are very easily misinterpreted.

RESPONSE 495:

Regarding the use of point estimates for fish concentrations, please refer to the response to General Issue 4.C. The revised HHRA will employ appropriate deconvolution algorithms to derive a plausible pair of distributions for both exposure frequency and intake rate from the distribution based on the Maine Angler Survey data.

Roger O. McClellan

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

RESPONSE 496:

Fish and waterfowl tissue concentrations were modeled as point estimates of the central tendency of the observed distributions, not upper-bound estimates. (This is the difference between a 95% upper confidence limit of the mean and a 95th percentile of the full distribution.) Please refer to the response to General Issue 4.C. The revised HHRA will employ appropriate deconvolution algorithms to derive a plausible pair of distributions for both exposure frequency and intake rate from the distribution based on the Maine Angler Survey data. Please refer to the responses to General Issues 8.A and 9.C for information on the productivity of the river with respect to fish and waterfowl.

Most significantly the Monte Carlo analyses were truncated and used only to describe uncertainty in the exposure estimates. They did not include uncertainty in the toxicity (exposure-response) parameters. Inclusion of the toxicity parameters in the Monte Carlo analyses would have explicitly recognized the high degree of uncertainty in both toxicity parameters; (a) the cancer slope factor (since PBCs are not known carcinogens, it would be necessary to recognize the potential for zero cancer risk) and, (b) for the RfDs the substantial uncertainty factors (100 to 300) used to extrapolate from No Observed Adverse Effect Levels or Lowest Observed Adverse Effect Levels to Reference Doses.

RESPONSE 497:

Please refer to the response to General Issue 12.B.

P. Barry Ryan

The description given in Attachments 4 and 5 of Volume I of the HHRA describe in detail the various procures used to develop the probabilistic assessments. While the material is both dense and voluminous, it does describe in detail the procedures used. Most interesting is the Table at the end of Attachment 5 (Page 62 of the attachment) that lays out an algorithm for selection of distribution types. Not only is this table of interest in this analysis, but should be used as a teaching tool by those of us developing classroom lectures for students.

Lee R. Shull

In general and except for the following comments, I believe the distributions used in the probabilistic assessment are well described and appropriate.

Page 6-13, Table 6-2 (input parameters for probabilistic exposure assessment). The maximum exposure frequencies presented for bass and trout are 1,042 and 761 meals per year, respectively, based on empirical data distribution. The adult ingestion rate is the CTE point estimate of 227 g/meal, which is EPA's default meal size value. The maximum EF for bass of 1,042 meals/year correlates to 2.9 meals per day, and essentially assumes that this individual consumes fish with every meal. At a rate of 2.9 meals per day and an ingestion rate of 227 g/meal, this individual would consume 648 g/day. This rate greatly exceeds the 90th percentile adult fish ingestion rate of 32 g/day selected as the RME point estimate ingestion rate for adults.

RESPONSE 498:

Please refer to the response to General Issue 8.A. The data underlying exposure frequency inputs in the probabilistic assessments will be revisited. However, given the available data, extreme values such as these are apparently possible, although EPA believes they are unlikely. Their low probabilities in the probabilistic assessments reflect this. Please refer to the response to General Issue 10.D for a discussion of the relevance of the extreme values to decisionmaking.

Also, please clarify why tPCB concentrations were not expressed as a range or distribution, rather than a point value.

RESPONSE 499:

Please refer to the response to General Issue 4.C. EPA guidance on probability analysis (EPA, 2001b) is to use the point estimate for the EPC. The uncertainty in tPCB concentrations was explicitly modeled in the accompanying probability bounds analysis.

Page 6-58, lines 16-17. Although the 90th and 99th percentiles can be more or less visualized from the inset boxes, it is not accurate to say the percentiles are highlighted. Also, showing an example (e.g., Figure 8-1) would help clarify for readers how to read these inset boxes.

RESPONSE 500:

This will be clarified and an example will be included in the revised HHRA.

Table 6-14 to 6-19. Suggest a more visual way, in addition to the tables, to show the relative uncertainty contribution of the variables.

RESPONSE 501:

A more graphical representation of the sensitivity analysis results will be developed for the revised HHRA.

Page 6-106, Section 6.10. In my opinion, the method used here to assess and convey professional judgment regarding each of the sources of uncertainty is not very effective. Why not apply a standard qualitative approach per RAGS.

RESPONSE 502:

A more effective method to convey professional judgment, including the suggestion by the Reviewer, will be considered for the revised HHRA.

Also, the fact that so many of the parameters in Table 6-23 are assigned a "?", which, as is explained on page 106 "…have mixed or uncertain bias consequences for the analysis", will likely be confusing to readers (e.g., risk managers). Is it not possible for professional judgment to be applied a assign either a "C" or "O" to the parameters assigned a "?"?

RESPONSE 503:

A more effective method to convey professional judgment will be considered for the revised HHRA.

Stephen T. Washburn

The distributions used in the probabilistic assessments were adequately described. However, in many instances the HHRA relies predominantly on professional judgment to define these distributions, due to a lack of relevant information available regarding the site or in the scientific literature. In addition, the probabilistic assessments do not include distributions for the toxicity data, a limitation that is consistent with current EPA guidance. Therefore, in my opinion, the probabilistic assessments in the HHRA do not provide a more accurate or complete depiction of risks at the site despite the apparent statistical rigor with which they were conducted.

RESPONSE 504:

The Monte Carlo analyses use a combination of point estimates, empirical data distributions, and parametric probability distributions. In some cases, the probability distributions rely on sparse data, in other cases they are the result of the published analysis of thousands of samples. Assumptions and professional judgment are integral to the process of any analysis, probabilistic or not, and the HHRA attempts to explicitly document the assumptions incorporated into the analyses. The probability bounds analysis serves as a comprehensive sensitivity analysis of the assumptions and judgments incorporated into the point estimate and Monte Carlo analyses by relaxing the specifications of precise points and distributions. The uncertainty thus modeled is propagated through the risk calculations, resulting in bounds around the result. These bounds circumscribe all exposure distributions that could result from variation in assumptions and judgments regarding the nature of each input variable. As to the consideration of uncertainty about toxicity data, please refer to the response to General Issue 12.B.

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

COMMENTS

F. Owen Hoffman

No. In general, the rationales for choosing which variables describe stochastic interindividual variability and which are associated with epistemic uncertainty are either missing or based on arbitrary assumptions.

RESPONSE 505:

It is not assumed in the HHRA that while some inputs are variable, others are uncertain. The assumption used was that any input could be both variable and uncertain. The best estimate of variability for each input was used in the Monte Carlo analyses. The extent and relative degrees of variability and uncertainty in any input are reflected in the p-box used to characterize it.

I have found the description of the probability bounds analysis and its implementation especially difficult to interpret. This difficulty has been compounded by an obvious upward bias introduced by ignoring the information contained in the lower confidence limit on the mean concentrations in fish and waterfowl and the upward bias introduced by using the EPA toxicity coefficients as point estimates, without including an estimate of uncertainty.

RESPONSE 506:

The criticism that there is an upward bias in the tissue concentrations is addressed in the response to General Issue 4.D. The issue of uncertainty in toxicity coefficients is addressed in the response to General Issue 12.B. Concerns about probability bounds analysis are addressed in the response to General Issues 10.A, 10.B, 10.C, and 10.D.

I have noted above that in the HHRA analysis of epistemic uncertainty, inter-individual variability of body mass is assumed to be known perfectly. On the other hand, the uncertainty in exposure duration for both the RME and the CTE is assumed to range from 1-64 years with heavy weights given to the extremes of this range (an assumption that I feel is unreasonable).

RESPONSE 507:

Uncertainty about the distribution of body weights will be reconsidered in the revised HHRA. The probabilistic assessments did not give heavy weights to the endpoints of the range of exposure duration. In the case of the Monte Carlo simulations, the method of matching moments was iteratively used to parameterize truncated lognormal distributions. The right tail was truncated by the dictates of guidance for cancer assessments, so the extremes were actually given zero weight. In the case of the probability bounds analyses, no weighting at all was applied to any of the values. These parameterizations constrained variability according to the available data; they did not assign any weights.

Likewise, only a negligible 10% uncertainty is arbitrarily assigned to the distribution of the average number of fish meals consumed in a year (which I consider to be an underestimate of epistemic uncertainty).

RESPONSE 508:

The variability in number of fish meals per year is characterized as an empirical distribution function (EDF) based upon the data from the Maine Angler Survey. The 10% uncertainty used to construct probability bounds around the EDF is meant to represent the uncertainty due to the characterization of Massachusetts anglers using data gathered from Maine anglers. Both the exposure frequency EDF and the probability bounds around it will be revisited in the revised HHRA.

No variability is assumed to occur in the average concentration of PCBs in fish, nor for the size of the average fish meal (which leads to an underestimate of stochastic variability).

RESPONSE 509:

Regarding the use of point estimates for fish concentrations, please refer to the response to General Issue 4.C. Uncertainty about this value was described by an interval in the probability bounds as discussed in the response to General Issue 4.D. The revised HHRA will employ appropriate deconvolution algorithms to derive a plausible pair of distributions for both exposure frequency and meal size from the distribution based on the Maine Angler Survey data.

The uncertainty in the mean concentration of PBC's in fish and waterfowl is too small and biased towards values that exceed the sample mean.

RESPONSE 510:

Please refer to the responses to General Issues 4.C and 4.D.

No consideration is given to the chance that some fraction of the total freshwater fish consumed is taken from locations other than the Housatonic River.

RESPONSE 511:

Please refer to the response to General Issue 8.B. The incorporation of an input to the probabilistic models accounting for uncertainty in the fraction of fish ingested from the Housatonic River will be considered in the revised HHRA.

The probability bounds analysis indicates that the HHRA point estimates of cancer risk and non-cancer risk calculated in Chapter 5 could be substantial understatements of the true risk. This impression is misleading. The very high values produced as upper bounds are partially an artifact of the PBA method itself and partly a function of the rather arbitrary assumptions made about which parameters were to be considered as determinants of stochastic variability and which were to be assigned a p-box to represent epistemic uncertainty in true but unknown quantities.

RESPONSE 512:

The probability bounds analyses do suggest that the point estimates might underestimate or overestimate risk. The purpose of the bounding analyses is to explore the reliability of these point and distributional estimates. Figures 5-5 to 5-8 in Volume I of the HHRA graph comparisons among these results and depict the reliabilities of the point estimates. These graphs, and the bounding results they are based on, are obtained by analyses of the considerable uncertainties respecting the various inputs. In relation to the idea that the probability bounds analysis yields very high values, please refer to the response to General Issue 10.D. EPA does not agree with the comment that arbitrary assumptions were made about which parameters were considered determinants of stochastic variability and which were modeled with p-boxes; all parameters were represented as p-boxes, which were used to assess the effects of both uncertainty and variability simultaneously but in a way that does not confound them.

The extent of bias towards high values of exposure and risk would become apparent if the uncertainty analysis of the HHRA were to be carefully re-evaluated and the attributes of the CTE and RME targeted explicitly in a one dimensional Monte Carlo uncertainty analysis of epistemic uncertainty. The extent of this bias would become further apparent if the uncertainty of the cancer slope factors and RfD's would be taken into account.

RESPONSE 513:

The idea of conducting one-dimensional Monte Carlo simulations for epistemic uncertainty is discussed in the response to General Issue 10.A.

John C. Kissel

Use of PBA to characterize uncertainty generally produces very wide bounds and provides no information regarding degree of confidence within those bounds. I believe that 2-dimensional Monte Carlo analysis is easier to implement and understand. I would much prefer to look at a set of 2-D Monte Carlo plots than Figure 8-2 in Vol. IV Appendix C.

RESPONSE 514:

The revised HHRA will include a comparison (for one site, path, receptor, and model) between a second-order Monte Carlo simulation and the current assessment consisting of the one-dimensional Monte Carlo simulation and probability bounds analysis.

Resolution of the question of whether Native American subsistence fishermen do or do not exist in the Housatonic watershed is necessary. A screening level assessment of exposure to a subsistence fisherman should probably be included in any case.

RESPONSE 515:

Please refer to the response to General Issue 3.C.

Roger O. McClellan

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

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

RESPONSE 516:

Please refer to the response to General Issue 4.C.

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

RESPONSE 517:

Please refer to the responses to General Issues 9.C and 9.D.

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

RESPONSE 518:

Please refer to the response to General Issue 8.B. The full distribution of fish consumption rates was included as an input variable into the probabilistic assessments.

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

RESPONSE 519:

Please refer to the response to General Issue 8.A.

(e) Assuming no loss of PCBs in cooking.

RESPONSE 520:

Please refer to the response to General Issue 8.C. Cooking loss was included In the probabilistic analyses.

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

RESPONSE 521:

Please refer to the response to General Issue 8.D. A distribution of exposure durations based on the MDPH data was included as an input variable into the probabilistic assessments.

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

RESPONSE 522:

Please refer to the response to General Issue 13.A.

P. Barry Ryan

There are many parameters in the models with uncertainty that may not be adequately described in the presentation. Further, there is little discussion about model uncertainty and other forms of uncertainty not directly discernable from the results. I would like to see at least some passing discussion of these as well.

RESPONSE 523:

Uncertainty in the exposure frequency and meal size parameters will be reconsidered in the revised HHRA and are discussed in General Issues 8.A and 9.B. Model uncertainty was assessed by analyzing both direct and microexposure event risk models. These two families of models bracket a range of important assumptions regarding intra-individual variability in exposure over time, the former assuming no intra-individual variability in meal size, cooking loss, or yearly number of meals over an individual's exposure duration, the latter assuming very high variability. However, this treatment represents only one dimension of model uncertainty. Other dimensions include dependency and alternate model exposure formulations. The discussion of model uncertainty will be expanded in the revised HHRA.

Lee R. Shull

Uncertainties in the data and models are not adequately characterized and expressed. Section 7 needs improvement. In general, Section 7 does not present uncertainty information in a way useful to risk managers in risk management decision making. There does not appear to be consistency in statements as to whether items discussed are considered to either under- or over-estimate risks. Section 7 could greatly benefit from an overall qualitative analysis of uncertainties and whether, in the view of the risk assessor, overall risk estimates are considered as either under- or over-estimating health risks.

RESPONSE 524:

Additional information on uncertainty will be provided in the revised HHRA. Alternative ways to organize and present the information will be considered.

Section 7.2: A general comment: There is no discussion of the uncertainty associated with the PCB analytical data and reporting of PCB concentrations as total PCBs (see additional discussion regarding total PCBs in Volume IV, Appendix C comments).

RESPONSE 525:

Additional information on uncertainty will be provided in the revised HHRA.

Page 7-2, line 25-page 7-3 line 5: The discussion of "Excess" PCB Congener Calculations describes the uncertainties associated with double counting Aroclor and TEQ risks, but does not address the uncertainty associated with the use of PCB TEFs relative to the use to Aroclor toxicity data. There is likely to be substantially more uncertainty associated with the estimation of risks using the PCB TEFs than using the Aroclor toxicity data. For Aroclor mixtures, toxicity data are based on in vivo studies focused on frank toxicological responses such as cancer, reproductive, development, and target organ effects. The congener-specific PCB TEFs are largely based on biological responses, not necessarily frank toxic effects, such as Ah receptor binding affinity and enzyme induction. Extrapolation from these types of biological responses to frank toxic effects is highly uncertain. Furthermore, the in vitro assays used to develop the PCB TEFs were largely based on studies of individual congeners, not mixtures as found in the environment or in the original PCB formulations, and therefore, due not account for synergistic and antagonistic interactions between the various congeners.

RESPONSE 526:

EPA agrees with the Reviewer's comments. The derivation of TEFs was discussed in HHRA Volume 1, Section 2.2.2. Section 2.2.2.4 focused on uncertainties associated with the TEQ approach. The “excess” PCB congener calculations will be eliminated in the revised HHRA. Please refer to the response to General Issue 5.A.

Page 7-3, line 10: Please clarify whether the reference to “pesticide” applies to all COPCs or just to pesticides?

RESPONSE 527:

The reference to just “pesticides” is correct. The use of 0.01 times the lowest SQL was used only for pesticides since tPCB was detected in every sample and non-zero TEQ concentrations were calculated for every sample in which the congeners were analyzed.

Page 7-4, line 3: The phrase “…changing substitution values…” is unclear. The text should define substitution values, or reference a location in the document where this terminology is defined.

RESPONSE 528:

This will be clarified in the revised HHRA.

Page 7-4, lines 33-39: Risks associated with pesticides were not estimated for this pathway. Therefore, it does not seem relevant to state that pesticides “…contribute less than 1% of the cancer risk and HI…”

RESPONSE 529:

Risks associated with pesticides were estimated for the waterfowl consumption pathway. See Tables 5-19, 5-21, and 5-22.

Moreover, nowhere in the document was it stated that the GE plant in Pittsfield is considered a source of pesticides in the Housatonic River.

RESPONSE 530:

The GE plant is not considered a source of pesticide release to the river. EPA policy is to include high background concentrations of hazardous substances, pollutants, and contaminants found at a site, and to consider these concentrations a factor in risk assessment and risk management. (Role of Background in the CERCLA Cleanup Program. OSWER 9285.6-07P; April 26, 2002d).

Page 7-5, section on Skin-off Filets: It is my opinion that a risk manager will have difficulty understanding the uncertainty associated with the skin-off fillet vs skin-on fillet from the discussion presented. Too much information is given. A more concise discussion should be provided, with greater emphasis on how this issue impacts the calculated risk estimates. 24 Draft Panel Review Report; November 10, 2003

RESPONSE 531:

The impact of skin-on/skin-off fillets on the risk assessment will be clarified in the revised HHRA.

Page 7-5, line 38-page 7-6, line 2: This section is too brief and deserves greater explanation. Specifically, a better understanding as to why the author(s) believe the dioxin/furan congener patterns are approximately the same in CT and MA is needed.

RESPONSE 532:

Please refer to the response to General Issue 4.F.

Page 7-6, lines 5-7: The authors should state that the reason they expect concentrations in smaller fish to have lower COPC concentrations, thus lower EPC and possible risk underestimation, is that the bioaccumulation time is less in younger fish.

RESPONSE 533:

This will be clarified in the revised HHRA.

Page 7-6, lines 30-39: It is difficult to ascertain what a risk manager would do with the information presented in this section. Some further clarification is suggested.

RESPONSE 534:

The revised HHRA will include more information to address this issue.

Page 7-8, lines 22-23: The assumption referred to in this sentence is not clear. It appears the assumption is that tissue concentrations measured in dabbling and perching ducks is the same as what would be found, if measured, in diving ducks. Clarification is needed. Also, if diving ducks are migratory, it would seem lower concentrations in tissues would be expected because of the briefer exposure duration.

RESPONSE 535:

This will be clarified in the revised HHRA.

Page 7-9, lines 1-12: Because frogs are harvested in the area and because frog leg tissue data were collected from Housatonic River frogs, it is surprising that risk estimates were not derived. The information could have been directly useful in risk communication with people who may wonder whether consuming frog legs harvested from the area poses an unacceptable health risk or not.

RESPONSE 536:

As noted in Section 7.2.2, tPCB concentrations in frogs are lower than tPCB concentrations in fish. Since the consumption rate of frog legs by individuals is anticipated to be much lower than the fish consumption, risks were quantified only for fish consumption. Additional discussion of this issue will be provided in the revised HHRA.

Page 7-9, lines 13-28: This section does not convey whether, in the author's view, that the way cooking loss was dealt with in the risk assessment leads to an over- or underestimation of health risk. This should be corrected.

RESPONSE 537:

Please refer to the response to General Issue 4.C for a discussion of revisions in the cooking loss term. The uncertainty section will also be revised with respect to cooking loss, and include an interpretation of the impact of this uncertainty on the risk estimates.

Page 7-9, lines 29-page 7-11, line 6: Part of this section seems redundant with the "fish preference" section on page 7-6. Also, it is not clear how "sharing" of a catch impacts individual fish consumption rates. The implication is that an individual's consumption rate is reduced through sharing the catch with others. Please clarify the basis for this assumption.

RESPONSE 538:

Please refer to the response to General Issue 8.A. The uncertainty section will also be revised with respect to consumption rate.

Page 7-11, lines 8-11: The use of the words "significantly underestimates exposure duration" is unclear in this statement. An increased exposure duration from 30 to 45 or even 63 years does not seem like a significant increase in risk.

RESPONSE 539:

Text will be modified accordingly in the revised HHRA.

Section 7.2.3: This section is too brief and doesn't convey uncertainty associated with toxicity information from laboratory animals used in deriving toxicity criteria used in the HHRA (e.g., CSFs, RfDs).

RESPONSE 540:

Please refer to the response to General Issue 12.A.

Section 7.2.3.1: Numerous commentaries and reviews have been published over the past 15-20 years describing the uncertainty associated with relying on toxicology data from laboratory animals administered high dosages in humans exposed to much lower dosages. This section is completely lacking any such discussion.

RESPONSE 541:

Please refer to the response to General Issue 12.B.

Furthermore, no epidemiology information in humans is given to assist the risk manager in evaluating the uncertainty (or over-estimation of risk estimates) associated with relying solely on animal toxicology data for assessing human health risk.

RESPONSE 542:

Please refer to the response to General Issue 12.B.

Page 7-14, lines 3-6: Statements such as this should be referenced, even if a personal communication. The statement is: "EPA is currently reviewing new studies on noncancer effects of PCBs as part of the ongoing IRIS review process. These studies report possible associations between developmental and neurotoxic effects in children from pre-natal or post-natal exposures to PCBs." Without dose-response information provided simultaneously, such statements fuel public concerns unnecessarily.

RESPONSE 543:

The revised HHRA will include the appropriate citations.

Section 7.2.3.2: In view of the overall importance of the use of TEFs in this HHRA, expanded discussion of TEFs and uncertainty associated with them is warranted. For example, the basis of the TEFs is Ah binding and CYP1A1 induction. The association between enzyme induction (AHH) and toxicity, and extrapolation of this effect in animals to humans, should be discussed.

RESPONSE 544:

This information was provided in the HHRA Volume I, Section 2.2.2, pages 2-7 to 2-12. The revised HHRA will include a reference to this additional discussion in the uncertainty sections of Appendices B, C, and D.

Section 7.2.3.3: This section refers to the EPA's proposed draft TCDD cancer slope factor (CSF) of 1E+06 (mg/kg-d)-1. The EPA's Science Advisory Board (SAB) has provided comments to EPA on this issue, yet the EPA has not yet released a revised document for public or peer review. The derivation of this CSF is a highly controversial issue due to EPA's failure to clearly describe and document its derivation, and because it appears to be based largely on epidemiological studies for which there are substantial confounding factors and spurious associations. Furthermore, the uncertainty discussion specifically fails to make reference to other alternative CSFs for TCDD published in the peer-reviewed literature and by other federal regulatory agencies, specifically those published by the FDA (1992) and Keenan et al. (1991). In the absence of a final consensus in the scientific and regulatory communities on the potential human carcinogenicity of TCDD, it is speculative and presumptuous to even discuss EPA's draft CSF for TCDD in this risk assessment. Should EPA decide to keep this discussion in the uncertainty section, it is recommended that the full range of possible TCDD CSFs published since the Pathology Working Group reported its findings of the 1990 reevaluation of the Kociba et al. (1978) rat liver pathology slides (Sauer 1990; Keenan et al. 1991; Goodman and Sauer 1992) be included also.

RESPONSE 545:

Please refer to the response to General Issue 12.C.

Section 7.3.2: Further clarification of this section is needed. For example, how would a risk manager use the information presented in the rightmost column of table 7-5 in his/her decision making? Information in this column is described as an "average effect" (page 7- 16, line 12), which implies there's a range.

RESPONSE 546:

Risk management and decisionmaking are beyond the scope of the HHRA. However, discussion of results from the Monte Carlo and probability bounds analyses will be added to the revised HHRA in appropriate sections along with better referencing to Attachment 5 in Volume I.

Stephen T. Washburn

See comments above.

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

COMMENTS

Holly Hattemer-Frey

I suggest the authors include a table summarizing each and every source of uncertainty associated with the Phase II assessment, whether the source is likely to over- or underestimate risks, and quantify (where possible) the extent to which the source is likely to over- or underestimate risk.

Then, major sources of uncertainty should be discussed in more detail as well.

RESPONSE 547:

The revised HHRA will have an expanded uncertainty discussion.

I note three issues below that warrant further evaluation/discussion.

Section 7 does a reasonably good job of qualitatively discussing sources of uncertainty and variability associated with the point estimates. It fails, however, to aggregate these sources to provide the reader with a revised risk estimate reflecting uncertainty and variability. For example, if individuals consumed skin-on fillets (point estimates for fish taken from the Massachusetts portion of the study area are based on skin-off fillets), risks could be increased by a factor of two to four.

RESPONSE 548:

The revised HHRA will have an expanded uncertainty discussion.

PCDDs/PCDFs were not analyzed for in Connecticut fish samples. The addition of PCDD/PCDFs could increase risk for Connecticut consumers by a factor of two. If an individual ate one species of fish (versus a mixture as assumed in RA), risks could increased by another factor of 2.5. If an individual consumed fish from one location (versus random access within an exposure area), risks could increase or decrease, depending on COPC concentrations. (This point needs to be discussed quantitatively in Section 7.) I recommend that at least two additional scenarios be discussed in Section 7, one worst-case and one best case. For example, what if an individual ate skin-on fillets only, ate the most highly contaminated species only , and consumed fish from one, highly contaminated area only, how much would risk estimates change? Conversely, what if an individual ate skin-off fillets only, consumed the least contaminated species only, and consumed fish from the least contaminated area only, how much would risk estimates change? This type of cumulative analysis would be more useful than simply listing all the types of uncertainty and their effect on risk estimates.

RESPONSE 549:

The revised HHRA will have an expanded uncertainty discussion.

Table 7-1, page 7-3: Data presented in Table 7-1 would be much more meaningful if actual concentration numbers were presented as well as percent change in the EPC.

RESPONSE 550:

Table 7-1 will be modified accordingly in the revised HHRA.

F. Owen Hoffman

No. The failure to address uncertainty in the toxicity coefficients used in the HHRA is a major shortcoming of the uncertainty analysis section of this report. In this analysis, probability distributions are used only to depict inter-individual variability in exposure as a stochastic process. Epistemic uncertainty in exposure is not addressed using probabilistic uncertainty analysis.

RESPONSE 551:

As to the uncertainty in toxicity coefficients, please refer to the response to General Issue 12.B. Epistemic uncertainty in exposures is addressed using probability bounds analysis. See the response to General Issue 10.B.

However, for the EPA toxicity coefficients, neither inter- individual variability nor epistemic uncertainty is addressed quantitatively (a practice that is unfortunately consistent with current EPA policy and guidance for Superfund risk assessment). In the absence of quantitative information on the uncertainty in the estimate of the cancer slope factors and the RfD's for PCB and PCB congeners, the quantitative uncertainty analysis of the HHRA for fish and waterfowl ingestion degrades into an evaluation of exposure only, not risk.

RESPONSE 552:

Please refer to the response to General Issue 12.B.

Because the PBA is based on the propagation of extreme values, the results of the HHRA PBA give the impression that the point estimates of cancer risk and HI's in Chapter 5 of Volume IV, Attachment C are potentially either over- or under-estimates of true exposures. I believe this result is an artifact of the PBA approach that propagates extreme values combined with a systematic bias of input assumptions that are skewed towards high values of exposure and risk.

RESPONSE 553

Please refer to the responses to General Issues 10.C and 10.D.

A systematic bias towards over-statement of the risk is partly due to

(a) the treatment of the toxicity coefficients as having no uncertainty,

(b) the failure to account for the full uncertainty on the mean concentration of PCB's in fish, including the mean concentration of PCB like congeners,

(c) the assumption that 100% of the fish consumed are from the river, and

(d) the assumption that fish are caught from the river in every month out of the year.

RESPONSE 554:

In regard to toxicity coefficients, please refer to the response to General Issue 12.B. In regard to concentrations, please refer to the response to General Issue 4.C. In regard to the proportion of fish consumed from the Housatonic River, the incorporation of an input to the probabilistic models accounting for uncertainty in the fraction of fish ingested from the Housatonic River will be considered in the revision. The HHRA does not assume that fish are caught every month of the year. It projects meals per year, but not the distribution throughout the year.

Because the size of the population of recreational anglers is not rigorously defined, it is difficult to determine what the upper-end of the distribution of exposures represents that is simulated by Monte Carlo analysis. The Monte Carlo analysis used in the HHRA to simulate inter-individual variability as a stochastic process is truncated at the upper 99th percentile of the frequency distribution of true individual exposures. If the population size were as large as 10,000 persons, the 99th percentile would underestimate exposure for the top 100 persons in the distribution. The 95th percentile would underestimate exposure for the top 500 persons. The 90th percentile would underestimate exposure for the top 1000 persons.

RESPONSE 555:

Please refer to the response to General Issue 1.B.

I have made a preliminary probabilistic evaluation of epistemic uncertainty in cancer risk ppm (see attached MS Excel spreadsheet workbook). This PCB concentration is roughly comparable to the EPC concentrations used for bass caught from West Cornwall/Bulls Bridge. In making this comparison, I have assigned probability weights to a range of plausible values to quantify epistemic uncertainty in model inputs, including uncertainty in the cancer slope factor and RfD. Monte Carlo simulation was employed to propagate epistemic uncertainty from inputs to exposure and risk. The results are expressed as a 95% credibility interval for the RME and the CTE (see Appendix 2, including attached MS Excel/Crystal Ball spreadsheet).

Based on these calculations, I conclude that the HHRA point estimates of risk in Vol. IV, Chapter 5 are in reasonable agreement with the upper limit of a 95% credibility interval of cancer risk and non-cancer HI for both the RME and CTE. This conclusion was maintained even after the analysis was re-run with toxicity coefficients held constant at their specified EPA regulatory defaults of 2 (mg kg-1 d-1)-1 for the cancer slope factor and 2 × 10-5 mg kg-1 d-1 for the RfD.

The relative range of my 95% credibility intervals for the RME and CTE was about two orders of magnitude for either the RME or CTE. This was reduced to about a factor of about 20 when the toxicity coefficients are assumed to be fixed without uncertainty, although the upper bound of the 95% credibility interval did not change appreciably (a similar result was reported by Land 2002 [Land C. Uncertainty, low-dose extrapolation and the threshold hypothesis. *J. Radiol. Prot.* 2:1–7. 2002]). By comparison, the range of the HHRA probability bounds analysis often approaches three orders of magnitude.

The upper bounds of the PBA exceed the limits of my 95% credibility interval for the RME and CTE by an order of magnitude (Appendix 2, Table 1). These upper bounds produced by the PBA appear implausibly high for a realistic population of avid recreational anglers. On the other hand, the relative range of uncertainty at a given percentile that is produced by the PBA for non-cancer HI is merely a factor of about 2 around a central value. This result for non-cancer risk implies a level of epistemic uncertainty (at a given percentile of the frequency distribution that describes interindividual variability of true exposure) that is intuitively implausible.

RESPONSE 556:

The Reviewer asserts that the results of the PBA that were reproduced in this table range over three orders of magnitude. Actually, the PBA results range from a factor of 5 to a factor of 600 in range, rather than 3 orders of magnitude (which would be a factor of 1,000). The Reviewer also notes that the upper bounds of the PBA results exceed the limits of his 95% credibility intervals. If the differences the Reviewer is concerned about relate to the extremities of the p-box tails, then it should be pointed out that these tails are associated with very small probabilities, suggesting that such extreme cases are unlikely even though they are possible in principle. In any case, the PBA is modeling uncertainties and variabilities that were not included in the Reviewer's reanalysis, so it is not surprising that the former should produce wider distributions. However, given the differences in the two approaches, it is remarkable that they do not show even larger disparities. For a graphical comparison of the Reviewers' results and those of the PBA, please refer to the responses to General Issues 10.C and 10.D.

The expectation of uncertainty much larger than a factor of two, even at a given percentile of the frequency distribution of true exposures, is based on the use of disparate sets of partially relevant data sets to define the true but unknown frequency distribution of exposure, the use of restricted bounds to describe the uncertainty in the mean PCB concentration in fish and waterfowl, the need to consider the fact that realistic harvesting of fish and waterfowl will include locations other than the Housatonic River, and the fact that the target population for which stochastic variability in exposure is simulated is essentially undefined. The range of uncertainty in HI at a given percentile will be expanded still further if the HHRA analysis were to include uncertainty in the RfD for PCB's and the dioxin- like PCB congeners, as the dominant source of uncertainty in these variables is epistemic.

RESPONSE 557:

The Reviewer is apparently suggesting that there is too much uncertainty in the results. The assessments were based on available relevant information, the paucity of which required the use of disparate sources and data with uncertainties that were sometimes substantial. For a discussion of the use of "restricted bounds" on concentration, please refer to the response to General Issue 4.D. As to the issue of the fraction ingested, please refer to the response to General Issue 8.B. As to the issue of the definition of the target population, please refer to the responses to General Issues 1.A and 1.B. As to the comment about including uncertainty of the RfD, please refer to the response to General Issue 12.B.

John C. Kissel

Use of point estimates within the Monte Carlo assessment that was supposed to characterize variability would be expected to produce an underestimate of population variability.

RESPONSE 558:

There were two instances in the Monte Carlo simulations where point estimates rather than distributions were used: concentrations and intake rate. Regarding the use of point estimates for concentrations, please refer to the response to General Issue 4.C. The revised HHRA will employ appropriate deconvolution algorithms to simultaneously derive plausible distributions for exposure frequency and intake rate from the distribution based on the Maine Angler Survey data.

Graphical presentation in Volume IV, Section 6 would have been improved in many cases by use of log scales on the x-axis.

RESPONSE 559:

EPA agrees that the presentation of results can be improved, and this suggestion will be addressed in the revised HHRA.

Roger O. McClellan

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

RESPONSE 560:

Variability and uncertainty were handled separately, and differently, in the HHRA through the use of Monte Carlo simulation complemented by probability bounds analysis. Sensitivity analysis was used to determine how each model's prediction of risks changes when a parameter is variable or uncertain. Sensitivity analysis of variability indicated how the magnitude and functional form of the differences between individuals influenced the model output. Sensitivity analysis of uncertainty in a parameter indicated the importance of ignorance (called epistemic uncertainty in other comments or responses) regarding that parameter on the output of each model. Information from these analyses can be used to determine whether more accuracy in the characterization of variability or uncertainty in particular parameters would result in a useful improvement in model reliability.

EPA guidance encourages separation of the effects of variability whenever possible. In some cases, there exists uncertainty regarding the nature of the variability. For example, in instances where only summary statistics are available to characterize a variable, we are uncertain what the distribution of variability is. Uncertainty and variability are kept separate in this case by a probability bounds analysis, which treats uncertainty regarding the nature of an unknown probability distribution in the same way as it treats uncertainty in the actual value of an unknown parameter. Sections 4.1, 4.2, and 4.8 in Attachment 5 of HHRA Volume I discuss Monte Carlo and probability bounds approaches to modeling uncertainty and variability in greater detail.

P. Barry Ryan

The comments under this heading are similar to those above.

Lee R. Shull

In general, as described in 6 above, uncertainty and variability were not adequately characterized.

Stephen T. Washburn

See comments above.

8. Overall, was the approach used to assess risk from consumption of fish and waterfowl and other wild food items reasonable for evaluating the baseline risk?

COMMENTS

Holly Hattemer-Frey

Yes, with the exception of other comments made.

F. Owen Hoffman

The deterministic analysis of the baseline risk assessment appears to be appropriate with the exception of the items mentioned in response to earlier questions. The chance that fish and waterfowl are harvested from locations other than the Housatonic River should be considered as well as the chance that PCB concentrations will be reduced in future time.

RESPONSE 561:

The incorporation of an input to the probabilistic models accounting for uncertainty in the fraction of fish ingested from the Housatonic River will be considered in the revision. In regard to harvesting fish and waterfowl from other locations, please refer to the responses to General Issues 8.B and 9.D. In regard to changing PCB concentrations over time, please refer to the response to General Issue 4.E.

Numerous sources of bias need to be removed from the quantitative uncertainty analysis and the PBA approach should either be replaced, or at least augmented, by a probabilistic analysis of epistemic uncertainty.

RESPONSE 562:

Please refer to the responses to General Issues 10.A and 10.B. The revised HHRA will include a comparison (for one site, path, receptor, and model) between a second-order Monte Carlo simulation and the current assessment consisting of the one-dimensional Monte Carlo simulation and probability bounds analysis.

The upper bound estimates of the PBA are unrealistically high for a population of avid recreational fishermen and thus violate a common sense of face validity. The quantitative uncertainty analysis should be extended to include uncertainty in the toxicity coefficients.

RESPONSE 563:

With regard to the upper bounds being too high, please refer to the responses to General Issues 10.C and 10.D. With regard to uncertainty in the toxicity coefficients, please refer to the response to General Issue 12.B.

John C. Kissel

Because multiple approaches were used, it is difficult to summarize. Some inputs to the deterministic assessment should be reconsidered and point estimates should not have been applied in the probabilistic assessment.

RESPONSE 564:

Please refer to the responses to General Issues 8.A, 8.B, 8.C, and 8.D for discussion of changes to exposure parameters in the deterministic assessment. The point estimates in the Monte Carlo analyses, concentration, and meal size, were treated as variables in the probability bounds analysis. Regarding the use of point estimates for fish concentrations in the Monte Carlo simulations, please refer to the response to General Issue 4.C. The revised HHRA will employ appropriate deconvolution algorithms to derive a plausible pair of distributions for both exposure frequency and meal size from the distribution based on the Maine Angler Survey data.

I am unable to quantitatively assess the effect of needed changes. However, I note that the alternative analysis of fish consumption in Reaches 5 and 6 provided in comments to the panel by AMEC on behalf of GE produces a 95th percentile risk approaching 10-3 even after downward adjustment of multiple exposure factors. This might be viewed as evidence of consensus regarding significant risk via fish consumption in at least a portion of the Rest of River study area.

RESPONSE 565:

EPA concurs with the interpretation that different analyses support this consensus.

Roger O. McClellan

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

RESPONSE 566:

Please refer to the responses to General Issues 8.A, 8.B, 8.C, 8.D, 9.A, 9.B, 9.C, 9.D, and 13A.

Most importantly, these same serious limitations apply to estimating risks of future use of the river.

RESPONSE 567:

Please refer to the responses to General Issues 8.A, 8.B, 8.C, 8.D, 9.A, 9.B, 9.C, and 9.D, and 13.A.

P. Barry Ryan

The following are concerns regarding this pathway. There are very few data on waterfowl in Massachusetts and essentially no information from Connecticut. Further, those data collected may not represent that actual population of waterfowl on the river during a hunting season due to the presence of migratory birds. The application of data relating Massachusetts sediment and waterfowl may not be applicable to Connecticut sediment and waterfowl. Hence this aspect of the risk assessment may be called into question. However, these are the best data available and thus the risk assessment has been done properly.

RESPONSE 568:

Please refer to the responses to General Issues 9.C, 9.D, and 9.E. The waterfowl consumption pathway was based on 25 samples of duck tissue, which EPA believes was an adequate sample size. The number of samples was constrained by the limitations in the collection permit issued by the state.

Lee R. Shull

In general, I believe the approach used to assess potential human health risks associated with consumption of fish and waterfowl and other wild food items in the Housatonic River area is reasonable, but lacks transparency and consistency in a number of instances. The assessment, as done, is highly likely to over-estimate risks to the receptors assessed via these pathways, as a result of the application of multiple upper-bound assumptions.

RESPONSE 569:

The clarity, transparency, and consistency of the presentation of risk will be improved as discussed in multiple, specific responses provided here. In regard to the use of multiple upper-bound assumptions in the point estimate approach, please refer to the response to General Issue 13.A.

This is all the more reason that a thorough identification and analysis of uncertainty should be included.

RESPONSE 570:

The revised HHRA will include an expanded discussion of uncertainty.

I also have concerns about the apparent miss-use of the Ebert et al (1993) fish consumption data; a number of incorrect applications of these data were presented by Dr. Ebert herself at the November 18-20, 2003 public meeting.

RESPONSE 571:

Please refer to the response to General Issue 8.A.

Although it is highly unlikely that EPA has underestimated risks to people who might consume fish or waterfowl taken from the Housatonic River area, I believe it is highly likely these risk have been grossly overestimated. I strongly recommend that EPA re-assess this fish/waterfowl consumption pathway, taking into consideration comments especially related to exposure assessment.

RESPONSE 572:

Please refer to the responses to General Issues 8.A, 8.B, 8.C, 8.D, 9.A, 9.B, 9.C, 9.D, 9.E, and 13.A.

ADDITIONAL REVIEWER COMMENTS

Lee R. Shull

- Table 3-4 indicates that an RfD of 1E-04 for methyl mercury will be used, but instead an RfD of 3E-04 for mercury chloride is used in the Risk Characterization to calculate HQs.

RESPONSE 573:

The Risk Characterization will be updated based on the use of the methylmercury RfD in the revised HHRA.

- All Tables should be checked to make sure that footnotes are added, as needed, to reference where in the text relevant explanations/discussion are given.

RESPONSE 574:

Consideration will be given to adding additional references where appropriate.

- In Section 5, risk characterization methods and results are clearly and well presented, both in graphic and tabular form.

- All cancer risk estimates should be termed "theoretical upperbound cancer risk estimates", rather than simply cancer risk. Readers need to understand the estimates are both theoretical and upperbound.

RESPONSE 575:

The cancer risk estimates are based, in part, on the slope factor, which is defined by EPA (RAGS, 1989, p. 8-2) as "a plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen." EPA will enhance the clarity of its risk presentation, including that the calculated cancer risks are upper-bound estimates.

- Section 5 (risk characterization) lacks a proper discussion that would assist readers in placing the results in proper perspective. With theoretical upperbound cancer and noncancer risks as high as these are, readers could benefit from the addition of some information that might help place these results in perspective (e.g., comparison of the calculated exposure levels associated with fish and waterfowl consumption with actual human exposures reported in the literature and data on associated toxic effects, if any).

RESPONSE 576:

Please refer to the responses to General Issues 1.C and 1.D.

As was mentioned in regards to the Phase 2 Direct Contact HHRA, comparison of estimated risks with study results such as those in MADH (1997) and ATSDR/MDPH (2002) would be appropriate. These studies, as presented by GE at the November 18-20, 2003 public meeting, indicate that no increase in neither human blood levels nor cancer incidence rates were measured in the Housatonic River area. Comparison to these kinds of studies help place the HHRA estimates in proper perspective.

RESPONSE 577:

Please refer to the response to General Issue 1.C.

- In Table 5-9, the RfD of 2E-05 mg/kg-day for Aroclor 1254 was used to estimate noncancer effects associated with Housatonic River PCBs, which are predominately Aroclor 1260. Based on available data, EPA specifically derived RfDs for Aroclor 1016 and 1254. EPA has not recommended the use of these RfDs for assessing noncancer risk to other Aroclor mixtures (IRIS Verification Date 2/16/1994). Neither EPA Region 3 nor Region 9 utilize the Aroclor 1016 and 1254 RfDs for deriving Risk Based Concentrations (RBCs) or Preliminary Remediation Goals PRGs), respectively, for other Aroclor mixtures (EPA 2002, 2003).

RESPONSE 578:

Because RfDs are available for only two commercial Aroclor mixtures, it was necessary to choose the Aroclor mixture most similar to that found at the site. The PCB mixture at the site resembles Aroclor 1260 which, like Aroclor 1254, is composed of congeners with a higher chlorine content and of greater persistence in the environment than other commercial mixtures such as Aroclor 1016. Thus, the RfD for 1254 was considered appropriate for evaluation of noncancer effects at this site.

ATTACHMENT C.4. TOTAL TEQ CALCULATIONS

Lee R. Shull

- PCB risks are calculated separately, and then summed, for tPCB and PCB congeners. To avoid double counting exposure/risk, the contribution of TEQ from tPCB (based on the TEQ fraction) was subtracted from the total PCB congener TEQ. Thus, Aroclor exposure/risks are based on the full measured concentration of tPCB, whereas the PCB congener risk is based on the fraction of exposure/risk not accounted for in the tPCB exposure/risk estimate. As an example, Table 5-3, Cancer Risks from Fish Consumption for Each COPC, gives RME cancer risks of 8E-03 for tPCBs and 5E-03 for TEQ risks (minus the contribution from tPCBs). Theoretically, since the source of the 12 PCB congeners is the Aroclor mixtures released, then the TEQ contribution from the Aroclor mixture subtracted from the TEQ based on measured congener concentrations should equal zero. However, the fraction of TEQ in the tPCBs appears to represent only 6.1% of the measured TEQs. There are several possible reasons:

  - PCB mixtures have weathered over time resulting in a relative increased proportion of the 12 coplanar congeners compared to other congeners either by transformation or degradation processes.

  - The TEFs upon which the TEQs are based may overstate the dioxin- like potency of individual congeners: Aroclor toxicity values are based on in vivo animal bioassays of the PCB mixture and therefore assess not only actual toxic endpoints but also account for possible synergistic and antagonistic relationships among congeners. Conversely, TEFs are based largely on Ah binding and AHH induction of individual congeners, and therefore, do not assess actual toxic endpoints and do not account for possible synergistic and antagonistic relationships among congeners.

  - The CSF for TCDD may be overstated to the extent that PCB congener TEQ risks are substantially higher than estimated Aroclor risks.

  The description of the TEQ method of applying the TEQ method to avoid double counting suffers from both lack of clarification and transparency. Based on information presented by Dr. Russ Keenan at the November 18-20, 2003 public meeting, it appears that there is in fact incorrect. I strongly recommend that EPA consider Dr. Keenan's information and re-evaluate the necessity of using the TEQ approach in this HHRA.

  RESPONSE 579:

  Please refer to the response to General Issue 5.A.

For a number of samples, the TEQ value for some dioxin, furan, and PCB congeners is 0.00. For these samples, the reported concentration in Attachment C.3 (Raw Data) is also shown as 0.00, sometimes with either a J or U data qualifier. It is unclear why these concentrations are shown as 0.00, and how these data are used in the risk assessment. If these analytes were not analyzed for or if these data were rejected during data validation, then this should be indicated. If these values of 0.00 were included in summary statistics or EPC calculations, then there may be errors in the calculations.

RESPONSE 580:

The zeros were the result of an error in a spreadsheet. The correct concentrations will be substituted for the zeros in the revised HHRA and the calculations revised appropriately.

Stephen T. Washburn

In addition to the comments above, the following recommendations are made:

- Data on PCB levels detected in fish and waterfowl from "reference areas" should be more fully discussed in the HHRA to put the risk estimates calculated for the Housatonic into context. According to the HHRA, waterfowl were captured from both Woods Pond (and its backwaters) and a reference area (Threemile Pond) for analysis of PCB concentrations in breast and liver tissue (p. 2-7; Volume 4; Appendix C). However, the HHRA does not present the results of the waterfowl data from the reference area or provide comparisons to the data from Woods Pond. Particularly given the migratory behavior of some waterfowl, the HHRA should compare the data from the reference area and Woods Pond.

RESPONSE 581:

A summary of reference area waterfowl concentrations and appropriate statistical comparisons with site waterfowl concentrations will be provided in the revised HHRA.

In addition, the HHRA states that fish were captured from four locations downstream of the GE facility and from two reference areas for PCB analysis (p. 2-4; Volume 4; Appendix C). The HHRA should include a more complete discussion comparing the fish data from the reference areas to the locations downstream of the GE facility.

RESPONSE 582:

Additional information and discussion on this topic will be included in the revised HHRA.

Based on information provided by EPA in response to Panel questions on this issue, and using the methodologies and assumptions presented in the HHRA, it appears that PCB concentrations in fish and waterfowl from the reference areas may pose risks that are smaller than those for the Housatonic, but that are still potentially significant relative to EPA risk management goals. Such a comparison of relative risks should be included in the HHRA to put the results for the Housatonic into better context.

RESPONSE 583:

Additional information and discussion on this topic will be included in the revised HHRA.

- As discussed above in the context of the direct contact scenarios, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis for the fish and waterfowl consumption scenarios.

RESPONSE 584:

Please refer to the response to General Issue 3.A.

D. PHASE 2 – AGRICULTURAL EXPOSURES (VOLUME V)

1. Were the exposure scenarios evaluated appropriate and reasonable for current and reasonably foreseeable future use of the floodplain?

COMMENTS

Holly Hattemer-Frey

I strongly disagree with using the "assumed" soil concentrations of 2 mg/kg and 0.5 mg/kg in lieu of measured or modeled values for non-parcel specific exposure scenarios. One reason given for adopting this approach was that it illustrates how risks would change with decreasing PCB concentrations. "For example, the result obtained by assuming a tPCB soil concentration of 0.5 mg/kg would also be obtained for a parcel where 10% of the land cultivated for corn silage was contaminated with 5 mg/kg and the remaining 90% of the cultivated land was not contaminated with tPCBs." While this is true, it is not representative of current site exposures, and associated results are not very meaningful. Furthermore, the approach represents a significant departure from EPA protocols. I strongly urge that the final HHRA use site-specific data to calculate a range of actual soil concentrations versus hypothetical values. While this could be done without calculating parcel-specific risk estimates, measured data from areas where agricultural practices do or could occur should be used.

RESPONSE 585:

Please refer to the response to General Issue 11.A.

F. Owen Hoffman

The approaches appear conceptually reasonable, but the analysis should be based on actual measured concentrations of PCB's in soil.

RESPONSE 586:

Please refer to the response to General Issue 11.A.

John C. Kissel

Assessment of exposures at the fixed and somewhat arbitrarily chosen soil contamination concentrations of 0.5 and 2.0 mg/kg is inconsistent with assessment based on actual contamination levels in the rest of the document. The 2.0 mg/kg value is based on an agreed upon cleanup level, but it represents a hypothetical future state and therefore leads to summary/graphical results that are not directly comparable to results generated for the other pathways.

RESPONSE 587:

Please refer to the response to General Issue 11.A.

Adequacy of the treatment of future land use is unclear. Tabular description of past and present land use showing trends (by parcel or reach, not land use) would improve the presentation.

RESPONSE 588:

Please refer to the response to General Issue 2.E.

Roger O. McClellan

The agricultural exposure scenarios evaluated do not appear appropriate nor reasonable as related to current and reasonably foreseeable future use of the flood plain. The assessment does not adequately describe current agricultural practices in the flood plain and adjacent areas. Likewise, it does not provide an adequate picture of likely future use. It appears that currently only a small portion of the flood plain within the 1 ppm isopleth is used for agricultural purposes. Moreover, commercial agricultural enterprises that use some flood plain land also appear to utilize substantial land outside of the flood plain. I recognize that this poses a challenge for developing a baseline case.

RESPONSE 589:

Please refer to the response to General Issues 2.E and 11.A.

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

RESPONSE 590:

Please refer to the response to General Issue 11.A.

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

RESPONSE 591:

Please refer to the response to General Issue 2.E.

The present “model farm” scenario is seriously flawed in several ways. A major flaw is the assumption that all of the agricultural activity is conducted within the 1 ppm isopleth with contamination at either 0.5 or 2.0 ppm tPCB. It is my understanding that this situation does not describe any actual existing agricultural enterprise. Thus, it would be inappropriate to use the assessments scenario in the assessment as a basis for extrapolating risks for individuals in the area consuming local agricultural products.

RESPONSE 592:

The representation in the risk assessment was not intended to be a “model farm,” but to provide calculations that could be scaled to any property under evaluation, and the instructions as to how to accomplish this were provided in Section 4.1 of the HHRA, Volume V. Please refer to the response to General Issue 11.A.

Beyond the issue of blended use of flood plain within the 1 ppm isopleth and non-flood plains land, the assessment does not make clear how it deals with the likely substantial use of grain, and perhaps forage, imported from outside the immediate area. This imported feed, very low in PCBs, will be a substantial contribution to the caloric intake needs of any livestock and poultry that may have access to the flood plain. The values used in the assessment do not seem to be linked to any local practices but rather appear to have been plugged into the equations. They may not be realistic either for commercial or backyard farms in this area.

RESPONSE 593:

Feed component intake factors were selected for commercial farm animals based on interviews with local farmers and the USDA Farm Services Agency. It was assumed that some fraction of the diet of nearly all commercial and backyard farm animals would include concentrates (i.e., grains or protein supplements) that originate outside the floodplain (Table 4-3). As explained in Section 4.2.2 of the HHRA, Volume 5, these concentrates were assumed to have a tPCB concentration of zero.

P. Barry Ryan

I have commented on some concerns I have for use of certain floodplain areas subjected to irregular flooding with concomitant new sediment deposition. This represents my chief concern and this concern affects the agricultural exposures as well.

RESPONSE 594:

Please refer to the response to General Issue 4.E.

Overall, I believe that the developed scenarios span the range of likely exposures to be experienced.

A few questions were raised in our discussion or in the public comment session. Ones that I noted as being relevant here include the following. In considering the appropriate scenarios, what consideration was there of the long-term secular trend in agricultural use in Western Massachusetts? For instance, is dairy farming on the decline with faming land being replaced by tract housing in this area? Trends in such area may suggest the need for different scenarios in the agricultural risk assessment.

RESPONSE 595:

Please refer to the response to General Issue 2.E.

Also, it is necessary to reconcile EPA's assessment that there are few family farms in the area (done by inspection) and the contention from the public comments that there are many. Clearly, the scenarios involving family farm product usage will have more bearing if many such farms exist. We need the data describing them.

RESPONSE 596:

The HHRA specifies backyard farming activities that occur within the 1-ppm tPCB isopleth, which were identified through field observations and interviews with the USDA Farm Services Agency (Section 2.1.1 and Table 2-1). During the November 2003 presentation at the Peer Review meeting, Mr. Tim Gray noted the existence of backyard farms and reported that these families tend to keep farming-related activities outside the floodplain to avoid contamination. His primary point was that more backyard farms, and commercial farms, might exist in the floodplain if not for the contamination. His presentation is consistent with EPA's finding that very few backyard farms currently exist within the floodplain. Also, backyard farming activities may change over time, and these changes may not be detected without repeated, systematic surveys. EPA does not know of any such surveys describing the number and type of backyard farming activities that have occurred in the past, are occurring now, or might occur in the future. However, the presence of such activities in the floodplain now, and the public comments, suggest that they can reasonably be anticipated in the future. The activities and goals of local agricultural organizations will be discussed in more detail in the revised HHRA.

Lee R. Shull

In general and except for the comments below, I believe the exposure scenarios evaluated for the current and future land use of the floodplain are appropriate and reasonable. The following comments relate primarily to lack of clarity and transparency for some items.

Page ES-5, lines 8-15: A more definitive statement about the potential for future backyard farms is needed. The extent of the potential for these farms should be more clearly discussed.

RESPONSE 597:

Additional discussion will be provided. The HHRA specified backyard farming activities that occur within the 1-ppm tPCB isopleth, which were identified through field observations and interviews with the USDA Farm Services Agency (Section 2.1.1 and Table 2-1). Backyard farming activities may change over time, and these changes may not be detected without repeated, systematic surveys. EPA does not know of any such surveys describing the number and type of backyard farming activities that have occurred in the past, are occurring now, or might occur in the future. However, the presence of such activities in the floodplain now, and the public comments suggest that they can reasonably be anticipated in the future. The activities and goals of local agricultural organizations will be discussed in more detail in the revised HHRA.

Page ES-8, line 21: It is important, even in the executive summary, to explain the basis of the assumed 0.5 mg/kg and 2 mg/kg soil concentrations of tPCBs. Also, a reference should be provided for the statement made in lines 21-22 that 2 mg/kg "…is the current remediation goal for current residential properties." The relevance this level to the HHRA should be clearly stated; whether or not any level greater than 2 mg/kg tPCBs means remediation will be done.

RESPONSE 598:

Please refer to the response to General Issue 11.A. The Executive Summary will no longer contain references to assumed soil concentrations of 0.5-ppm and 2-ppm PCBs. A full range of concentrations will be evaluated explicitly. The relevance to the 2-mg/kg concentration will be clarified.

Page 1-1, line 25: As already indicated, it is somewhat confusing as to why 2 mg/kg was the assumed soil concentration for risk assessment purposes instead of 1 mg/kg, which seems more logical. The 1 mg/kg concentration is equated to the 10-year floodplain area.

RESPONSE 599:

Please refer to the response to General Issue 11.A. The revised HHRA will no longer contain references to assumed soil concentrations of 0.5-ppm and 2-ppm tPCBs. A full range of concentrations will be evaluated explicitly. The relevance to the 2-mg/kg concentration will be clarified.

In Section 2, various food and livestock feed media that were sampled and analyzed for PCBs and sometimes PCDD/PCDFs are described. Some sections note that data were reported on a wet weight basis and some on a dry weight basis. Please clarify whether these data are all normalized to a standard weight basis consistent with applicable consumption rates.

RESPONSE 600:

Dry weight plant concentrations were used to estimate contaminants of potential concern (COPC) intakes for farm animals consuming corn silage and grass, and wet weight concentrations were used to estimate COPC intakes for people consuming garden produce. Additional text will be added to the revised HHRA to clarify this approach.

Also, there is no data usability discussion and very little mention of data validation. In some cases, the analytical method used is not identified (e.g., milk samples analyzed by the USFDA, which is mentioned in Section 2.3.1.2).

RESPONSE 601:

With the exception of milk data and MDEP's fiddlehead fern data, all data were validated by EPA. This process will be described briefly in the revised HHRA. Laboratory records are not available for milk samples analyzed by USFDA. Through interviews, EPA learned that the laboratory used the FDA *Pesticide Analytical Manual* to analyze the milk samples. The results of these interviews are described in Section 2.3.1.2.

Page 2-1, lines 24-25: Please clarify whether cattle access to the river, which has been observed near the CT border, represents a potential exposure pathway in the MA Reaches.

RESPONSE 602:

Historically this pathway existed at the DeVos farm property, which is now owned by GE. This pathway currently exists for non-lactating animals grazing in Reach 9 where tPCB concentrations in floodplain soil are generally low or below detection limits. Beef cattle on a backyard farm in Reach 7 have not been observed accessing the river. Dairy animals on the only farm with operations in the floodplain along Reach 5 are currently confined and do not have access to the floodplain. In general, farm animals are not likely to experience significant river sediment and surface water exposures in the more contaminated reaches of the river, relative to floodplain soil and feed exposures, if they are provided with an adequate water supply.

Page 2-2, line 12: The farmer interview information, which is compiled and summarized elsewhere in the HHRA (I don't recall where), should be referenced here.

RESPONSE 603:

This reference is provided just after line 12.

Page 2-3, lines 10-11: Please clarify and discuss the potential significance of the growing of field corn for sale as corn silage to other farmers (e.g., a commercial dairy outside the floodplain area). Also, please note any analytical data that ma y have been collected on this corn.

RESPONSE 604:

Contamination in crops grown in the 1-ppm tPCB isopleth might reach animal products produced on farms entirely outside the 1-ppm tPCB isopleth if farmers purchase and feed such crops to their animals. Analytical data for corn grown within the 1-ppm tPCB isopleth is reported in Section 2.3.2, and a reference to this section will be added to Section 2.1.1.1.

Page 2-4, lines 25-26: While it is highly likely that the assumption that high-moisture corn grown on the floodplain does not contain levels of COPCs greater than background concentrations, this assumption should be verified at some point with sampling data.

RESPONSE 605:

It has not been verified that high-moisture corn is being used and, if it is, only one farmer might be producing this crop, according to the USDA Farm Services Agency. Therefore, verification is not warranted, particularly given that tPCBs were not detected in corn ears sampled from two Reach 5 farms.

Page 2-6, Section 2.1.2: In light of the presentations made at the November 18-20, 2003 public meeting, this section needs to be more concise as to the potential for noncommercial, backyard farms. The point was made rather strongly at the meeting that significant backyard farming interest exists in the Housatonic River area.

RESPONSE 606:

The HHRA identifies backyard farming activities that occur within the 1-ppm tPCB isopleth, which were identified through field observations and interviews with the USDA Farm Services Agency (Section 2.1.1 and Table 2-1). During the November 2003 presentation at the Peer Review meeting, Mr. Tim Gray noted the existence of backyard farms and reported that these families tend to keep farming-related activities outside the floodplain to avoid contamination. His primary point was that more backyard farms, and commercial farms, might exist in the floodplain if not for the contamination. His presentation is consistent with EPA's determination that very few backyard farms currently exist within the floodplain. Also, backyard farming activities may change over time. However, the presence of such activities in the floodplain now and the public comments suggest that they can reasonably be anticipated in the future. Further examination of future use will be performed while revising the HHRA.

Page 2-8, Section 2.2.1: Better justification for using residential PRG values for screening agricultural produce should be provided. It is interesting that the COPC selection for agricultural and livestock exposure pathways utilized a screen against Region 9 PRGs whereby chemicals were excluded as COPCs if less than 10% of the samples exceeded PRGs. Since Region 9 PRGs do not address any food consumption pathways, this screen is not relevant. Please provide rationale for not developing agricultural SRBCs for this purpose.

RESPONSE 607:

Please refer to the response to General Issue 5.B.

Page 2-10, Section 2.3.1: This section suggests that milk samples were analyzed for tPCBs. Since there exists different analytical methods for Aroclors, congeners, and total PCBs, all reference to PCB analysis should specify exactly what was analyzed for so that reviewers and risk managers can put into perspective the data used in the risk assessment. This is extremely important for understanding risk characterization findings since the toxicity values used to estimate risk are based on specific congeners or PCB mixtures, not tPCB.

RESPONSE 608:

The requested information is provided as notes in all data tables. The milk data are not presented in a data table because no PCBs were detected in these samples. Also, the only analytical record available for these samples is a letter from the USFDA laboratory to the MDPH's Division of Food and Drugs. In this letter, USFDA reports the concentration of "PCB's" in each sample as "none." USFDA laboratory staff told EPA that these analyses were conducted using the USFDA's *Pesticide Analytical Manual* (see HHRA Volume 5, Section 2.3.1.2). The applicable PCB method in effect at the time will be described to the extent possible in the revised HHRA.

Page 4-1, Section 4.1: This comment relates to the 0.5 mg/kg and 2 mg/kg assumed concentrations. Exposures were estimated based on assumed average soil tPCB concentrations of 0.5 and 2 mg/kg; the 2 mg/kg tPCB soil concentration correlates to the residential cleanup goal and the 0.5 mg/kg tPCB soil concentration was selected represent a lower tPCB concentration. The rationale for not using actual data for the agricultural exposure pathways was that it would be too difficult to assess every parcel individually. It was further assumed that 100% of pasture and cultivation areas are within the 1 ppm tPCB isopleth. If the assumption was to use average tPCB concentrations of 0.5 and 2 mg/kg, what does this latter statement mean? Also, isn't soil concentration directly (linearly) related to exposure and risk? Thus, what is the point of this exercise? The report further states that, "the result obtained by assuming a tPCB soil concentration of 0.5 mg/kg would also be obtained for a parcel where 10% of the land cultivated with corn silage was contaminated with 5 mg/kg tPCBs, and the remaining 90% of the cultivated land was not contaminated with tPCBs." What is the rationale for this analogy? It seems that regardless of the percentage of land contaminated with PCBs, the total acreage of land that is contaminated with an average tPCB concentration of 5 mg/kg may still support feed for all livestock raised on a particular farm.

RESPONSE 609:

Please refer to the response to General Issue 11.A.

Page 4-2, lines 13-15: Soil PCB and PCDD/PCDF congener concentrations were estimated from regression equations that related tPCB concentrations to congener concentrations. This approach seems reasonable for predicting PCB congener concentrations, however, only specific PCDF congeners (not PCDD congeners) have been associated with PCBs, and this association has only been demonstrated in cases where PCBs have been subjected to elevated temperatures such as in the Yusho and Yu- Cheng rice oil incidents, and as demonstrated in studies of combustion and incineration of PCB mixtures.

RESPONSE 610:

Please refer to the response to General Issue 4.F.

Page 4-2, lines 16-27: The report indicates that only the following food exposure pathways were quantitatively evaluated: (1) commercial dairy, beef, and poultry; (2) backyard dairy, beef, and poultry; (3) home gardens. However, Section 4.2 also describes methods for estimating PCB and PCDD/PCDF concentrations in goats, sheep, and deer. In Section 4.2.1.3 (Other Mammalian Species), it is stated that "the BCFs for milk and beef in cattle are used to estimate the milk and meat accumulation by these species [goats, sheep, and deer] in this assessment." It appears that the BCF selected for cattle is based on a dietary exposure (feeding study) that directly reflects the animals' rate of intake of food. Rationale should be provided explaining how this BCF is applicable to other livestock species that have different food intake rates and dietary requirements.

RESPONSE 611:

The rationale for this approach is provided on page 4-7, Section 4.2.1.3. In addition, feed intake is correlated to some extent with body size, growth rate, and the amount of milk produced. Thus, one might expect a general similarity among species in similar physiological states.

Stephen T. Washburn

The overall exposure scenarios selected for evaluation were reasonable as hypothetical possibilities. However, based on the information provided in the HHRA, many of the scenarios do not appear to be likely (e.g., commercial beef cattle) or incorporate elements that do not appear likely (e.g., 100% of grazing occurs within contaminated portions of the floodplain).

RESPONSE 612:

Please refer to the responses to General Issues 2.E and 11.A. Also, the assumption of 100% grazing within the 1-ppm tPCB isopleth was not made because it was believed to be reasonable in all cases. Rather, it was a simplifying assumption that allowed Reviewers to extrapolate results to any parcel where a fraction of the farmland is within the 1-ppm tPCB isopleth. Application of this fraction to exposure calculations incorporates an assumption of zero tPCB concentration outside the 1-ppm tPCB isopleth, which is likely to underestimate risk slightly.

In addition, as discussed above in the context of the direct contact scenarios, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis for the agricultural exposure scenarios.

RESPONSE 613:

Please refer to the response to General Issue 3.A.

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

COMMENTS

Holly Hattemer-Frey

Soil-to-grass transfer factors for tPCBs and dioxin-like PCB congeners were mean concentration ratios based on measured, site-specific data (n = 10). Soil-to-corn transfer factors for tPCBs were mean concentration ratios based on measured, site-specific data (n = 5). Soil-to-corn transfer factors for dioxin-like PCB congeners were based on soil-to-grass ratios.

For exposed vegetables, the soil-to-plant transfer factor was defined as the maximum transfer factor for corn. The maximum value reported in Table 4-6 is 6x10-3, while the transfer coefficient for exposed vegetables listed in Table 4-5 is 6x10-4. Table 4-5 appears to contain a typo, which should be corrected.

RESPONSE 614:

This error will be corrected in the revised HHRA, and risk estimates will be re-calculated accordingly. Also, the uncertainty in transfer factors will be explicitly addressed in the quantitative uncertainty analysis for this exposure pathway.

For root vegetables, the higher of the transfer factors reported for beets and turnips based on site-specific data for Aroclor 1260 was used. This value is likely to underestimate exposures since beets and turnips were washed before analysis. Beet and turnip values reported for Aroclor 1248 are 75 and 275 times higher than values for Aroclor 1260, while values for total PCBs are similar to values for Aroclor 1260.

RESPONSE 615:

The Reviewer notes two separate sources of uncertainty that will be discussed in more detail as part of a quantitative uncertainty analysis:

1. Washing of beets and turnips. The HHRA acknowledges the potential for crop washing to underestimate exposure (see HHRA Volume 5, Section 4.3.4.1 and Section 6.3.2.1.3). Note that the transfer factor selected to represent these crops was based on unwashed, site-specific corn stalk data rather than beet or turnip data in an effort to address this possible underestimate.

2. Variation in Sawhney and Hankin's (1984) transfer factor estimates for different Aroclors. The mixture of PCB congeners in Housatonic River floodplain soil most closely resembles Aroclor 1260, and additional discussion will be provided regarding tPCB patterns observed in floodplain soil and the rationale for selected transfer factors.

Both sources of uncertainty will be characterized explicitly in a quantitative uncertainty analysis for this exposure pathway.

For exposed fruits, the soil-to-plant transfer factor was set equal to the transfer factor for exposed vegetables (6x10-4). Thus, the discrepancy noted above (with respect to the correct exponent) for exposed vegetables applies here.

RESPONSE 616:

This error will be corrected in the revised HHRA, and risk estimates will be re-calculated accordingly. Also, the uncertainty in transfer factors will be explicitly characterized in a quantitative uncertainty analysis for this exposure pathway.

While weak correlations between site-specific plant and soil concentrations were blamed on several factors (e.g., influence of background levels and contaminant transfer from one area to another), the fact that several plant species were washed and scrubbed before analysis, which could potentially remove contamination, and small sample size were minimized. Data from washed and scrubbed plants can not be used to reliably estimate plant concentration factors.

RESPONSE 617:

The HHRA acknowledges the potential for crop washing to underestimate exposure (see HHRA Volume 5, Section 4.3.4.1 and Section 6.3.2.1.3), and this source of uncertainty will be explicitly characterized in a quantitative uncertainty analysis for this exposure pathway. Limitations in the available site-specific data due to sample size will be acknowledged. The Reviewer does not distinguish among COPCs in commenting on sample size. There are considerably more site-specific tPCB data than site-specific congener data, which are only available for grass. This is one reason why congener-specific risk estimates will be presented in the uncertainty section instead of the risk characterization section of the revised HHRA. Please refer to the response to General Issue 11.B.

Given the uncertainty associated with using site-specific data (e.g., some samples were scrubbed before analysis, small sample size), I strongly recommend that more site-specific data be collected to provide more accurate biotransfer factors for plants and animals.

RESPONSE 618:

Additional data will not be collected, but the uncertainty in available data will be explicitly characterized in a quantitative uncertainty analysis for this exposure pathway. There are considerably more site-specific tPCB data than site-specific congener data, which are only available for grass. This is one reason why congener-specific risk estimates will be presented in the uncertainty section instead of the risk characterization section of the revised HHRA. Please refer to the response to General Issue 11.B.

In the absence of such data and in the presence of such high levels of uncertainty, I must recommend that the maximum (versus mean or best estimate values) be used, at least for the RME scenario.

RESPONSE 619:

The deterministic assessment will not be modified in response to this comment. Instead, the comment will be addressed with quantitative uncertainty analysis of exposure pathways. Please refer to the responses to General Issues 11.B and 11.C.

Given the uncertainty associated with the site-specific data (and resulting transfer factors), I strongly recommend that the authors gather information on soil-to-plant transfer factors available in the literature or those generated from predictive equations available in the literature and compare the range of literature and predicted values with site-specific values. My guess is that this comparison will show that the site-specific values are conservative and will lend credibility to the risk calculations.

RESPONSE 620:

Please refer to the response to General Issue 11.B.

I agree with Mr. Washburn's assessment that given the uncertainty and limitations associated with the site-specific data available, the regression analyses used to estimate congener-specific plant concentrations for PCBs are highly dubious and unreliable. Therefore, risks for the agricultural scenario should be limited to exposure to total PCBs only. The lack of congener specific biotransfer data for PCBs precludes a reliable calculation of congener-specific uptake by plants and animals.

RESPONSE 621:

Regression models were used to predict congener concentrations in floodplain soil. These predicted concentrations were used in conjunction with soil-to-plant transfer factors, not regression models, to estimate congener concentrations in plants.

Please refer to the responses to General Issues 11.B and 11.C.

Section 4.3.3.1: Since PCDDs/PCDFs were not detected in the 10 grass samples analyzed from the site (despite elevated detection limits), it was assumed that "PCDD/PCDF concentrations are likely to be small contributors to TEQ concentrations compared with PCB concentrations." The small sample size and relative high detection limits do not warrant exclusion of PCDDs and PCDFs from quantitative calculation when literature values are available. This approach is likely to underestimate risks associated with exposure to ingestion of cow beef and milk. Again, before relying solely on weak site data, I suggest a review of the literature (e.g., the Dioxin Reassessment documents). Unless additional site-specific data are gathered (as recommended), literature values may need to be adopted or incorporated, since site values are tenuous as best.

RESPONSE 622:

Please refer to the responses to General Issues 11.B and 11.C.

Section 4.4.4, page 4-34, lines 1-6: Predicted home garden vegetable concentrations are based on an assumed soil concentration of 2 mg/kg, the residential soil cleanup level for this site. The HHRA is supposed to evaluate potential risks to individuals under current and future scenarios in the absence of remediation. Therefore, using the soil cleanup level as the basis for baseline risk assessment calculations is inappropriate.

RESPONSE 623:

Please refer to the response to General Issue 11.A.

F. Owen Hoffman

There is so much uncertainty associated with the estimation of soil- to-plant transfer, that a formal quantitative uncertainty analysis should be performed.

RESPONSE 624:

This will be included in the revised HHRA. Please refer to the response to General Issue 11.C.

John C. Kissel

Use of site specific data is generally good practice, but in this case so little data are available that the overall effort must be considered very uncertain. In the absence of formal (quantitative) uncertainty analysis, this weakness is effectively hidden.

RESPONSE 625:

This will be included in the revised HHRA. Please refer to the responses to General Issues 11.B and 11.C.

Use of data from washed beets and turnips does not appear reasonable.

RESPONSE 626:

Data from washed beets and turnips were considered among other data to select soil-to-plant transfer factors for garden produce. The HHRA acknowledges the potential for crop washing to underestimate exposure (see HHRA Volume 5, Section 4.3.4.1 and Section 6.3.2.1.3). For this reason, transfer factors for washed beets and turnips were not selected. Instead, the transfer factor selected to represent these crops was based on site-specific unwashed corn stalk data in an effort to address this possible underestimate.

Roger O. McClellan

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

RESPONSE 627:

Please refer to the response to General Issue 4.F.

Although the majority of tPCB data used to develop regression models exceeds 2 ppm, the models include numerous data points corresponding to tPCB concentrations in the 0.5- to 2-ppm range and below. This approach will be discussed in more detail in the revised HHRA Volume 1, Attachment 2. Also, the Reviewer's concern will be addressed in the revised HHRA, where congener concentrations will be predicted from the range of tPCB concentrations that have been detected on current and potential future agricultural properties. This range will include concentrations that are higher than the assumed concentrations of 0.5 mg/kg and 2 mg/kg.

The soil- to-grass transfer factors are based on only 10 samples. Moreover, the samples (a) were collected in warm months of the year rather than throughout the growing season, (b) during a period with limited rain that would potentially wash off particulate surface contamination and (c) in an area adjacent to the river with potential for flooding.

RESPONSE 628:

The factors noted by the Reviewer are discussed in the HHRA (Executive Summary, Section 2.3.5.1 and Section 4.3.3.3). For these and other reasons, a quantitative uncertainty analysis will be performed for agricultural pathways.

It is important to recall that the Massachusetts Wetlands Protection Act places a limitation on agriculture within 200 feet of the river bank. This clearly makes the soil-to-grass data developed from samples collected near the river irrelevant.

RESPONSE 629:

Please refer to the response to General Issue 2.E.

All of these factors introduce uncertainties and probably result in over-estimates of the transfer factors. Indeed, lower transfer factors have been reported by Chaney *et al* (1996). In the absence of a more robust data set based on Housatonic River flood plain soil, it would be appropriate to use the values from Chaney *et al* (1996).

RESPONSE 630:

Please refer to the response to General Issue 11.B. All soil-to-plant transfer factors used in the assessment are within the relatively large range of factors reported in the scientific literature for a variety of plant species, PCB mixtures, soil characteristics, and other site-specific conditions that influence contaminant transfer to plants.

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

RESPONSE 631:

Separate sampling of stalks and ears provided site-specific confirmation that the ears are protected from COPC contamination by the husks. In Section 6.3.2.1.2 of the HHRA Volume 5, it is acknowledged that the soil-to-corn transfer factors could be overestimated by about a factor of two if one does not account for the fact that silage is composed of ears and stalks. The uncertainty in the data is discussed in the HHRA, and this discussion will be expanded as part of a quantitative uncertainty analysis. Additional data will not be collected.

It is important to recall the earlier discussion of the Massachusetts Wetlands Protection Act and the limitation on agriculture within 200 feet of the river bank.

RESPONSE 632:

Please refer to the response to General Issue 2.E.

Extensive research on the transfer of contaminants from sludge amended soils suggests that PCBs are not translocated from soil to corn. (Gan and Berthouex, 1994; Webber *et al*, 1994; O'Connor *et al*, 1990). Thus, the analysis in the assessment would appear to be at odds with the scientific literature.

RESPONSE 633:

Translocation is not among the mechanisms assumed to be relevant in the analysis performed for the HHRA. Instead, the evaluation of plant exposures is based on the assumption that there are two primary mechanisms for PCB, dioxin, and furan transfer from soil to plants:

1. Deposition of particle-phase contaminants on, or sorption of vapor-phase contaminants to aboveground vegetation. This mechanism can be occurring with corn (e.g., contamination in dust or rain splash might adhere to the corn).

2. Partitioning from contaminated soil to belowground vegetation (HHRA Volume 5, Section 4.3.1). This mechanism is not relevant to corn because belowground plant parts are not consumed by people or farm animals.

Also, the Reviewer cites three studies (Gan and Berthouex, 1994; Webber et al., 1994; O'Connor et al., 1990). O'Connor did not report any corn data. Webber et al. (1994) and Gan and Berthouex (1994) analyzed corn ear-leaf, grain, and stover (i.e., the dried stalks and leaves) samples grown on sludge-amended coal refuse and soil, respectively. The Reviewer does not explain the relevance of these media to soil characteristics in the Housatonic River floodplain. In these studies, PCBs were either not detected or detected at very low concentrations in corn grain, which is consistent with the corn ear data collected from the Housatonic River floodplain in which PCBs were not detected. PCBs were detected in corn ear-leaf and stover in the low-ppb range, which is consistent with the low-ppb concentrations detected in corn stalks from the Housatonic River area. However, Gan and Berthouex (1994) report that many of the values might represent "pure random error." Also, as in the HHRA, clear associations between soil and corn concentrations were not observed in either study. The revised HHRA will include discussion of these studies along with other relevant literature as described in the response to General Issue 11.B and, specifically, discussion of uncertainty associated with PCB concentrations near detection limits.

P. Barry Ryan

A question arose regarding the soil-to-grass transfer rates and models. Why are the values for PC-126 transfer coefficient an order of magnitude higher than others? Is this reasonable based on any kind of model or was something amiss?

RESPONSE 634:

Soil-to-plant transfer factors are reported to one significant figure in the HHRA Table 4-5. The transfer factor for PCB-126 is 4 to 7 times higher than most other congeners, with the exception of other planar congeners (i.e., PCB-77 and PCB-169). No soil-to-plant transfer factors were found in the literature for PCB-126, and EPA knows of no models specific to PCB-126. The study of congener-specific transfer to plants is a relatively new area of research, with attention focused on air-to-plant transfer rather than soil-to-plant transfer. However, octanol-air partition coefficients (K_{oa}) have been measured for a number of PCB congeners (e.g., see Komp and McLachlan, 1997). The revised HHRA will refer to this study and others that provide a mechanistic understanding of the variation in estimated soil-to-plant transfer factors.

The risk assessment used site specific data for the uptake ratios. While site -specific data are indeed the most useful, this utility must be tempered by the small number of samples analyzed. The panel suggests expanding the dataset to include non-site-specific data as a comparison to determine whether the small number of data points accessible from the current measurements is indicative of other sites. If not, what is special about this site that affects this plant uptake ratio? If they are the same, then it adds credence to the method.

RESPONSE 635:

Please refer to the response to General Issue 11.B.

The discussion of the TEQ approach really is a discussion of uncertainty in the risk associated with a given tPCB concentration. One may reasonably argue that this discussion should be in a section on Uncertainty rather than in the body of the report. Regardless, an assessment of uncertainty is very important in this regard.

RESPONSE 636:

Please refer to the responses to General Issues 11.A and 11.C.

Lee R. Shull

In general and except for the following comments, the approaches used to estimate transfer of COPCs from soil to plants are appropriate.

Page 4-24, Section 4.3.3.2: Soil-corn transfer factors were estimated for PCB congeners based on the ratio of the tPCB soil- grass to tPCB soil-corn transfer factor and then application of the ratio to the PCB congener soil- grass transfer factors. It is not clear why this approach was not also applied in deriving soil-exposed vegetable transfer factors. Clarification is needed.

RESPONSE 637:

The approach was also applied to derive soil-to-exposed vegetable transfer factors for PCB congeners (see Section 6.3.2.1.3).

Page 4-25, Section 4.3.4: Because neither PCBs nor PCDD/PCDFs are highly volatile and neither group of chemicals appear to accumulate significantly by translocation via the roots, the only remaining viable pathway is airborne deposition of soil dust (containing PCBs and PCDD/PCDFs). Thus, bioaccumulation does not technically occur to any great extent, but rather these compounds are adsorbed to the surfaces of plants and fruits.

RESPONSE 638:

The evaluation of plant exposures is based on the assumption that there are two primary mechanisms for PCB, dioxin, and furan transfer from soil to plants:

1. Deposition of particle-phase contaminants on, or sorption of vapor-phase contaminants to aboveground vegetation. This mechanism can be occurring with corn (e.g., contamination in dust or rain splash might adhere to the corn).

2. Partitioning from contaminated soil to belowground vegetation (HHRA Volume 5, Section 4.3.1). This mechanism is not relevant to corn because belowground plant parts are not consumed by people or farm animals.

It was assumed in the agricultural assessment that translocation of COPCs is not occurring. While the Reviewer is correct that COPCs do not bioaccumulate to any great extent in plants, they can be transferred to plants by the mechanisms listed above, and not only the one cited by the Reviewer.

Since such deposition is dependent on the generation of fugitive soil dust and subsequent deposition on plant and fruit surfaces, which is virtually 100% a function of site-specific conditions, it seems then that only site-specific data should be used for deriving transfer factors for assessing soil- to-plant exposure pathways. The relevance of applying soil-to-plant transfer not based on site-specific data is questionable.

RESPONSE 639:

Only site-specific data were used in the assessment for reasons stated in Section 6.3.2.1. Note that there are mechanisms other than fugitive dust that can result in transfer of COPCs to plants.

As a minimum, this subject should be addressed in the uncertainty discussion.

RESPONSE 640:

The revised HHRA will include the recommended discussion.

Page 4-26, lines 27-29: The tPCB soil-exposed vegetable transfer factor is based on the "mean of the soil samples corresponding to corn ear and stalk and leafy material samples." Does this suggest that individuals consume corn leaf and stalk material?

RESPONSE 641:

No, it does not. In this case, the corn data were used to address the fact that the beet and turnip data were washed prior to analysis and, consequently, their soil-to-plant transfer factors might underestimate exposure. Therefore, the corn data were selected as a surrogate crop to represent aboveground garden plants.

Page 4-28, lines 5-6: The soil-exposed fruit transfer factor was set equal to the soil-exposed vegetable transfer factor since no data were available for transfer of PCBs and PCDD/PCDFs from soil to exposed fruits. The authors note that this is "…a conservative estimate…". The authors further note that this pathway may not be important. The authors should consider eliminating this pathway as an insignificant pathway, and also because data are insufficient for making reliable exposure estimates.

RESPONSE 642:

No site-specific data are available, but there are data in the literature that will be discussed in the revised HHRA, as described in the response to General Issue 11.B. The revised HHRA will discuss the reduction in estimated risks if risk from this garden produce category is not quantified due to the uncertainties noted by the Reviewer.

Figure 4-3 should specify (on the figure) that the plant uptake factors and vapor pressures are for PCB congeners. Note that this relationship should not be considered causal based on the data presented (i.e., it should not be inferred from this association that plant uptake of PCBs is caused by volatilization of PCBs).

RESPONSE 643:

The figure will be revised to specify that the information presented is for PCB congeners. The figure is consistent with the current understanding of possible mechanisms for PCB transfer to plants, but EPA agrees that there are other possible explanations for the observed pattern (e.g., preferential retention of lower molecular weight congeners in plant cuticle). The HHRA does not conclude that the relationship is causal.

Figure 4-5 presents several soil-plant transfer factor values of 0.00. Values of 0.00 were also observed in several other tables in the risk assessment. In most cases, a value of 0.00 is meaningless; rather than using a value of 0.00, it is recommended that a footnote or other character such as "N/A" be used to indicate that a value could not be determined or that the measure is not applicable.

RESPONSE 644:

The Reviewer appears to be referring to Table 4-5 rather than Figure 4-5. The zero values for PCB-81 and PCB-114 occur because these congeners were detected in soil but not in corresponding grass samples. In these cases where a value could not be calculated, table entries will be changed from zero to a note indicating that a value is not available. Zero entries also appear in Tables 4-4a and 4-4b, and these tables will be modified in a similar fashion.

Stephen T. Washburn

In general, much of the site-specific agricultural data do not appear to be reliable for the purposes of estimating transfer of COPCs from soil to plants in the HHRA. Examples include the following:

- PCB concentrations in corn cobs and corn stalks. PCBs were not detected in any corn ears, and all stalk concentrations are qualified as "J" (estimated) values. The stalk regression equation is strongly influenced by a single value (corresponding to a PCB concentration of 5.9 ppm in soil); without that data point, there would be no apparent relationship between soil concentration and corn stalk concentration. Furthermore, the regression does not include the samples where PCBs were detected in soil but not in stalks. If those nondetect (ND) data were included, the slope of the relationship between soil concentration and stalk concentration could vary significantly, from positive (increasing stalk concentration with increasing soil concentration) to negative (decreasing stalk concentration with decreasing soil concentration), depending on whether the ND is assumed to be equal to zero, ½ the detection limit, or equal to the detection limit. In addition, if the site-specific corn data are used in the HHRA, then the transfer factor for silage should be modified to reflect that the protected portion of the corn does not contain detectable levels of PCBs.

  RESPONSE 645:

  No regression analyses were performed with the corn data, so it is unclear to what regression model the Reviewer is referring. However, the uncertainties identified by the Reviewer are largely noted in the HHRA Volume V. They will be incorporated into a quantitative uncertainty analysis of the agricultural exposure pathways. Please refer to the response to General Issue 11.C.

- PCB concentrations in acorn squash. The highest PCB concentration detected in the flesh of acorn squash is reported from a floodplain area where PCBs were not detected in soil (Table 2-5; Volume V; Appendix D). The second highest PCB concentration detected in the whole squash is reported from this same location. Thus, based on the site-specific data, there is no apparent relationship between PCB concentrations in soil and squash.

  RESPONSE 646:

  This lack of correlation is discussed in Section 6.3.2.1 of the HHRA Volume V, and this source of uncertainty will be incorporated in a quantitative uncertainty analysis of the agricultural exposure pathways. Please refer to the response to General Issue 11.C.

- PCB concentrations in fiddlehead ferns. Based on the data collected in 2000, PCBs were detected only in washed fiddlehead ferns. PCBs were not detected in any of the unwashed ferns (Table 2-6; Volume V; Appendix D). This would suggest that the PCBs detected in the 2000 sampling event may have been introduced by the washing process, and are not related to concentrations in soil.

  RESPONSE 647:

  Laboratory staff were contacted to investigate this possibility. However, no cause for PCB introduction into plants during the cleaning process could be identified. This apparent discrepancy might be due simply to the fact that the detected concentrations are very low, and the effect of washing might also be small and difficult to detect. In addition, fiddlehead ferns are not aboveground very long prior to harvesting, so there might not be as much soil adhering to them as to crops such as potatoes, where washing has been shown to reduce PCB concentrations (Cullen et al., 1996).

- In addition, there does not appear to be a strong relationship between soil concentration and fiddlehead fern concentration in the 1995 MDEP sampling event (Table 2-7; Volume V; Appendix D). Specifically, PCBs were routinely detected in the fern samples collected from the "reference" area, in some cases at levels similar to those from floodplain areas where PCB concentrations in soil are reported to be up to 156 ppm.

  RESPONSE 648:

  This source of uncertainty will be addressed with a sensitivity analysis.

- PCB concentrations in grass. The regression equation for total PCBs in grass (Figure 4-4a) is strongly influenced by a single value (corresponding to a total PCB concentration of 21.3 ppm in soil); without that data point, there would be no apparent relationship between soil concentration and grass concentration. (For example, the lowest total PCB concentration in grass was detected at the location of the second highest concentration in floodplain soil). The relationship between total PCBs in soil and grass improves when the grass is normalized for lipid content, and the soil for organic carbon content (Figure 4-4b), although it is still strongly influenced by two or three samples.

  RESPONSE 649:

  This source of uncertainty will be incorporated in a quantitative uncertainty analysis of the agricultural exposure pathways. Please refer to the response to General Issue 11.C.

  Similarly, the regression for PCB-126 (which contributes most significantly to EPA's estimate of congener-specific risk) is also strongly influenced by a single data point (corresponding to a PCB-126 concentration of about 1.1 ppb in soil). Without this data point, the slope of the relationship between PCB-126 concentrations in soil and grass would likely change from positive to negative.

RESPONSE 650:

This source of uncertainty will be incorporated in a quantitative uncertainty analysis of the agricultural exposure pathways. Please refer to the response to General Issue 11.C.

Unlike total PCBs, the relationship between PCB-126 in soil and grass does not improve when the grass is normalized for lipid content, and the soil for organic carbon content (Figure 4-4b). The limitations in the site-specific data for PCB-126 are particularly important given its contribution to the estimated congener risks and the relatively high soil- to-grass transfer factor assigned to PCB-126 in the HHRA (i.e., 0.2). By comparison, ATSDR (2000) reports that the soil- to-grass transfer factor for PCBs is less than 0.02 for most terrestrial plant species.

RESPONSE 651:

This source of uncertainty will be incorporated in a quantitative uncertainty analysis of the agricultural exposure pathways. Please refer to the response to General Issue 11.C.

ATSDR (2000, page 501-502) states that

> "Plant BCFs of PCBs from soil are summarized in Table 6-8, and are estimated to be <0.02 for most terrestrial plant species (Cullen et al. 1996; O'Connor et al. 1990; Pal et al. 1980)."

ATSDR does not specifically mention grass in this reference or in Table 6-8. More important, ATSDR does not specify whether the BCF is based on wet weight or dry weight concentration data. Regardless of whether it is based on dry weight or wet weight concentration data, the Cullen et al. (1996) results do not support the ATSDR conclusion. Pal et al. (1980) report a range of values, some of which exceed 0.02. O'Connor et al. (1990) did not detect PCBs in a number of plant species above a wet weight detection limit of 0.02.

However, many values in ATSDR's Table 6-8 are greater than 0.02. The values in the table that are taken from Cullen et al. (1996) are based on dry weight plant concentrations, which are expected to be higher than values based on wet weight plant concentrations. The PCB-126 soil-to-plant transfer factor of 0.2 cited by the Reviewer is based on dry weight plant concentration, and the corresponding soil-to-plant transfer factor based on wet weight plant concentration is 0.07. It is possible that PCB-126 is accumulated in plants to a greater extent than tPCBs based on its planar structure; however, there are few data available to test this or any other hypothesis. Despite this limitation, the transfer factor used for PCB-126 is in the range of values measured for PCBs that are reported in the literature, which will be summarized in the revised HHRA.

Finally, as stated in the HHRA (p. 4-25; Volume V; Appendix D), the grass samples were collected from areas located immediately adjacent to the river with evidence of recent floodwater inundation. Therefore, the grass samples do not appear representative of the larger areas and other timeframes over which livestock may graze.

RESPONSE 652:

The Reviewer's observation is accurate. The grass data are intended to represent an upper bound on exposure for cattle grazing within the 1-ppm tPCB isopleth in areas further removed from the river where floodwater inundation is less likely.

Overall, given the limited data available for estimating congener-specific uptake by produce, the congener-specific evaluation for the agricultural pathways should be discussed only as a sensitivity analysis.

RESPONSE 653:

Please refer to the responses to General Issues 11.B and 11.C.

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

COMMENTS

Holly Hattemer-Frey

Section 4 provides a well-researched, detailed summary of the difficulties and uncertainties associated with deriving BCFs for animal tissues.

A BCF for Aroclor 1254 of 3.6 was adopted as the BCF for tPCBs. EPA (1994) reported that BCFs for PCBs in beef and dairy cattle ranged from 2.1 to 5.9, with most values reported for Aroclor 1254. While use of the slightly higher BCF (e.g., 5.9) is recommend, it would not substantially alter risk estimates.

RESPONSE 654:

This comment will be addressed with quantitative uncertainty analysis of this exposure pathway. Please refer to the response to General Issue 11.C.

There are little or no data on the transfer of dioxin-like PCBs to animal products. BCFs for dioxin-like PCBs in beef and dairy cattle were (after reviewing data available in the literature) estimated using the predictive equation presented on the top of page 4-18. While I do not have a problem with using predictive equations to estimate biotransfer factors in the absence of measured data, results obtained for the PCB congeners do not seem defensible.

RESPONSE 655:

This is one reason why congener-specific risk estimates will be presented in the uncertainty section instead of the risk characterization section of the revised HHRA. Also, please refer to the response to General Issue 11.C.

The BCF used for PCB 126 is 10 times higher than the BCF used for other PCB congeners. As a result, PCB 126 accounts for 70-90% of total risk. This may be due (as Mr. Washburn noted), to the lack of reliable fate and transport data for the individual PCB congeners. Regardless, given the uncertainty associated with deriving reliable BCFs for PCB congeners, it seems more prudent to focus risk calculations for the agricultural scenario on total PCBs only and PCDDs/PCDFs but not dioxin-like PCB congeners.

RESPONSE 656:

The BCF for PCB-126 is not 10 times higher than BCFs for other congeners (see Table 4-4a). The TEF for PCB-126 is at least 10 times higher than other dioxin-like congeners, which explains much of the difference in risk estimates among congeners. Congener-specific risk estimates will be presented in the uncertainty section instead of the risk characterization section of the revised HHRA. Also, please refer to the response to General Issue 11.C.

Mammalian BCFs for PCDDs and PCDFs were the mean of three studies whose results are reported in Table 4-4c. Results of these three studies are in good agreement and use of the maximum versus mean value (while recommended) will not substantially alter risk estimates. The text states that non-commercial beef and dairy cattle are likely to graze more and have a higher soil ingestion rate relative to commercially-raised cattle. Table 4-3 indicates that the percent soil in the diet for home-raised and commercial beef cattle to be identical (2%), which seems contradictory to the previous statement. Minor point.

RESPONSE 657:

Selection of BCFs and intake factors will be revisited in the context of a quantitative uncertainty analysis that will address the concerns raised by the Reviewer, including the noted inconsistency between commercial and backyard beef farms.

F. Owen Hoffman

There is so much uncertainty associated with the estimation of the transfer of PCB's to animal tissue, milk and eggs, that a formal quantitative uncertainty analysis should be performed.

RESPONSE 658:

Please refer to the response to General Issue 11.C.

John C. Kissel

Did not evaluate.

Roger O. McClellan

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

RESPONSE 659:

Please refer to the responses to General Issues 11.B and 11.C.

EPA does not agree with the Reviewer's conclusion that 100% bioavailability from feed is assumed in the model. Most BCFs were determined using the background concentrations that occurred normally in the feed. Thus, if bioavailability were reduced in feed, this reduction would be reflected in the calculated BCFs. As long as the matrices containing COPCs are similar for both the experimental animals and the farm animals, no correction for bioavailability is required.

The Agricultural Product Consumption Risk Assessment (HHRA Volume V) includes a table that summarizes the selection of input values from the range of possible values for the agricultural exposure pathways (Table 6-1). To avoid compounding conservatism, a mix of mean and upper percentile values was selected. The question of compounding conservatism will be addressed further with quantitative uncertainty analysis of agricultural pathways in the revised HHRA.

Also, note that toxicity equivalence (TEQ) concentrations predicted in the HHRA for animal products are compared to background concentration data for the U.S. food supply (Section 4.4). TEQ concentrations predicted for milk from commercial farms are similar to TEQ concentrations in the U.S. milk supply (Section 4.4.1). TEQ concentrations predicted for beef from commercial farms are higher than TEQ concentrations in the U.S. beef supply, and the HHRA lists potential reasons for this difference (Section 4.4.2). TEQ concentrations predicted for backyard farming and free-range poultry scenarios are higher than TEQ concentrations in the U.S. food supply, but this result is expected for the reasons provided in Sections 4.4.1, 4.4.2, and 4.4.3.

P. Barry Ryan

In general, the approaches involved attempting to measure simultaneous soil and plant/agricultural commodity levels and using the ratio to simulate uptake. This seems appropriate. However, there is need to validate this approach further. It would be a small investment to perform the experiments when compared with the likely cost of a full cleanup. It may be that the models overestimate the uptake and that reduced cleanup levels are excessively stringent. The opposite may also be the case. Until validation of the approach is available, the uncertainty may propagate into unnecessary cost or lack of protection for the community.

RESPONSE 660:

The proposed quantitative uncertainty analysis will inform decisionmakers about the level of confidence in risk estimates. Please refer to the response to General Issue 11.C.

It would also be of interest to look at congener - specific bioaccumulation. The mix in the bloodstream or in the tissues may not match that in the environment due to differential uptake. Thus the calculated risk may differ, perhaps even substantially, from that projected. Experiments could aid in this, perhaps through the use of an animal model.

RESPONSE 661:

Please refer to the response to General Issue 11.C.

Validation of the animal intake and transport models is not a simple effort. Field observations of animals exposed to soil contaminated with other chemicals (cited in Fries, 1995) support the conclusion that the results of the agricultural assessment are reasonable.

Lee R. Shull

In general and except for the comments below, the approaches used to estimate the bioaccumulation of COPCs in animal tissues is appropriate. However, the discussion of all BCFs needs improvement in clarity and transparency. For example, the weight basis upon which BCFs are derived and are applicable, and specifically what the BCF represents (e.g., soil-to-whole egg BCF, grass-based feed to beef fat BCF, etc.).

RESPONSE 662:

The revised HHRA will provide the requested clarification.

It appears that some BCFs are based on lipid or fat data, and it needs to be clarified that all data and rates were adjusted to a whole edible tissue basis.

RESPONSE 663:

Predicted animal fat concentrations for dairy, beef, and poultry were converted to edible tissue concentrations, as described in Section 4.5.2.1. Concentrations in eggs were predicted on a whole-egg basis; therefore, no conversion was required.

Page 4-3, Section 4.2.1: Two "important" pathways are described; Soil ? Vapor/Particulate ? Plant ? Animal ? Product, and Soil ? Animal ? Product. The "Soil ? Vapor/Particulate ? Plant" pathway is quantitatively evaluated using soil-to-plant transfer factors. The "Soil ? Animal and Plant ? Animal Product" pathways are quantitatively evaluated using BCFs. The discussion of BCFs (Section 4.2.2.2) precedes the discussion of soil-plant transfer factors (Section 4.3.3.1). From a systematic perspective, it seems more logical to present the soil-plant transfer factors before the BCFs.

RESPONSE 664:

Soil-to-plant transfer factors will be discussed prior to BCFs in the revised HHRA.

Page 4-8, Section 4.2.2: The equation used to estimate livestock animal fat PCB and PCDD/PCDF concentrations is presented in Equation 5:

Cprod = (BCF*R*Dsoil*Csoil) + (BCF*Dsil*Csil) + (BCF*Dgrass*Cgrass) + (BCF*Dcon*Ccon)

Where:

R = bioavailability, assumed to equal 1.0

Dsoil = fraction of dry matter intake assumed to be soil

Csoil = PCB or PCDD/PCDF soil concentration

Dsil = fraction of dry matter intake assumed to be corn silage

Csil = PCB or PCDD/PCDF corn silage concentration

Dgrass = fraction of dry matter intake assumed to be grass based foods

Cgrass = PCB or PCDD/PCDF grass based food concentration

Dcon = fraction of dry matter intake assumed to be concentrate

Ccon = PCB or PCDD/PCDF concentrate concentration

From this equation, it appears that the same BCF, which also appears to be based on unspecified dietary exposure, was applied to soil, corn silage, and grass-based feed. Since concentrates were assumed to be grown outside the floodplain, Ccon was set to zero, thus canceling the concentrate term. PCB and PCDD/PCDF concentrations in corn silage and grass-based feed were estimated using soil-plant transfer factors. It is not transparent as to how the soil term in equation 5 was addressed with respect to ingestion of soil particles in feed. It is not clear whether the BCFs for grass-fed animals, for example, already include the soil component (i.e., were the BCFs derived based on unwashed feed). Clarification is needed.

RESPONSE 665:

The revised HHRA will provide the requested clarification.

Table 4-4a: This table, which is a summary of BCFs used in the risk assessment, should indicate (footnote) the weight basis of the BCFs presented and the primary study(s) upon which each BCF is based. Also, it should be made clear whether the mammal BCFs are on a whole body basis or on a fat basis.

RESPONSE 666:

The revised HHRA will provide the requested clarification.

Page 4-17, line 28-page 4-18, line 17: A multi-step process was used to estimate BCFs for PCB congeners using the equation and information given. Estimating the BCF by this method utilizes a substantial number of factors, each with an unknown degree of variability and uncertainty, including Kow, percent absorption, Kow – absorption regression, intake rate of dry matter, milk production rate, and degree of metabolism. The multiplication of these uncertainties in the BCF equation is likely to result in a highly uncertain estimate of the BCF. Apparently, the rates for dry matter intake and milk production were averages from the Thomas et al. (1999) study. In view of the fact that Thomas et al. (1999) reported metabolism scores for each of the 12 PCB congeners assessed in the risk assessment, it is unclear why the scores were used to estimate either 50% or 0% metabolism for specific PCB congeners rather than using the actual measured percent metabolism values from the Thomas et al. (1999) study. Similarly, Thomas et al. (1999) apparently also measured percent absorption for each of the 12 PCB congeners, as presented in Figure 4-1; it seems that the actual measured values would be preferred over values estimated from Kow.

RESPONSE 667:

Thomas reported metabolism values for only three of the dioxin-like PCBs. The proposed quantitative uncertainty analyses will assist in characterizing the uncertainties mentioned by the Reviewer. Please refer to the response to General Issue 11.C.

Figure 4-1: It would be useful to identify each of the PCB congeners presented in Figure 4-1.

RESPONSE 668:

The PCB congener identities will be added to Figure 4-1.

Page 4-18, Section 4.2.2.2.3: The BCFs for 2,3,7,8-CDF; 1,2,3,7,8-CDF; and 1,2,3,7,8,9- CDF presented on Table 4-4a are 0.0. No discussion is given in the text regarding these data gaps and how they will be addressed in the risk assessment. However, the footnote on the table indicates that the concentrations of these congeners in the experimental studies were below detection limits, and that these congeners have not been detected in milk and beef surveys. Nevertheless, it is highly improbable that actual bioaccumulation is zero.

RESPONSE 669:

The BCFs were set to zero because the compounds were not detected in the applicable animal tissue. In these cases where a value could not be calculated, table entries will be changed from zero to “not available.” Also, the revised HHRA will be modified to demonstrate that use of BCFs based on ½ detection limits or even detection limits for these congeners would not result in appreciable changes in risk estimates.

Page 4-19, Section 4.2.2.2.4: The approach for estimating BCFs for Aroclor 1260 seem reasonable. However, more detail should be provided on the variation in the ratios of PCDD/PCDF BCFs for spiked and non-spiked data, and how it was applied to reduce the 2,3,7,8-TCDD spiked BCF to an estimated non-spiked BCF. The statement is made on page 4-20, lines 7-10 that “Results for 1,2,3,7,8-PCDF differed significantly between the two dose groups even though this congener was not spiked. The soil concentrations in both dose groups were near or below the quantitation limits; therefore, a BCF of zero was selected for use in this risk assessment.” If the soil concentrations in one of the dose groups were near the quantitation limit, this suggests that it was detected, and data were available to calculate a BCF. This issue should be clarified.

RESPONSE 670:

The revised HHRA will provide the requested clarification.

Page 4-20, lines 11-22: The extrapolation of poultry meat (adipose tissue) and whole egg BCFs from dairy cow BCFs seems quite a stretch across not only species, media, but also chemicals. Perhaps greater supportive rationale could be provided.

RESPONSE 671:

The revised HHRA will provide the requested clarification. Also, new data for PCB congeners have become available since the HHRA was prepared. This section will be revised to incorporate these new data.

Stephen T. Washburn

The overall approaches used to estimate bioaccumulation of COPCs in animal tissue are conservative, and would be expected to overstate potential risks. However, data with which to refine these approaches are extremely limited. Thus, for total PCBs, the approaches are generally appropriate, if the conservative nature of the calculations is considered in interpreting the results of the bioaccumulation estimates. However, due to the extremely limited data available for estimating congener-specific uptake by livestock as acknowledged in the HHRA it is recommended that the congener-specific evaluation for the agricultural pathways be discussed only as a sensitivity analysis.

RESPONSE 672:

Please refer to the responses to General Issues 11.A, 11.B, and 11.C.

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

COMMENTS

Holly Hattemer-Frey

Yes, except for the following comments.

Page 4-37, line 22: Use of 75th percentile (versus 90th or 95th percentile) consumption rates for RME scenario is not consistent with EPA guidance. Upper-bound ingestion values should be used for the RME scenario.

RESPONSE 673:

The 75th percentile was used to account for uncertainty in the underlying database, which is based on a 1-week survey for home-produced foods. The 75th percentile was chosen rather than the mean to err on the side of conservatism, while attempting to avoid compounding conservatism. This is consistent with EPA guidance which defines the RME (EPA, 1989, RAGS Part A, p. 6-21; FR Vol. 57, No. 104, May 29, 1992, pp. 22922-22923).

The variability and uncertainty of consumption rates will be addressed by incorporating the entire consumption rate distribution in a quantitative uncertainty analysis. Please refer to the response to General Issue 11.C.

Use of an FI=1 is overly conservative. It is not likely that 100% of the fruits and vegetables consumed by residents would originate from the study area. I recommend that FI be adjusted to account for seasonal versus year-round consumption rather than modifying ingestion rates.

RESPONSE 674:

The variable FI accounts for the fraction of produce ingested from the contaminated source. In this case, FI is the fraction of produce consumed by residents that comes from home gardens located within the 1-ppm tPCB isopleth. The homegrown produce consumption rates used in the HHRA are, in fact, the amount of produce consumed from a home garden and not from other sources. The fact that home gardens might not be located entirely within the 1-ppm tPCB isopleth will be addressed with the risk matrix where results will be reported for different fractions of garden area within the 1-ppm tPCB isopleth. Please refer to the response to General Issue 11.A.

The Reviewer is correct that the homegrown produce consumption rates used in the HHRA are not seasonally adjusted. This limitation and the quantitative implications for risk estimates are discussed in Section 5.1.5 of the HHRA. EPA knows of no quantitative way to adjust FI to account for seasonal variability as the Reviewer suggests. Instead, EPA will seasonally adjust consumption rates with the limited amount of data available for this purpose and will use these adjusted rates in the revised HHRA. The uncertainties associated with the seasonal adjustment and their implications for risk estimates will be discussed in the revised HHRA.

Table 4-3 shows that FI was set to 1 for agricultural animals (i.e., "100% of the cultivated and grazing areas are within the 1-ppm isopleth.") This assumption applies to both commercial and non-commercial farmers. While this number seems high to me, I did not find evidence in the document to dispute that assumption, nor did I find evidence to support it. Section 4.2.2.1 needs to provide more information about the reasonable availability of cultivated and grazing areas within the affected area both now and in the future (in the absence of remediation) to clarify this point.

RESPONSE 675:

The assumption of 100% grazing within the 1-ppm tPCB isopleth was not made because it was believed to be reasonable in all cases. Rather, it was a simplifying assumption that allows Reviewers to extrapolate results to any parcel where a fraction of the farmland is within the 1-ppm tPCB isopleth. Application of this fraction to exposure calculations incorporates an assumption of zero tPCB concentration outside the 1-ppm tPCB isopleth, which is likely to underestimate risk slightly. Please refer to the response to General Issue 11.A.

Table 4-8: FGI, fraction absorbed in the GI tract is listed in Table 4-8 but not in the equation on page 4-35, nor is it discussed in the text.

RESPONSE 676:

The revised HHRA will provide the requested clarification.

Table 4-8: No loss during cooking is assumed for the RME scenario but a cooking loss factor is applied to the CTE scenario, which seems reasonable.

RESPONSE 677:

Some amount of cooking loss is assumed for the CTE scenario and the RME scenario as discussed in Section 4.5.3.2.1.

Given the small number of fiddlehead ferns analyzed, I recommend that the maximum measured concentration (versus site-specific mean) be used to calculate risks.

RESPONSE 678:

This comment will be addressed with a sensitivity analysis.

F. Owen Hoffman

There is a need to evaluate the potential for compounded conservative assumptions leading to a strong bias in the over-all result.

RESPONSE 679:

The Agricultural Product Consumption Risk Assessment (HHRA Volume V) includes a table that summarizes the selection of input values from the range of possible values for the agricultural exposure pathways (Table 6-1). To avoid compounding conservatism, a mix of mean and upper percentile values was selected. The question of compounding conservatism will be addressed further with quantitative uncertainty analysis of agricultural pathways in the revised HHRA. Please refer to the response to General Issue 11.C.

John C. Kissel

Use of a 75th percentile consumption rate for RME estimation is inconsistent with use of 90-95th percentiles elsewhere in the document.

RESPONSE 680:

The 75th percentile was used to account for uncertainty in the underlying database, which is based on a 1-week survey for home-produced foods. The 75th percentile was chosen rather than the mean to err on the side of conservatism while attempting to avoid compounding conservatism. This is consistent with EPA guidance, which defines the RME (RAGS Part A, p. 6-21; FR Vol. 57, No. 104, May 29, 1992, pp. 22922-22923).

The variability and uncertainty of consumption rates will be addressed by incorporating the entire consumption rate distribution in a quantitative uncertainty analysis. Please refer to the response to General Issue 11.C.

Roger O. McClellan

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

RESPONSE 681:

The Agricultural Product Consumption Risk Assessment (HHRA Volume V) includes a table that summarizes the selection of input values from the range of possible values for the agricultural exposure pathways (Table 6-1). To avoid compounding conservatism, a mix of mean and upper percentile values was selected. The question of compounding conservatism will be addressed further with quantitative uncertainty analysis of agricultural pathways in the revised HHRA. Please refer to the response to General Issue 11.C.

P. Barry Ryan

The presentation of these agricultural exposures was detailed and well developed. The exposure values selected appear well founded in the science and data currently available. Where judgments had to be made, such judgments are consistent with good scientific practice and with EPA guidance.

Lee R. Shull

The exposure assumptions and parameter values are considered appropriate and reasonable for this HHRA.

- Page ES-20, line 7: Since ED is such an important factor in this HHRA, a brief explanation of the basis of the 45 year ED should be provided, even in the executive summary.

  RESPONSE 682:

  The revised HHRA will include more background information regarding exposure duration than is currently provided in Section 4.5.2.6.

Stephen T. Washburn

The exposure assumptions and parameter values were generally appropriate for the scenarios described, although some of these scenarios have only a very low likelihood of occurring based on information provided in the HHRA and at the November public meeting.

RESPONSE 683:

Please refer to the responses to General Issues 2.E and 11.C.

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

COMMENTS

Holly Hattemer-Frey (same as comments for 4)

RESPONSE 684:

Please refer to the responses provided to this Reviewer's comments under Question 4.

F. Owen Hoffman

Mostly. But there is a need for an evaluation of the effect of uncertainty on the final result of exposure and risk. This is an area that would benefit from directed research to increase the base of knowledge about agricultural transfer coefficients for PCB's and dioxin- like congeners.

RESPONSE 685:

Additional research is beyond the scope of this risk assessment and will not be performed. The effect of uncertainty on exposure and risk estimates will be determined with the proposed quantitative uncertainty analysis.

John C. Kissel

Generally assumptions were explained. Justification for those assumptions was in some cases less obvious.

RESPONSE 686:

The HHRA will be reviewed for any assumptions that would benefit from additional justification to make selections transparent.

Roger O. McClellan

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

P. Barry Ryan

The selection of the parameters was well described in the detailed appendixes and summarized well in Volume I of the HHRA. However, clarity in presentation is required. Ms. Hattemer-Frey made several good comments in her write-up and I defer to her comments in that regard.

RESPONSE 687:

Please refer to the responses provided to the referenced Reviewer's comments under Question 4.

Lee R. Shull

In general, all values are either clearly described and/or referenced.

Stephen T. Washburn

The basis for selection of values was generally well described and referenced.

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

COMMENTS

Holly Hattemer-Frey

No, since hypothetical versus site-specific soil concentrations were used to model exposures.

Otherwise, the approach used is appropriate with the exception of the other comments made.

RESPONSE 688:

Please refer to the response to General Issue 11.A.

F. Owen Hoffman

Yes, with the possible exception of the consumption of milk. The milk pathway usually affects infants and very young children more than adults. The consideration of childhood exposure, especially early in life, is potentially important for the evaluation of non-cancer risks.

RESPONSE 689:

Please refer to the responses to General Issues 3.A and 3.B.

John C. Kissell

Since exposures were calculated using the chosen EPC values of 0.5 or 2.0 mg/kg rather than measured/estimated values, RMEs and CTEs calculated here are not directly comparable to RMEs and CTEs calculated elsewhere in the document.

RESPONSE 690:

Please refer to the response to General Issue 11.A.

Roger O. McClellan

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

RESPONSE 691:

The Agricultural Product Consumption Risk Assessment (HHRA Volume V) includes a table that summarizes the selection of input values from the range of possible values for the agricultural exposure pathways (Table 6-1). To avoid compounding conservatism, a mix of mean and upper percentile values was selected. The question of compounding conservatism will be addressed further with quantitative uncertainty analysis of agricultural pathways in the revised HHRA. Please refer to the response to General Issue 11.C.

P. Barry Ryan

The approach used was for estimating the RME and CTE for this exposure pathway was developed in a manner similar to the other exposure pathways. With the caveats included for previous pathways, I believe that the presentation is consistent with the evaluation criteria provided by EPA. It is my assessment that the approach used to estimate the RME and CTE are consistent with best science and are appropriate under the evaluation criteria.

Lee R. Shull

In general, RME and CTE estimates are considered appropriate for this HHRA.

Page 4-41, Section 4.5.2.3: The authors applied cooking loss factors for both the CTE and RME exposure for poultry and beef, yet in the fish consumption exposure scenario, applied cooking loss was applied only to the CTE. Clarification is needed.

RESPONSE 692:

The home-produced poultry and beef consumption rates are based on the amount of food brought into the home, including inedible portions. Therefore, some loss factor needs to be applied to account for this discrepancy between consumption rates and what can be consumed. In the revised HHRA, EPA will further explain the losses calculated for poultry and beef. As a point of comparison, fish consumption rates were calculated assuming 30% of the whole fish was edible fillet. Please refer to the responses to General Issues 8.A and 8.C regarding consumable portions and cooking loss for the fish consumption exposure pathway.

Stephen T. Washburn

See comments above.

RESPONSE 693:

Please refer to responses provided for previous comments from this Reviewer.

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

COMMENTS

Holly Hattemer-Frey

Given the high degree of uncertainty associated with the calculation of risks from ingestion of home grown produce and agricultural products, I strongly recommend that 1) a formal, quantitative uncertainty analysis be performed for the agricultural analysis,

RESPONSE 694:

Please refer to the response to General Issue 11.C.

and 2) that site-specific vegetable/plant, milk, and beef tissues be analyzed if possible to yield more reliable BCFs.

RESPONSE 695:

Additional sampling will not be performed, but uncertainties associated with available data will be characterized in a quantitative uncertainty analysis.

F. Owen Hoffman

No. There is a need for a formal uncertainty analysis to be performed for the agricultural pathway.

RESPONSE 696:

Please refer to the response to General Issue 11.C.

John C. Kissel

As in the Direct Contact exposure case, uncertainties are discussed in qualitative terms, but the Agricultural Exposure Assessment is a deterministic analysis. The numerical results simply do not express uncertainty.

RESPONSE 697:

Please refer to the response to General Issue 11.C.

Roger O. McClellan

I have a high degree of concern as to the validity of the estimates developed for agricultural products. The use of the "model farm" approach is flawed by the limited data available for use as crucial input parameters. I have great reservations about using the "model farm" estimates to draw conclusions as to the potential risks associated with any specific parcel that has potential for agricultural use (land more than 200 feet from the river bank) and likely consisting of property both within the 1 ppm isopleth and outside the 1 ppm isopleth.

RESPONSE 698:

Please refer to the responses to General Issues 2.E, 11.A, 11.B, and 11.C.

It is certainly possible to more adequately describe the uncertainties in the present assessment for agricultural products. However, a better description of a flawed approach may not be the answer.

RESPONSE 699:

EPA acknowledges the uncertainties inherent in the HHRA but does not believe that the approach used to evaluate agricultural pathways is flawed. Please refer to the responses to General Issues 2.E, 11.A, 11.B, and 11.C.

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

RESPONSE 700:

Additional sampling will not be performed, but uncertainties associated with available data will be characterized in a quantitative uncertainty analysis.

P. Barry Ryan

Volume V devotes an entire section (Section 6) to uncertainties in each component of the risk expression. The discussion includes analytical methods, regression model uncertainty, model characterization problems, and many other factors. The uncertainty analysis is an especially strong component of this section of the report. However, the next step has not been taken. The question remains: What is the impact of these uncertainties on the risk assessment? Are the uncertainties so large I magnitude as to swamp the efforts? There needs to be some qualitative discussion of the impact and quantitative assessment if possible.

RESPONSE 701:

Please refer to the response to General Issue 11.C.

Lee R. Shull

Generally no, for the reasons given below.

In general, the qualitative uncertainty analysis presented is very incomplete. Not all factors that could impact risk estimates, either over- or under-estimates, are identified and evaluated. For the sources that are identified, an informative discussion of information is presented, but no conclusion is presented as to whether the source of uncertainty is believed to result in either an under-estimation, no affect, or over-estimation of human health risks. In my view, the risk assessor should, if at all possible, use his/her judgment, experience, etc to put forward a position whether risks are under- or over-estimated or not affected by sources of uncertainty.

RESPONSE 702:

Please refer to the response to General Issue 11.C.

Page 6-1, lines 7-9: While I agree with this statement, the uncertainty analysis does not present enough information about the relative contribution of individual sources of uncertainty to support such a conclusionary statement.

RESPONSE 703:

Please refer to the response to General Issue 11.C.

Section 6.1: This section is too brief. It does not identify the sources of uncertainty related to hazard identification (e.g., data) and evaluate the degree that each source either underestimates risk, has not impact on risk estimates, or overestimates risk.

RESPONSE 704:

Please refer to the response to General Issue 11.C.

Page 6-1, Section 6.2: Comments on uncertainty associated with dose-response have been provided in uncertainty sections of other volumes. In general, the section is sorely lacking and provides risk managers little to no useful information on the uncertainties associated with PCB and dioxin/furan toxicity criteria.

RESPONSE 705:

Please refer to the responses to General Issues 12.A, 12.B, and 12.C.

The discussion on EPA's dioxin cancer reassessment should be removed in its entirety.

RESPONSE 706:

Please refer to the response to General Issue 12.C.

Page 6-2, Section 6.3: No information is provided about the degree to which each source of uncertainty is believed to affect estimated human health risks.

RESPONSE 707:

Please refer to the response to General Issue 11.C.

Stephen T. Washburn

The uncertainties in the assessment were not adequately characterized or expressed in many cases. In particular, the portion of Section 6 (Uncertainty Analysis) in Volume V, Appendix -16-D that addresses prediction of COPC concentrations in animal feed and human food products is largely a simple recitation of uncertainties, without any quantitative or even semiquantitative evaluation of the effect of the uncertainties on the results of the assessment (see, for example, the discussion of PCB-126 on p. 6-5 in Section 6.3.2.1.1).

RESPONSE 708:

Please refer to the response to General Issue 11.C.

> ***8. Overall, was the approach used to assess risk from consumption of agricultural products and other wild food items reasonable for evaluating the baseline risk?***

COMMENTS

Holly Hattemer-Frey

I strongly recommend that more site-specific data on the biotransfer of PCBs to plants and agricultural animals be collected to reduce uncertainties in the agricultural RA. I agree that given the limited site-specific data available, risks associated with agricultural pathways are speculative. Even if there are no beef or dairy cows grazing on floodplain soils, an experiment could be done where site soil was fed to cows and site-specific, BCFs calculated. Similarly, various agricultural and home-grown crops could be grown in site soils, and BCFs quantified.

RESPONSE 709:

Additional sampling will not be performed, but uncertainties associated with available data will be characterized in a quantitative uncertainty analysis. Please refer to the response to General Issue 11.C.

Instead of summarizing risks in Section 5 as "exceeded or within EPA acceptable range," listing the actual risk level would be much more informative. Classifying risks as within the acceptable range means that they can vary from 1x10-6 to 1x10-4. Risks for consumption of commercial and farm-raised animal products (milk, beef, poultry, and eggs) were at the high end of EPA's acceptable risk range (4x10-4 for commercial milk to 8x10-4 for home-raised poultry) or exceeded the acceptable range (1x10-3 to 6x10-3) for the remaining agricultural pathways. All of these risk levels are associated with a soil concentration of 2 mg/kg.

RESPONSE 710:

EPA believes that tables (which will have a different appearance after implementing the matrix approach) are much clearer than adding numbers to the text. The appropriate table(s) will be referenced in the revised text.

F. Owen Hoffman

The evaluation of the overall approach would be facilitated if a full quantitative uncertainty analysis were to be performed. This analysis should be extended to include the uncertainty in the toxicity coefficients as well. The uncertainty analysis need not attempt to simulate inter-individual variability of exposure in a large population. It would be sufficient for the analysis to address epistemic uncertainty in exposure and risk to the RME and CTE as separate exposure scenarios.

RESPONSE 711:

Please refer to the response to General Issue 11.C.

Careful consideration should be given to the appropriate age groups and ratios of intake to body weights of children when estimating the non-cancer HI.

RESPONSE 712:

Please refer to the response to General Issue 3.B.

John C. Kissel

Given the shortage of data for some key factors such as transfer coefficients, this section would benefit greatly from formal uncertainty analysis.

RESPONSE 713:

Please refer to the response to General Issue 11.C.

Roger O. McClellan

As noted above, the modeling approach used is not satisfactory in large part because of the limited input data. Also, as noted above, if this pathway is truly important for the Housatonic River "Rest of River" and its residents then it may be appropriate to proceed to the empirical approach suggested above. If it proves impractical to obtain site-specific agricultural data because of the difficulty in locating relevant farms, then the answer is at hand – the agricultural pathway is not likely to be important for the Housatonic River "Rest of River."

RESPONSE 714:

Please refer to the response to General Issue 2.E. Current agricultural scenarios and potential future agricultural scenarios are described in HHRA Volume Section 2.1, Table 2-1, and Figures 2-1a through 2-1j. These figures include a delineation of the 1-ppm tPCB isopleth so that the reader can see the approximate fraction of each current cultivation area or grazing area that is located within the 1-ppm tPCB isopleth.

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

RESPONSE 715:

EPA acknowledges the uncertainties inherent in the HHRA but does not believe that the approach used to evaluate agricultural pathways is flawed. Please refer to the responses to General Issues 2.E, 3.A, 3.B, 11.A, 11.B, and 11.C. The Reviewer does not identify specific flaws beyond those asserted in the Reviewer's other detailed comments. Therefore, please also refer to responses to other detailed comments from this Reviewer.

P. Barry Ryan

Despite all the comments made, it is my assessment that the approach used in evaluating risks for the consumption of agricultural products and other wild foods is reasonable for calculating baseline risk. The data are sparse and many parameters needed to assess risk from this pathway are lacking. Nonetheless, the risk assessment as presented represents the state-of-the-science and may actually exceed such. New ground is being broken (See below.)

Lee R. Shull

Considering the reliance on numerous assumptions because of lack of data in this particular risk assessment, the approach employed generally represents as reasonable an estimation of potential health risks associated with COPCs in the floodplain as possible. However, I believe a risk manager will have great difficulty determining how the information should be applied in risk management decision making. The exceptional amount of uncertainty is all the more reason for a much more extensive uncertainty analysis than has been presented. Most of the concerns embodied in my comments are the result of limited data, and, as a result, the application of many upperbound assumptions, which would be expected to overestimate potential health risks by perhaps several orders of magnitude. It is highly recommended that further studies of agricultural products, both plant and animal, in the flood plain be done to validate some of the assumptions in the HHRA.

RESPONSE 716:

Additional sampling will not be performed, but uncertainties associated with available data will be characterized in a quantitative uncertainty analysis. EPA does not agree that risks have been overestimated by "several orders of magnitude." In particular, please refer to Table 6.1, which shows the mix of mean and upper-bound input values that were used. It is not accurate to state that "many upperbound assumptions" were used.

ADDITIONAL REVIEWER COMMENTS

Lee R. Shull

- Page ES-10, line 5: The use of the word "consideration" (here and elsewhere) is misleading. In the context of this sentence, "consideration" conveys the idea that a particular exposure scenario is given careful thought, and then a decision made as to it should be assessed or not. The sentence should explicitly state that this exposure scenario WAS assessed in this risk assessment.

RESPONSE 717:

The revised HHRA will provide the requested clarification.

- Page ES-17, lines 10-11: This sentence deserves greater explanation. Also, Attachment 2 of Volume 1 should be referenced here.

  RESPONSE 718:

  The revised HHRA will provide the requested clarification.

- Page ES-17, lines 19-20: In this sentence, reference is made to cattle grazing on soil containing 1 mg/kg, whereas the risk assessment assumed 2 mg/kg. Please clarify.

  RESPONSE 719:

  The revised HHRA will provide the requested clarification.

- Page ES-18, lines 8-10: Rationale for this statement should be provided.

  RESPONSE 720:

  The revised HHRA will provide the requested clarification.

- Page ES-18, lines 16-24: Should state whether or not any COPC concentration data have been collected for poultry eggs in the study area.

  RESPONSE 721:

  The revised HHRA will provide the requested clarification.

- ES-21, line 23: A statement of this importance should be accompanied by at least a brief explanation by the risk assessor as to why "all cancer risk estimates were dominated by 2,3,7,8-TCDD TEQ from PCB-126."

  RESPONSE 722:

  The revised HHRA will provide the requested clarification.

- Page 2-8, lines 17-18: Should reference the appropriate table where these data are given.

  RESPONSE 723:

  The revised HHRA will provide the requested clarification.

- In characterizing risks (Section 5), it appears that risk associated with tPCBs and PCB congeners were summed without any adjustment for the contribution to risk from PCB congeners within tPCBs (i.e., potential double counting) as was done in the fish consumption pathway risk assessment. For consistency, this approach should have also been applied in this risk assessment.

RESPONSE 724:

This approach was applied in the Agricultural Product Consumption Risk Assessment. The HHRA will be revised as described in the responses to General Issues 5.A and 12.C.

Stephen T. Washburn

See comments above.

E. PHASE 2 – INTEGRATED RISK EVALUATION

> ***1. Were the bases for the toxicity assessment adequately described including the cancer slope factors, reference doses, and calculations of TEQ?***

COMMENTS

Holly Hattemer-Frey

Toxicity constants used in the risk assessment were adequately described with the exception of the proposed (new) reference dose and cancer slope factor for dioxin-like compounds. This issue has been discussed earlier in these comments.

RESPONSE 725:

Please refer to the response to General Issue 12.C.

Discussion of the potential noncancer effects of dioxin-like compounds was sparse, probably since the authors chose not to quantify noncancer effects from dioxin-like compounds. Even if noncancer effects from exposure to dioxin-like compounds are not quantified, information on possible noncancer health effects should included.

RESPONSE 726:

Please refer to the response to General Issue 12.C.

Furthermore, some discussion of mechanism of action and target endpoints for PCBs and PCDDs/PCDFs should be included. Even if noncancer risks for PCDDs/PCDFs were quantified, the mechanism of action and target endpoints for PCDDs/PCDFs may be sufficiently different than that for PCBs, that HQs for these two groups of chemicals probably shouldn't be summed.

RESPONSE 727:

Discussion of mechanism of action and target endpoints for tPCBs, PCB congeners, and PCDDs/PCDFs will be expanded in the revised HHRA. The HHRA included discussion of the noncancer effects from chronic exposure to PCBs in Volume 1, Section 2.3.3 pp. 2-24 to 2-29. Effects of in utero and perinatal exposures were discussed in HHRA, Volume 1, Section 2.3.4, pp. 2-29- to 2-33. The section on chronic exposure included subsections for multiple target endpoints including skin, eyes, liver, reproductive, cardiovascular, nervous system, immune system, and endocrine system. These subsections focused on adverse effects, and information on the mechanism of action is provided for dioxin-like PCBs. Please refer to the response to General Issue 12.C regarding toxicity information on PCDDs/PCDFs.

Calculation of TEQs is an acceptable method of integrating risks associated with exposure to a mixture of PCDDs, PCDFs, and PCBs that have dioxin-like properties. The TEFs used to calculate TEQs were appropriate and consistent with the current literature. The appropriateness of calculating "excess" PCB TEQ concentrations was confusing, hard to follow, and may not be technically accurate. Section 2.2.2.3 describes how total cancer risks were lowered slightly to account for the amount of dioxin-like PCBs in the CSF for PCBs. Dr. Keenan presented a compelling argument contradicting the accuracy of this approach. EPA needs to clearly refute Dr. Keenan's arguments or eliminate the adjustment for excess PCBs. I vote for eliminating the calculation, as incorporating this adjustment seems to add a lot of confusion to the process for something that (I'm guessing) has a minimal effect on risk estimates. If the adjustment is left in, it would be helpful if this section also included information on how much risks would change if this adjustment had not been used. Furthermore, page 2-11, lines 5-6 states that uncertainty associated with calculation of the expected TEQ could over- or underestimate cancer risk from exposure to PCBs. I recommend including here a quantitative estimate of the extent to which risks could be over- or underestimated using this method.

RESPONSE 728:

Please refer to the response to General Issue 5.A.

F. Owen Hoffman

The assessment would be markedly improved if the uncertainty in slope factors, reference doses, and calculations of TEQ were to be included in a quantitative uncertainty analysis. The bases for the chosen slope factors and reference doses should include a discussion about the fact that PCB's have long residence times in the human body and thus the daily average intakes normalized to body weight might not be as pertinent in determining the actual risk as would the accumulated body burden over time.

RESPONSE 729:

Please refer to the responses to General Issues 12.B and 12.C. In addition, as part of the expanded discussion of uncertainty, the revised HHRA will include the topic of cumulative body burden of PCBs.

John C. Kissel

The toxicity assessment for tPCBs generally followed longstanding EPA practice and could be readily understood. Treatment of TEQ risks was much less clear. I did not make an attempt evaluate the latter and defer to reviewers with more expertise in toxicology.

RESPONSE 730:

Please refer to the response to General Issue 5.A.

Roger O. McClellan

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

RESPONSE 731:

Individual sections of HHRA Volume 1 contained descriptions of the derivation of the toxicity factors citing the IRIS source documents, including, for example, the uncertainty factors included in the derivation of the RfD for PCBs (Section 2.2.3.1). Additional discussion of sources of uncertainty in the experimental information used in the derivation of the PCB cancer slope factor will be included in the revised HHRA. Please refer to the response to General Issue 12.B.

The uncertainty associated with toxic equivalency factors (TEFs), which are part of the TEQ methodology, is described in the HHRA Volume 1 Section 2.2.2.2, as follows: "TEFs are consensus values based on scientific judgment of REPs (relative potency to TCDD), which can vary by 3 to 4 orders of magnitude for an individual congener." Section 2.2.2.4 was devoted to discussing uncertainties associated with the TEQ approach. Please refer to the response to General Issue 5.A for a discussion of the proposed approach regarding the TEQ process in the revised HHRA.

P. Barry Ryan

This is not my area of expertise. I defer to my colleagues with greater knowledge of toxicity assessment. I do suggest that uncertainty in the toxicity assessment become a significant part of this document. Are values for toxicity-related factors, e.g., cancer slope factors, TEQs, etc., well-quantified? If so, the details should be stated here. If not, the impact of the uncertainties in such values should be discussed.

RESPONSE 732:

Please refer to the responses to General Issues 12.B and 12.C.

Lee R. Shull

Generally yes. A few comments on TEQ appear in the comments on Attachment C.4 Phase II – Direct Contact HHRA. Comments on toxicity criteria (CSFs, RfDs) generally appear under "other reviewer comments." I have concerns about the TEQ process, which are expressed in comments on Attachment C.4. In general, all toxicity criteria employed are standard EPA criteria.

RESPONSE 733:

Please refer to the response to General Issue 5.A for a discussion of the proposed approach regarding the TEQ process in the revised HHRA.

Stephen T. Washburn

The bases for selection were adequately described.

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

COMMENTS

Holly Hattemer-Frey

The risk characterization section of several volumes of the report was frustratingly vague.

Instead of summarizing risks as "exceeded, were within, or were below EPA's acceptable range," listing the actual risk level would be much more informative.

RESPONSE 734:

Please refer to the response to General Issue 13.B.

F. Owen Hoffman

Yes, but I would prefer that information about the results for the RME and CTE risk be kept separate, as well as information about the risks for each specific reach of the Rest of River.

RESPONSE 735:

Please refer to the response to General Issue 13.B.

John C. Kissel

Bar charts that show ranges from lowest CTE to highest RME are not a good communication tool. CTE and RME ranges should be shown separately.

RESPONSE 736:

Please refer to the response to General Issue 13.B.

Roger O. McClellan

The risk characterization is not a succinct and clear presentation of what was done and the results. The total assessment seems to be anchored at two extremes. Most of the documentation is turgid with details. The relevant information can usually be found if one spends days searching. At the other extreme are some summaries that are so minimalist as to not be informative. I suspect very few well-educated "lay persons" would be able to grasp what was done and what was found. The authors seem to have bent over backwards to avoid offering any interpretations.

RESPONSE 737:

EPA made every effort to convey clearly and completely the analyses that were performed in the HHRA and the results of those analyses. The revised HHRA will include additional clarification as described in this response to comments.

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

RESPONSE 738:

Please refer to the response to General Issue 13.B.

P. Barry Ryan

During the course of presentations and discussion, it became apparent that more clarity and transparency is needed in this area. A better, more concise but more complete discussion is warranted.

RESPONSE 739:

Please refer to the response to General Issue 13.B.

Lee R. Shull

Generally yes. Comments on Risk Characterization sections in each of the risk assessments are provided under “other reviewer comments.” In particular, comments on the Risk Characterization section of the Phase 2 – Consumption of Fish and Waterfowl Exposure Assessment is noted. The presentation of risk results in graphic and tabular format is particularly well done and clearly conveys the results.

Stephen T. Washburn

See comments above.

3. Were the potential risks associated with exposure to a combination of pathways and COPCs (direct contact, fish and waterfowl consumption, and agricultural product consumption) adequately characterized?

COMMENTS

Holly Hattemer-Frey

No, there was virtually no calculation of cumulative risks (summing of risks across all pathways for a given receptor group), and I strongly disagree with this omission. The only two aggregate risks calculated are an angler and hunter who may have contact with contaminated soil while fishing or hunting, and who eat what they catch. Risk to individuals who could who live in the floodplain, participate in recreational activities in floodplain soils, and consume fish and/or agricultural products taken from affected areas are not quantified. Granted, risks from fish ingestion and consumption of agricultural products are substantially higher than risks from other pathways, it is still appropriate and beneficial to sum risk across pathways so that 1) the contribution from all pathways can be evaluated and 2) a total (cumulative) is risk quantified.

RESPONSE 740:

Please refer to the response to General Issue 13.B.

I do strongly agree, however, the background risks from exposure to PCBs should NOT be added to site risks. The purpose of the RA is to evaluate risks from exposure to site-related contamination. Because background risks are typically much higher than site risks, adding in background levels dwarfs site risks to the point that it makes it extremely difficult to determine where action within the affected area needs to be taken (i.e., where existing site levels pose a threat to human health).

RESPONSE 741:

EPA interprets the reference in the Review's comment to "background risks from exposure to PCBs" to mean risks from historical exposures and exposure to PCBs from other sources. Such exposures are of potential concern for several reasons, including the persistence and accumulation of PCBs in body tissues, as noted by several other Reviews. However, the revised HHRA will retain the approach used in the HHRA of assessing risks due to current and future exposures, but not historical exposures, because this is the approach prescribed in EPA guidance for risk assessments for hazardous waste sites. As indicated in the response to General Issue 1.C, the revised HHRA will present and discuss the results of the MDPH PCB serum studies, which serve as a marker of previous PCB exposure of the individuals tested.

F. Owen Hoffman

Not with respect to uncertainty. A full quantitative uncertainty analysis is recommended for the direct contact and agricultural product pathways. Probabilistic approaches are preferred for addressing epistemic uncertainty as opposed to the non-probabilistic PBA.

RESPONSE 742:

Please refer to the responses to General Issues 7.F and 11.C.

John C. Kissel

Aggregate exposures were generally not considered. Aggregation was essentially dismissed by comparing fish eating or waterfowl eating to soil eating risks for fishermen and hunters. No attempt was made to estimate, for instance, how many different Direct Contact pathways a non hunting/fishing individual might experience.

RESPONSE 743:

Please refer to the response to General Issue 13.B.

The panel was not briefed on the manner in which cleanup decisions will ultimately be made. Conceivably, evaluation of individual direct contact pathways in isolation could lead to a no action decision that is inconsistent with EPA policy.

RESPONSE 744:

The cleanup decisions at this site will be made in accordance with the process that is laid out in the Consent Decree. GE will propose the Interim Media Protection Goals (IMPG) to EPA, taking into account the conclusions of the final risk assessment. EPA will be guided by the "Role of the Baseline Risk Assessment in Remedy Selection Decisions" Memorandum from D. Clay, Assistant Administrator, to Division Directors, April 22, 1991 (OSWER Directive 9355.0-30) in reviewing and responding to the IMPG proposal. Please refer to the response to General Issue 14, which addresses cumulative risks.

Roger O. McClellan

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

RESPONSE 745:

Please refer to the response to General Issue 14.

P. Barry Ryan

The combination pathways were only addressed in Section 7.3 of Volume 1 and are covered in only somewhat less than one page. It would be useful to look at these combination pathways in some more detail. This should not be limited to anglers and hunters, for example, but rather include standard scenarios for direct contact risk on a daily basis coupled with hunter/angler scenarios, etc. While one runs the risk of running into absurdities such as someone who hunts every day and wades in sediment all the time, realistic combination scenarios can be imagined that can account for multiple activities. It would help address the question of additive risk to some degree.

RESPONSE 746:

Please refer to the response to General Issue 14.

A discussion arose under this heading regarding the inclusion of background risk in these calculations. This was one important point brought forward by public comments. It is my contention that risk assessments such as this one typically perform incremental risk assessment, that is risk assessments that focus on the added risk associated with the source. I believe that this is the appropriate way to proceed in that it is not "fair" to require a potentially responsible party to clean up an area because it is perceived that that party's contribution to the risk has "filled up the risk cup." All others have contributed and have not been required to perform activities to reduce their component of risk. Risk from other activities is not in the picture since they affect a different part of the community. The PRP should not have to reduce the risk of contracting lung cancer from smoking, for example, because they have increased the risk of another type of cancer through contamination of the river. This being said, it is important to realize that risk from PCB exposures are almost completely due to one source, namely the manufacturing site under consideration. They should be required to reduce the contamination and thus risk to which they have contributed directly.

RESPONSE 747:

The revised HHRA will retain the approach of assessing risks due to current and future exposures, but not historical exposures. As indicated in the response to General Issue 1.C, the revised HHRA will present and discuss the results of the MDPH PCB serum studies.

Lee R. Shull

Except in Section 7.3 of Volume I (HHRA), no cumulative risk scenarios were assessed. Mention was made of the difficulty and complexity associated with deriving cumulative risk estimates in several places in the various reports. Rationale presented for not deriving these estimates is reasonable and clear.

RESPONSE 748:

Please refer to the response to General Issue 14.

Regarding Section 7.3, the information for the two scenarios presented is clear and reasonable. However, further basic instruction and cautions should be provided for non-technical readers who may attempt to derive cumulative risk estimates based on a personal exposure scenario.

RESPONSE 749:

Please refer to the response to General Issue 14.

Stephen T. Washburn

Yes.

> ***4. Were the uncertainties associated with both cancer and noncancer health effects adequately characterized and expressed?***

COMMENTS

Holly Hattemer-Frey

No, the Toxicity Assessment needs to describe in much greater detail the uncertainties associated with the cancer and noncancer toxicity constants used in the RA.

RESPONSE 750:

Please refer to the responses to General Issues 12.B and 12.C.

F. Owen Hoffman

See above comments. I do feel, however, that the baseline deterministic risk estimates approach the upper bounds of a 95% credibility interval when a probabilistic uncertainty analysis was conditionally focused on the RME and CTE as separate exposure scenarios. This means that the deterministic risk estimates are reasonably protective without being a gross overestimate of true risk. The extent to which the deterministic estimates may be an overestimate of true risk would require that the uncertainty in the cancer slope factors and the RFI be accounted for quantitatively.

RESPONSE 751:

Please refer to the responses to General Issues 12.B and 4.B.

John C. Kissel

Generally By policy, EPA does not consider probabilistic treatment of uncertainty in toxicological dose response factors, but does prescribe point values to be used. While derivation of those values includes adjustment (in a conservative direction) for uncertainty, the resulting point estimate does not express either variability in population response or uncertainty due to ignorance. Discussion buried in text is not an adequate substitute for numerical and graphical representation of confidence bounds.

RESPONSE 752:

The Reviewer is correct; EPA policy is to use point values for toxicological dose response factors in probabilistic assessments. The revised HHRA will continue to be consistent with this policy. However, the qualitative discussion of the uncertainty of toxicity factors will be expanded in the revised HHRA. Please refer also to the responses to General Issues 12.B and 12.C.

Roger O. McClellan

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

RESPONSE 753:

Please refer to the responses to General Issues 12.A, 12.B, and 12.C.

P. Barry Ryan

I may have missed it, but I do not recall an overall evaluation of uncertainties for the combined risk assessment. While the risk values for each component were well characterized, the overall risk uncertainty has not been addressed. However, the authors report that under normal circumstances and for a given individual, it is most likely that a single pathway will dominate exposure; uncertainty in risk from aggregate exposure is most likely also dominated by a single pathway. However, I have been convinced by my colleagues and through my own reading that a better characterization of the uncertainties in these estimates should be forthcoming. I think this is best handled through a separate section within the document- a section dedicated to qualitative and quantitative, if possible, uncertainty evaluation.

RESPONSE 754:

EPA will review methods for evaluating the uncertainty associated with the combined exposures. As suggested by the Reviewer, EPA will add a subsection to the revised HHRA regarding uncertainties of the combined exposures.

Lee R. Shull

With the exception of the Phase 2 – Consumption of Fish and Waterfowl Risk Assessment, which included quantitative uncertainty analysis, characterization of uncertainty is the most disappointing part of all the risk assessments presented. My comments on uncertainty analysis are quite extensive as related to all of the risk assessments. Perhaps the most extensive comments are presented on the Phase 2 – Consumption of Fish and Waterfowl Risk Assessment report.

RESPONSE 755:

Please refer to the responses to General Issues 7.F and 11.C.

Stephen T. Washburn

See comments above.

F. GENERAL

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

COMMENTS

Holly Hattemer-Frey

Yes, the toxicity data were applied appropriately.

F. Owen Hoffman

Yes.

John C. Kissel

Consideration of toxicity in the ROR HHRA appears to be consistent with current EPA guidance. Note limitations cited above.

Roger O. McClellan

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

RESPONSE 756:

The toxicity values used in the HHRA were derived from EPA's IRIS database as the primary reference, and HEAST and other sources when values were not provided in IRIS. This methodology was consistent with EPA guidance and policy at the time the HHRA was written. The use of IRIS as the primary reference will be retained. However, in the revised HHRA, the hierarchy of sources will change for toxicity values not in IRIS in a manner consistent with the 5 December 2003 OSWER Directive 9285.7-53 titled "Human Health Toxicity Values in Superfund Risk Assessments."

P. Barry Ryan

This is not my area of expertise. However, it does appear that the values were used consistently and extracted from appropriate datasets

Lee R. Shull

Generally yes. All of the toxicity criteria referenced in Table 2-1 of the HHRA are either listed in IRIS or HEAST. Whereas Table 2-1 shows no non-cancer value for alpha-BHC, NCEA has derived a value of 0.0005 mg/kg/day. Also, as noted in several comments (e.g., comment 8.b.xix under "additional reviewer comments" on Phase 2 – Consumption of Fish and Waterfowl Exposure Assessment (Volume IV, Appendix C), the documents should not discuss EPA proposed CSF for 2,3,7,8-TCDD.

RESPONSE 757:

The revised HHRA will incorporate the toxicity values based on the revised recommended toxicity value hierarchy described in the previous response. It will include a noncancer value for alpha-BHC. For discussion of how the revised HHRA will handle the proposed cancer slope factor (CSF) for 2,3,7,8-TCDD, please refer to the response to General Issue 12.C.

Stephen T. Washburn

Yes, with the exception of the approach for evaluating "dioxin-like" PCB congeners. Based on the information and references cited in the HHRA, it appears that this approach is not contained within existing EPA guidance although it is currently under review. If the evaluation of "dioxin-like" PCBs is retained in the HHRA, it should be included as a sensitivity analysis only.

RESPONSE 758:

Please refer to the response to General Issue 12.C.

Furthermore, a flawed approach appears to be used in the HHRA to "adjust" the results of the TEQ risk associated with dioxin- like PCB congeners to account for the presence of these congeners in the Aroclor test materials used in the animal studies that form the basis of the PCB cancer slope factor (see Section 2.2.2.3 in Volume I). Specifically, according to p. 2- 11, the TEQ content assumed to be present in total PCBs (7.1 mg dioxin- like TEQ per kg PCBs) is based on the content in Aroclor 1260, because "that is the Aroclor that most closely resembles the environmental mixture at this site…" However, it appears that the TEQ content used in the "adjustment" approach should instead be based on the highest TEQ content in the PCB mixtures used in the animal studies that form the basis of the PCB cancer slope factor. From the discussion of p. 2-11, this would be Aroclor 1254, not Aroclor 1260.

RESPONSE 759:

The cancer slope factor is based on the results of animal studies of Aroclor 1260, as well as Aroclor 1254. The environmental mixture at this site most closely resembles Aroclor 1260. The adjustment the Reviewer refers to was included to avoid "double-counting" the toxicity equivalence (TEQ) present in the commercial mixture used in the animal studies. This approach was confusing to Reviewers and will not be used in the revised HHRA. Please refer to the responses to General Issues 12.C and 5.A.

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

COMMENTS

Holly Hattemer-Frey

Yes, with exceptions noted in responses to other comments.

F. Owen Hoffman

Yes, with the exception of the numerous cautions mentioned above about the need to formally assess uncertainty. This is also an area that would benefit from additional research.

John C. Kissel

Yes, assumptions were generally stated.

Roger O. McClellan

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

> **RESPONSE 760:**
>
> Please refer to the responses to General Issues 12.B and 12.C for the revised HHRA regarding assumptions and uncertainties associated with toxicity values. Please refer to the response to General Issue 13.B for discussion regarding clarity in the risk characterization and presentation sections. The revised HHRA will also include expanded uncertainty discussions for all exposure scenarios.

P. Barry Ryan

This is a difficult question to answer. We had several days of presentations over the course of our evaluation and many documents to read. The documents outline the assumptions quite well. I do not see any that have been missed and therefore conclude that the essential ones are present.

Stephen T. Washburn

See comments above.

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

COMMENTS

Holly Hattemer-Frey

Yes, the calculation of dose and risk were performed correctly and are consistent with EPA guidance.

F. Owen Hoffman

Yes, but EPA guidance is unclear with respect to the use of probabilistic uncertainty analysis for quantifying epistemic sources of uncertainty. EPA guidance remains to be developed to address quantifying uncertainty in toxicity coefficients.

RESPONSE 761:

Please refer to the responses to General Issues 10 and 12.B.

John C. Kissel

Risk calculation for total PCBs in the ROR HHRA appears to be consistent with current EPA guidance. I did not review the estimation of carcinogenic risks attributable to TEQs and take no position on that aspect of the work.

Roger O. McClellan

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

RESPONSE 762:

Please refer to the responses to General Issues 12.A and 12.B.

The calculations for non-cancer risks are flawed by the inappropriate use and handling of the reference dose. A reference dose is an estimate (with an uncertainty spanning perhaps an order of magnitude) of a continuous intake for human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious non-cancer health effects during a lifetime.

Stated another way, exposure at a level equal to the Reference Dose does not equate to a level of specific excess risk. It follows that exposure at a level of 10 or 100 times the Reference Dose does not equate to 10 or 100 times more risk. Such exposures would warrant further evaluation but it is inappropriate to relate the exposures as producing 10 or 100 times more risk. I will elaborate with two relevant examples.

Early in the assessment (starting on pg 2-12) there is a brief description of how the Reference Dose is calculated for Aroclor 1254 and Aroclor 1016. For Aroclor 1254, the starting point is a study of the compound in monkeys ingesting 0.005 to 0.08 mg/kg-day doses. Subtle immunological changes, as well as other changes, were observed at 0.005 mg/kg-day. Hence, this level was designated as the Lowest Observed Adverse Effect Level (LOAEL). To obtain the Reference Dose the LOAEL was reduced by a total uncertainty factor of 300. This included uncertainty factors of (1) 3 for extrapolation for monkeys to humans, (b) 3 because the study was less than lifetime, (c) 10 to account for inter- individual variability, and (d) 3 for extrapolation from a LOAEL for effects not considered of marked severity.

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

RESPONSE 763:

The reference doses (RfDs) or hazard indices (HIs) were not interpreted in the HHRA in the manner described by the Reviewer. Please refer to the responses to General Issues 12.A and 12.B.

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

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

RESPONSE 764:

The RfDs or HIs were not interpreted in the HHRA in the manner described by the Reviewer. Please refer to the responses to General Issues 12.A and 12.B.

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

RESPONSE 765:

The RfDs or HIs were not interpreted in the HHRA in the manner described by the Reviewer. Please refer to the responses to General Issues 12.A and 12.B.

P. Barry Ryan

Generally, yes but that is the point of all of the comments that preceded this one. Overall, the HHRA provides a good assessment of the risk associated with this site. Given the assumptions and scenarios, I think they did a very good job.

Lee R. Shull

Yes. Theoretical upperbound cancer risks and hazard indices for non-cancer effects were calculated properly and consistent with EPA guidance.

Stephen T. Washburn

Yes, with exceptions as discussed in comments above.

4. Were the significant uncertainties inherent in the risk evaluation properly addressed and characterized? If not, please identify those that were not properly addressed or characterized and how they should be addressed in the HHRA.

COMMENTS

Holly Hattemer-Frey

One major data gap is the lack of a formal, quantitative uncertainty analysis for the agricultural analysis. Many of the exposure parameters, particularly chemical-specific transfer factors, are highly uncertain. Performing a quantitative uncertainty analysis for the agricultural analysis would be useful.

RESPONSE 766:

Please refer to the response to General Issue 11.C.

F. Owen Hoffman

No. The failure to quantify uncertainty in the toxicity coefficients used and the TEQ's calculated is a major shortcoming of the present analysis.

RESPONSE 767:

Please refer to the response to General Issue 12.B.

Uncertainty in the EPC for sediment, soil, fish, and waterfowl should be further evaluated and inappropriate bias removed from the uncertainty analysis.

RESPONSE 768:

Please refer to the responses to General Issues 4.B, 4.C, and 4.D.

John C. Kissel

EPA's standard practice in conducting Superfund risk assessments remains primarily deterministic in character. With the exception of the Fish and Waterfowl Exposure Assessment that is the case here. By definition a deterministic approach cannot adequately address uncertainty and variability which are statistical concepts. Paired CTEs and RMEs, which represent point estimates at unknown and undoubtedly variable percentiles of the overall population distribution, provide little or no characterization of uncertainty. If one accepts that EPA's deterministic risk assessment methods lead not to predictions of absolute risk, but rather to estimates of relative risk that permit consistent decisions to be made, those methods can still be useful. However, that fact is often not adequately expressed in risk assessment documents. In fairness, implementation of fully probabilistic analyses of risks at Superfund sites remains problematic due to inadequate input data and failure to conduct such an analysis is not in conflict with current EPA guidance.

RESPONSE 769:

EPA guidance (RAGS Volume 3 Part A Chapter 2) suggests proceeding from a tier one assessment (point estimate) to a tier two (probabilistic) assessment when the results of the tier one assessment might be further clarified for decision makers by the quantitative treatment of variability or uncertainty in the inputs. The methodology used in the HHRA is consistent with this guidance. The tiers are not "intermingled," although multiple analytical tools are used in tiers two and three, a practice also in keeping with guidance (please see, for example, RAGS Volume 3, Part A, Chapter 2, Section 2.3.5).

The ROR HHRA should include at least a screening level assessment of exposures to infants via breast feeding.

RESPONSE 770:

Please refer to the response to General Issue 3.A.

Roger O. McClellan

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

RESPONSE 771:

EPA does not agree with this comment. Professional opinion regarding whether individual parameter values used in the risk assessment would lead to an over- or underestimate of the risk, and in some cases estimates of the magnitude of the over- or underestimate, were provided in the uncertainty analyses in each of the appendices, and in Volume I.

In considering the issue of uncertainty it is important to recognize that the assessment is largely deterministic in character. A deterministic approach cannot adequately address the inter-related statistical concepts of uncertainty and variability.

RESPONSE 772:

Please refer to the responses to General Issues 7.F and 11.C.

This assessment, as are most risk assessments, are loaded with both uncertainty and variability. In several instances only limited data were available on which to proceed, for example, exposure duration and exposure frequency. In other cases specific data were identified but the number of samples available precluded the development of reliable estimates of variability.

RESPONSE 773:

EPA considers the data available from the MDPH (1997) report, *Housatonic River Area PCB Exposure Assessment Study,* to be an adequate source of site-specific data, including data on variability. The study included 1,529 individuals in the prevalence study and another 158 individuals in the volunteer study from which to develop statistical distributions for exposure duration. The source of the exposure frequency data differed in the different exposure pathways. Please refer to the response to General Issue 8.D for additional discussion of exposure duration for the fish consumption exposure assessment. Please refer to the response to General Issue 7.E for discussion regarding exposure frequencies for direct contact exposures. Exposure frequencies for food consumption were based on daily exposures, with the intake rate calculated on a daily consumption basis. Please refer to the responses to General Issues 8.A and 9.B for discussion of intake rates of fish and waterfowl, respectively.

In some cases, such as the Agricultural Product scenario, extensive use was made of models building on very limited data and dubious extrapolations.

RESPONSE 774:

Please refer to the responses to General Issues 11.A and 11.C.

P. Barry Ryan

As has been stated a number of times, there is need for a formal qualitative and quantitative uncertainty analysis placed in a separate section that thoroughly addresses this question in a clear and concise manner. As it stands now, the treatment of uncertainty is uneven and scattered throughout many places in the document. In particular, the agricultural pathway has many uncertainties that could result in significant change. However, overall, there would appear to be little likelihood that the problems found would lead to large-scale, major problems in the risk assessment results.

RESPONSE 775:

Please refer to the responses to General Issues 7.F and 11.C.

Lee R. Shull

No. As noted under "Charge Question E" above, characterization of uncertainty is the most disappointing part of all the risk assessments presented. The exception is the uncertainty analysis presented in the Phase 2 – Consumption of Fish and Waterfowl Risk Assessment, which is greatly improved because of the inclusion of a quantitative uncertainty analysis. My comments on uncertainty analysis are quite extensive as related to all of the risk assessments. Perhaps the most extensive comments are presented on the Phase 2 – Consumption of Fish and Waterfowl Risk Assessment report.

In general, the other risk assessments presented only a very cursory and inadequate qualitative uncertainty analysis. Not all factors that could impact risk estimates, either over- or underestimates, are identified and evaluated. For the sources that are identified, an informative discussion of information is generally presented, but no conclusion is presented as to whether the source of uncertainty is believed to result in either an under-estimation, no affect, or overestimation of human health risks. In my view, the risk assessor should, if at all possible, use his/her judgment, experience, etc to put forward a position whether risks are under- or overestimated or not affected by sources of uncertainty.

RESPONSE 776:

Please refer to the responses to General Issues 7.F and 11.C for a discussion of additional uncertainty evaluations that will be included in the revised HHRA. EPA does not agree with the portion of this comment suggesting that no conclusions were made regarding whether individual parameter values used in the risk assessment would lead to an over- or underestimate of the risk. This information was provided, along with estimates of the magnitude of the over- or underestimate for several parameters, in the uncertainty analyses in each of the appendices, and in Volume I.

The general approach for qualitative uncertainty analysis presented in RAGS is recommended.

RESPONSE 777:

The qualitative characterization of uncertainty for individual parameters in the HHRA is consistent with the approach described in RAGS. Presentation formats that improve clarity will be considered for the revised HHRA.

Stephen T. Washburn

See comments above.

5. To the best of the Panel's knowledge, have relevant peer-reviewed studies that support, are directly relevant to, or fail to support any estimate of risk been identified and considered, and has an appropriate methodology been used to reconcile inconsistencies in the scientific data?

COMMENTS

Holly Hattemer-Frey

The recent publication by Simon on soil ingestion rates should be considered as well as the recent study by Kimbrough reporting the epidemiological effects of worker exposure to PCBs.

RESPONSE 778:

Please refer to the responses to General Issues 7.E and 12.B.

F. Owen Hoffman

See "Soil ingestion by humans: A review of history, data, and etiology with application to risk assessment of radioactively contaminated soils."(S. Simon. *Health Physics* 74:6, 647-672. 1998.) and "Uncertainty, low-dose extrapolation and the threshold hypothesis" (C. Land. *J. Radiol. Prot.* 2:1–7. 2002.) concerning the influence of threshold values of risk within a probability distribution defining epistemic uncertainty in the cancer slope factor for radiation. See the attached references documenting the use of probabilistic approaches for addressing epistemic uncertainty.

RESPONSE 779:

Please refer to the response to General Issue 7.E.

John C. Kissel

Note discussion of child soil ingestion estimates attributable to Davis et al (1989) above.

RESPONSE 780:

Please refer to the response to General Issue 7.E.

Roger O. McClellan

By and large, most of the relevant peer-reviewed literature has been considered. However, in most cases it is apparent that the assessors used EPA guidance documents and review articles rather than the primary literature.

RESPONSE 781:

Please refer to the responses to General Issues 7.E, 12.B, and 12.C.

Several key publications which should be considered have been noted elsewhere in this report.

P. Barry Ryan

Speaking only for myself, it is my assessment that the relevant studies have been presented factually and in a manner consistent with good scientific practice.

Lee R. Shull

For the most part, the HHRA does attempt to incorporate and rely on relevant peer-reviewed scientific literature throughout.

A concern is the fact that the risk assessments made no attempt to reconcile the derived estimates of risk with actual public health studies conducted in the Housatonic River area. Two studies, which have been mentioned in my comments in regards to risk characterization and uncertainty analysis, are the MDPH (1997) exposure assessment study and the ATSDR/MDPH (2002) cancer incidence study. These studies were also discussed in the November 18-20, 2003 public meeting. Considering the overall importance of the findings of the HHRA, I recommend that EPA afford greater emphasis on placing the risk estimates in proper perspective. Certainly, the one way to accomplish this objective is to compare the risks estimated in the HHRA with epidemiology studies in the literature.

RESPONSE 782:

Please refer to the responses to General Issues 1.C and 1.D.

Another concern that was also mentioned in my comments is the failure of the HHRA to quantitatively address potential impacts associated with neonatal exposure (transplacental transfer of PCBs, breast milk pathway). The recent scientific literature on developmental effects in children (e.g., Schantz, 2003; Stewart et al., 2003) strongly supports the notion that EPA should assess neonatal risks associated with PCBs in the Housatonic River area.

RESPONSE 783:

Please refer to the responses to General Issues 3.A and 12.B. The revised HHRA will continue to address risks from transplacental transfer of PCBs in a qualitative manner.

In addition to assessing theoretical neonatal health risks, I recommend that EPA consider a public health study consisting of sampling fetal blood and breast milk. These data, in addition to a risk assessment of neonates, would provide a basis for evaluating the potential impacts of PCBs in the area on neonates.

RESPONSE 784:

ATSDR and MDPH are the agencies responsible for conducting public health studies for the GE/Housatonic River site, not EPA. MDPH conducted biomonitoring (blood serum in adults), and cancer incidence studies, which will be summarized in the revised HHRA. EPA considers the studies suggested by the Reviewer to be beyond the scope of an EPA baseline risk assessment.

Stephen T. Washburn

See comments above.

6. To the best of the Panel's knowledge, is there other pertinent information available that was not considered in the HHRA? If so, please identify the studies or data that could have been considered, the relevance of such studies or data, and how they could have been used in the HHRA.

COMMENTS

Holly Hattemer-Frey

Potential risks to infants from consuming breast milk were not quantified. Guidance for performing this type of assessment can be found in the following references. I am sure other sources are available as well.

U.S. Environmental Protection Agency, *Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Waste*, Office of Emergency and Remedial Response, Office of Solid Waste, April, October, and December, 1994.

Smith, A.H., 1987. Infant Exposure Assessment for Mother's Milk Dioxins and Furans Derived from Waste Incinerator Emissions, Risk Analysis, 7:347.

RESPONSE 785:

Please refer to the response to General Issue 3.A.

The serum data available from two MDEP studies should be incorporated into the risk assessment. First, the authors need to report if levels measured in local residents are consistent with the range of "background" levels currently reported in the literature. This discussion needs to include information on different age groups (versus making generalities about the entire population as a whole). Secondly, the RA can use the serum data to provide a limited reality check on the RA results. The RA should be careful to note that blood levels are not necessarily indicative of actual exposures since individuals sampled may not be representative of the entire range of potentially exposed individuals. I agree with Mr. Washburn's comments on this topic.

RESPONSE 786:

Please refer to the response to General Issue 1.C.

I also recommend that more information on the susceptibilities of different ages (particularly young children and fetuses) be included in the toxicity assessment. Information contained in the Schantz paper might be useful.

RESPONSE 787:

Please refer to the response to General Issue 12.B.

F. Owen Hoffman

The HHRA has not considered the possibility that future concentrations of PCB's will be lower in the future due to natural processes of sedimentation. Note that the HHRA for the Hudson River did include the effect of long-term sedimentation on reducing future lifetime exposures.

RESPONSE 788:

Please refer to the response to General Issue 4.E.

The use of Kriging should be explored for estimating exposure area EPC's, and formal uncertainty analysis used to obtain the 95% UCL.

RESPONSE 789:

Please refer to the response to General Issue 4.B.

The harvesting of uncontaminated fish and waterfowl from locations other than the Housatonic River need to be considered.

RESPONSE 790:

Please refer to the responses to General Issues 8.B and 9.D.

A discussion needs to be given about the relatively long residence time of PCB's in the human body and the build-up of PCB's in human tissue over time that could result from many years of chronic exposure. The question remains about how the cumulative body burden of PCB's relate to the estimate of cancer and non-cancer health risk (as opposed to a daily averaged dose). To the extent that biokinetics of long term exposure indicate a potential underestimate of life-time health risk, this source of uncertainty should be taken into account explicitly.

RESPONSE 791:

Please refer to the response to General Issue 12.B. As part of the expanded discussion of uncertainty, the revised HHRA will include the topic of cumulative body burden of PCBs.

John C. Kissel

Regional biomonitoring results are suggestive of a non-occupational contribution to elevated serum PCB levels in local populations. The panel was provided a 1997 MA DPH report (Housatonic River Area PCB Exposure Assessment Study – Final Report) describing blood serum levels observed in two study groups designated "Exposure Prevalence" (n=69) and "Volunteer" (n=79). The panel was not provided raw data from this report, so only limited interpretation is possible. However in both study groups, persons scoring in the top quartile on a questionnaire regarding behaviors that might reasonably lead to environmental PCB exposure (i.e., persons most likely to receive non-occupational exposure) had numerically higher median blood PCB levels than did persons who scored in the lower three quartiles. (See Figures 13 and 14 in the MA DPH report.) This effect was observed in persons with and without occupational exposures who were appropriately segregated. (So the effect occurs in 4 of 4 cases.) Behaviors queried in the survey were directly relevant to pathways considered in the ROR HHRA (e.g., fishing, flood plain activity, etc.). It would be reasonable for EPA to examine these apparent differences for statistical significance and compare implied doses to exposure predictions generated in the ROR HHRA. Observed blood PCB levels exhibit strong dependence on age. If those scoring in the upper quartiles on the behavioral survey were older than those scoring in the lower quartiles, the apparent environmental contribution to body burden may be artifactual. Differences could also be attributable to exposure pathways other than those considered in the ROR HHRA. For instance, elevated body burdens might be expected in family members of occupationally exposed persons or in persons living in housing contaminated by prior occupants who were occupationally exposed. Those persons might have coincidentally scored higher on the behavior survey. (This would not explain higher blood levels at higher scores within the occupationally exposed groups however.) Nevertheless, it is useful to extract dose estimates from the ROR HHRA and compare them to estimated inputs that would be required to maintain observed body burdens.

Differences in median blood levels between highest quartile behavioral score individuals and lower score groups appear to be 2-4 ppb. Making rough assumptions about body weight, body fat, blood- fat partitioning, and physiological half- lives of PCBs, it is possible to make back-of-the-envelope estimates of steady state inputs required to account for incremental increases in that range. Resulting doses are roughly those that are projected in the ROR HHRA to present lifetime excess carcinogenic risk on the order of 10-5. In Figure 7-1 (Vol. I) all pathways that have upper bounds in the 10-4-10-5 range are rendered plausible in that some individuals in the population appear to have body burdens elevated (over within-study occupational or non-occupational background) by amounts that would be produced by the projected exposures if they were actually occurring now. The highest risk projections shown in Figure 7-1 (Vol. I) do imply PCB doses that would lead to very high blood levels (~ 1 ppm). Failure to identify any such person in the MA DPH biomonitoring studies could indicate that those projections are very conservative or that the sample size was too small to find them. But most projected PCB doses underlying the risk estimates presented in the ROR HHRA cannot be dismissed as unduly conservative on grounds of lack of consistency with observed body burdens.

RESPONSE 792:

Please refer to the response to General Issue 1.C. The revised HHRA will consider the points in this comment. Note that, as a policy, MDPH does not release any raw data; therefore, EPA will not be able to conduct more in-depth analyses.

Roger O. McClellan

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

P. Barry Ryan

Speaking only for myself, it is my assessment that the relevant studies have been presented and no additional studies done would have changed the evidence or conclusions in any substantive way. During our deliberations, others mentioned studies that might be considered relevant. However, I do not believe that incorporation of such studies would have a major effect of the risk assessment.

Lee R. Shull

None noted that have not already been brought to EPA's attention.

Stephen T. Washburn

See comments above.

7. With respect to the conclusions in the HHRA report:

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

COMMENTS

Holly Hattemer-Frey

I agree that risks presented in the HHRA report (Section 7) are supported by information presented in earlier sections, but I dislike the method of presenting risks. Figures 7-1 through 7-4 present CTE and RME risks combined (the lowest CTE risk to the highest RME risk). I would prefer to see CTE and RME risks presented separately, so that I could readily differentiate between the two exposure scenarios.

RESPONSE 793:

EPA will examine different graphical approaches to the presentation of risks for use in the revised HHRA. Please refer to the response to General Issue 13.B.

F. Owen Hoffman

In general, this is true. In fact, the critical details of earlier discussions probably are not sufficient to conclude that PCB exposure in the Housatonic River is not a health risk of concern, especially for the ingestion of fish and waterfowl. The fact that human epidemiological information in worker populations is inconclusive cannot be used as evidence of no risk, especially since workers are not exposed to the same pathways and congeners of PCB's as are recreational anglers and other members of the public. Nevertheless, the EPA policy not to engage in a quantitative uncertainty analysis for the toxicity coefficients prevents evaluation of the likelihood that the deterministic estimates of risk could be overly pessimistic due to the effects of multiple compounded conservative assumptions. Although this uncertainty is undoubtedly large and, will probably dominate over the uncertainty in exposure, I doubt (based on my own independent analysis of uncertainty) that the uncertainty in the risk coefficients will be so large as to negate the conclusion that the present levels of PCB's in the Housatonic River represent an important source of environmental contamination.

RESPONSE 794:

EPA agrees with the Reviewer that human epidemiological information in worker populations cannot be used as evidence of no risk, since workers are not exposed to the same pathways and congeners as the general public and food consumers, nor are the ages at which exposure occurs necessarily similar. EPA also agrees that there is uncertainty associated with the toxicity values for PCBs and other COPCs. Please refer to the response to General Issue 12.B for additional discussion about evaluating the uncertainty associated with PCB toxicity.

John C. Kissel

Generally the qualitative arguments leading to the risk estimates can be followed through the documents. However, the sheer complexity of the case precludes presentation of all intermediate numerical steps and therefore renders actual reproduction of all numerical estimates impossible.

RESPONSE 795:

It is the goal of EPA risk assessments to be transparent and to provide adequate information for a Reviewer to reproduce numerical estimates. The revised HHRA will enhance the presentation of each exposure pathway to increase the transparency of both the overall strategy used and the individual calculations involved. Please refer to the response to General Issue 13.B.

Roger O. McClellan

This is a very large and complex assessment with substantial documentation. The reviewer faces two major challenges. First, it is not easy for the reader to gain a big picture in view of what was done and what was found. The Executive Summary is very terse and the author appears to have bent over backwards to simply state the facts without communicating very well what was actually done and the results.

RESPONSE 796:

It is the goal of EPA risk assessments to be transparent. The revised HHRA (Volume I) will include a new section that describes the overall strategy used in conducting the risk assessment. Each appendix document will include a discussion of the strategy relevant to that appendix. Summaries of these discussions will be added to the Executive Summaries. Please refer to the response to General Issue 13.B.

Second, the rest of the material is turgid with details. Although it is apparent the authors have strived to provide linkages between inter-related material, it is still difficult to dig out specific information and place it in context. I hesitate to request yet more tables and figures. However, I think a few additional selected figures and tables would be very helpful, especially in the Executive Summary and Volume 1. This would definitely include listings of all the key parameter values and underlying assumptions used in evaluating each scenario.

RESPONSE 797:

Please refer to the response to General Issue 13.B.

P. Barry Ryan

It is my assessment that the conclusions presented are backed by information presented in the report.

Lee R. Shull

Generally yes.

Stephen T. Washburn

See comments above.

- ***Do the conclusions (risk characterization) objectively and reasonably characterize potential current and reasonably foreseeable future risks to human health in the Rest of River area?***

COMMENTS

Holly Hattemer-Frey

I do have some concerns about the delineation of future land uses. The assessment seems to focus primarily on current land use conditions, because future land use conditions are not expected to change substantially. While this may be true, arguments for this position are weak. The text (Section 7.2.2.5) states that only properties currently used for residential or agricultural purposes were evaluated. Phase 1 screenings were based on current land use (and zonings) only, which seems to discount the possibility that some areas could be converted to agricultural or residential use in the future. Section 7 of the Phase II assessment (page 7-4) states that only Reaches 7 & 8 have areas where land use could change. Reaches 5 & 6 have "no properties that could have their screening result changed based on realistic future land use." The text should elaborate on what land uses are currently designated for Reaches 5 thru 8, and document how these land uses may change (Reaches 7 & 8) or provide justification for why the land use would not change (Reaches 5 & 6). Although this information may be summarized in Table 7-1, it is not clear to the reader as written.

RESPONSE 798:

Please refer to the responses to General Issues 2.A and 2.B.

I also believe that the lack of modeling data substantially hinders the RA process. Without modeling results, it is impossible to estimate how future concentrations and congener profiles may change over time. Without such information, the reliability of future risk estimates is questionable. PCB concentrations are likely to decrease over time but congener profiles could change such that the PCB congeners present in river soil and sediment could be more or less toxic. Some discussion on the lack of modeling data may have on reliably estimating future concentrations should be included in the RA.

RESPONSE 799:

Please refer to the response to General Issue 4.E.

It is very risky (and inappropriate in my opinion) to relate cancer incidence to PCB exposure. Just because ATSDR/MDPH results may not show an increase in the rate of any cancer type does not mean that the RA is overly conservative. The latency period between exposure and cancer can be several years, so it is inappropriate to use a lack of cancer incidence as verification no adverse health effects.

RESPONSE 800:

Please refer to the response to General Issue 1.D. Although information such as cancer incidence ratios will be included in the revised HHRA, EPA agrees with the Reviewer that these data cannot be used to relate PCB exposure to cancer incidence.

F. Owen Hoffman

Yes, with the exception of numerous comments made above. I feel that the PBA analysis performed to address epistemic uncertainty for the ingestion of fish and waterfowl is misleading and biased towards high values of exposure and risk. I recommend that the PBA be replaced or augmented by a probabilistic assessment of epistemic uncertainty about the quantification of RME and CTE exposures and risks and that the rationales for the choice of probability distributions to address state of knowledge uncertainty be strengthened.

RESPONSE 801:

Please refer to the response to General Issue 10.

The potential future risks have not been adequately addressed.

RESPONSE 802:

The revised HHRA will more clearly describe current and future land uses and activity patterns and more clearly distinguish between current and potential future risks. Please refer to the responses to General Issues 2.A and 7.D.

There is no procedure for incorporating the results of sediment modeling into the HHRA.

RESPONSE 803:

Please refer to the response to General Issue 4.E.

Quantitative uncertainty analysis remains to be performed for the Phase II Direct Contact Exposure Scenarios and exposures from the agricultural pathway.

RESPONSE 804:

Please refer to the response to General Issue 7.F.

The presentation of the context of results should include more than the EPA target risk range. I recommend that risks be placed into perspective with the background risk of cancer and anticipated non-cancer diseases for a non-exposed population. Risks can be given as lifetime absolute risk (background + exposure), excess lifetime absolute risk above background, and excess relative risk above background. These estimates would help the affected local population evaluate the extent to which exposures to PCB contamination are likely to affect the background incidence of disease and the extent to which such exposures are at or above epidemiological limits of detection for a large cohort size. In putting risks into perspective, the size of the potentially exposed population should be addressed.

RESPONSE 805:

Please refer to the responses to General Issues 1.C and 1.D. It will be clarified that the risk estimates in the revised HHRA are excess lifetime cancer risks above background cancer risk, which will be described. A similar approach is not possible for noncancer effects; however, the estimated intake of dioxin-like chemicals as a result of exposure to the site will be compared to the background intake of dioxin-like chemicals. Please refer to the response to General Issue 12.C.

John C. Kissel

Reasonable characterization of risk must be evaluated in context. The ROR HHRA is primarily a deterministic risk assessment. While this is consistent with past EPA practice and current EPA guidance, I view deterministic assessments not as true characterizations (predictions) of expected outcomes, but rather as socially negotiated conventions that enable decisions to be made. Ultimately they lead to action at some sites and no action at others. Generally it is reasonable to expect that sites will be appropriately ranked on a relative scale. Any assumption that absolute risk is well defined by a deterministic risk assessment is questionable at best. Nevertheless it appears that there is substantial reason to expect, under current conditions, elevated human exposure to PCBs as a direct consequence of contamination of the Housatonic River and its flood plain.

RESPONSE 806:

EPA agrees with this comment. In the revised HHRA, there will be a greater use of probabilistic assessment techniques in addition to the deterministic assessments.

This question also specifically invites consideration of the foreseeable future. However the ROR HHRA does not address the environmental fate of PCBs (or other COPCs). Some increased downstream transport of PCBs might reasonably be anticipated, especially if a dam holding significant mass of PCB-contaminated sediment were to fail or deliberately be removed or if bridge construction/repair were to disturb sediments. A large flood event might also transport relatively high concentration sediments to areas currently delineated as flood plain or extend the 1 ppm isopleth. These kinds of events might lead to higher PCB exposures among upper reach or downstream populations than would be currently estimated. Conversely degradation or volatilization loss of PCBs (if significant) could lead to reduced exposures. The ROR HHRA assumes static environmental conditions and in this sense does not adequately characterize possible future conditions.

RESPONSE 807:

Please refer to the response to General Issue 4.E.

Consideration of future land use is also marginal. Generally the ROR HHRA assumes that land uses will not change or will change in a way that reduces potential for exposure (e.g., less farming). The possibility that existing land use represents an artificially depressed state as a consequence of public concern over contamination and that a general decline in concern with time (issue fatigue) will lead ultimately to less cautious uses does not appear to have been considered. Discussion of changes in land uses that might lead to increased exposures would inform more appropriate discussion of need, if any, for statutory restriction on land use.

RESPONSE 808:

Please refer to the response to all subsections of General Issue 2.

Roger O. McClellan

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

RESPONSE 809:

EPA believes that the HHRA evaluated current and plausible potential future exposures. EPA does not agree with the Reviewer's statement that the "assessment conclusions do not objectively and reasonably characterize" current and future risks. In recognition of the comments provided by the Reviewers, the revised HHRA will further address the future risk scenarios, as discussed in the subsections of the response to General Issue 2.

A major shortcoming of the assessment is that it assesses risks to "hypothetical individuals " using extreme worst cases assumptions with regard to exposure frequency, exposure duration, fish caught and consumed, birds shot and eaten, where cows graze, the consumption of cows and goats milk, beef, mutton, goat meat, etc.

RESPONSE 810:

All scenarios were defined based on knowledge of observed human uses of the Housatonic River floodplain. Based on this comment, the Reviewer apparently believes that EPA used "extreme worst case assumptions" for all or nearly all exposure factors. EPA does not agree with this assertion; mean and upper-bound exposure assumptions were balanced to develop the reasonable maximum exposure. However, in recognition of the comments provided by the Reviewers, EPA has and will continue to assess the exposure parameters used for both the RME and CTE exposures. Please refer to the responses to General Issues 7.E, 7.F, 11.A, 11.C, and 13.A.

Many of the assumed values for usage of the Housatonic River and its flood plain are at extreme odds with a use survey conducted by General Electric. The results of that survey appear to have been totally ignored. Rather, values in some cases seem to have been pulled out of the air and would appear not to pass a "common sense" test.

RESPONSE 811:

Please refer to the response to General Issue 7.E. This survey was received by EPA after the draft of the risk assessment received by the Reviewers was completed. The values used in the HHRA were based upon observed uses of the floodplain. The GE survey will be considered, along with the other observations of uses, in the revised HHRA.

The assessment would be substantially strengthened if it were built on current demographic and land use data. The General Electric Use Survey has already been mentioned. Specific data on the potential productivity of the river for fish and waterfowl would help provide a "common sense" evaluation of the Reasonable Maximum Exposure and Central Tendency Estimates for anglers and waterfowl hunters. Are the estimates of fish and bird intake consistent with what the river can likely produce? To state the obvious, a fish can only be caught and eaten once and a bird can only be shot and eaten once. What is the use of the river by canoeists and hikers? Are the values used in the assessment consistent with the Survey conducted by General Electric? What is the actual use of areas more than 200 feet from the Housatonic River for agricultural purposes? Are the backyard cows, beef animals, goats, sheep and chickens referred to in the assessment plausibly real or clearly hypothetical? If real, is it one, ten or hundred of each? These questions were asked and not answered. In some cases, the answer was we are following the "rules" and assessing risks to individuals, not 34 populations. That answer may be bureaucratically satisfying but it does not pass the "common sense" test.

RESPONSE 812:

Please refer to the responses to General Issues 1.A, 1.B, 2.E, 7.E, 8.A, and 9.C.

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

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

RESPONSE 813:

EPA does not know of any portion of the HHRA where "It has been implied that such consideration (of the likely foreseeable use) would involve crossing the line into the risk management areas."

Potential future use of the floodplain was investigated thoroughly during the development of the HHRA. These investigations included interviews with the Berkshire Regional Planning Commission and local planners in Pittsfield, Lenox, Lee, Great Barrington, Stockbridge, and Sheffield, as well as local agricultural officials, state wildlife officials, and managers of non-profit recreational areas. In addition, various Master Plans were reviewed to provide more detailed information.

Although projection of a future Wildlife Preserve for much of the floodplain may well have yielded different risk estimates, such a future use is not reasonable. One parcel of land is owned by the Massachusetts Audubon Society and such a future use was evaluated; however, the majority of the floodplain within Reaches 5 and 6 is currently Wildlife Management Area or State Forest with active stocking of pheasants and is open to hunting of all legally permitted types. The plans are to maintain or enhance such uses in the future. There is currently discussion by MassWildlife regarding stocking trout in the river immediately below Woods Pond (Reach 7), and currently trout are stocked upstream of the confluence in both the East and Southwest Branches and in major tributaries to the Housatonic River. Please refer to the responses to all subsections under General Issue 2.

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

RESPONSE 814:

The HHRA will be revised to incorporate comments made by the Reviewers; however, EPA does not agree that additional sampling is necessary to support these revisions. Please refer to the response to General Issue 2.E.

P. Barry Ryan

It is my assessment that the risk characterizations are reasonable for most current and reasonably foreseeable future risks with the exceptions noted in the above comments.

Lee R. Shull

Generally yes. As noted elsewhere in this report, I have concerns that neonatal risks have not been adequately characterized. As noted, I recommend EPA design and undertake a study to better understand the level of exposure (and theoretical risks) of human neonates to PCBs in the Housatonic River area.

RESPONSE 815:

Please refer to the response to General Issue 12.B.

In addition, the concerns raised in regards to the Schaghticoke Tribe should be addressed through the performance of a quantitative human health risk assessment focused on this group of people and their surroundings.

RESPONSE 816:

Please refer to the response to General Issue 3.C.

Stephen T. Washburn

See comments above.

COMMENTS ON VOLUME 1, HHRA ATTACHMENTS

Lee R. Shull

ATTACHMENT 1: APPROACH FOR TREATING NON-DETECTS

- The approach presented in this section for dealing with analytical non-detects is adequate and consistent with EPA guidance.

- Page 6, line 12 and page 7, line 19: What is mechanistic knowledge and how is it applied? Please clarify.

  RESPONSE 817:

  The term "mechanistic knowledge" was used in the context of the discussion in Attachment 1 to refer to any credible independent information that can be used to replace a "non-detect" result with a numerical value, typically zero. Specifically, what is being referred to are independent analytical results or information such as Aroclor composition that demonstrate that a non-detected congener was not present in the parent Aroclor mixture and, therefore, the congener is not likely present in the sample and can reasonably be replaced with a zero value.

- Page 8, line 11: The statement is made that "The data in area H6 do not appear to be skewed…" What is the basis of this statement?

  RESPONSE 818:

  The data from area H6 were plotted and inspected visually.

ATTACHMENT 2: CONGENER VS. AROCLOR REGRESSION ANALYSES

General Comments

- In general and except for the following comments, Attachment 2 is well written and provides a succinct description of the Congener *vs*. Aroclor regression analyses for floodplain soils.

- Suggest providing soil physicochemical information to justify the prediction/ extrapolation of congener concentrations from soil samples used in the regression data set to other floodplain soils. Although extrapolations may be supported from a statistical point-of- view, it may not be supported based on soil science. For example, are there soil physicochemical characteristics that suggest that degradation rates of PCBs might be the same/different between soils used in the regression analyses and soils for which predicted congener concentrations were performed (*i.e.,* soils from other geographic areas where congener concentrations were not measured)?

RESPONSE 819:

Please refer to the response to General Issue 5.

- Suggest EPA consider adding simple descriptive statistics and scatter-plots of the nontransformed data, which would be helpful (though not absolutely necessary) to provide the reader a better understanding of the distribution of the data and to support the logtransformation of the data. This information can be placed in an appendix to Attachment 2 to maintain the "readability" of this section.

RESPONSE 820:

Please refer to the response to General Issue 5.

- Suggest adding a discussion on the consequences of using the sum of Aroclors as a measure of tPCBs as related to (a) the regression analyses and (b) the prediction of PCB congeners. Are there specific Aroclors that would be better indicators of congener concentrations (*e.g.,* due to initial composition of PCB congeners, degradation rates)?

RESPONSE 821:

Please refer to the response to General Issue 5.

Multivariate analyses (*e.g.,* principal component analysis [PCA]) can be performed to explore/identify possible "best" indicators that could undergo more focused analyses (*e.g.,* regressions).

RESPONSE 822:

Please refer to the response to General Issue 5. Additional data analyses (e.g., summary statistics and scatter plots) will be provided in the revised HHRA to support the regression modeling effort. PCA analyses of Reach 5 and 6 floodplain soil samples indicate limited PCB congener pattern variability among floodplain soil samples (ERA, Appendix C.7). However, this analysis did not include all congeners that were the subject of regression models. Therefore, summary statistics of the weight percent contribution of dioxin, furan, and dioxin-like PCB congeners to tPCB concentrations in each sample will be reviewed. If these statistics indicate significant congener pattern variability among floodplain soil samples, appropriate multivariate analyses will be performed as recommended by this Reviewer and will be described in the revised HHRA.

- Suggest a discussion be added as to whether the four assumptions of linear regression (*i.e.,* "fixed" independent variable, linearity, dependent variable normality, homoscedasticity) are met for the analyses, and, if not met, whether the regression is robust enough for the purpose of predicting congener concentrations. For example, do the regressions meet the assumption that variance around the regression line is constant [homoscedastic] and, hence, independent of the magnitude of the independent and dependent variables)?

RESPONSE 823:

Please refer to the response to General Issue 5.

- Additional rationale should be added regarding the selection of regression models for predicting congener concentrations based only on the p-value (*i.e.,* p = 0.01) and sample size (when more than one regression met the p-value selection criterion). It is appears that the p-value referred to in the Results and Recommendations (page 4, lines 14-17) is related to whether the slope is significantly different than a slope of zero. Given that the only purpose of these regression analyses is to predict congener concentrations, EPA should consider including the r^2-value in selecting regression models as well. The r^2-value is a measure of the variance in the dependent variable that is explained by the regression model—the "tighter" the fit to the regression line, the higher the r^2 (r^2 ranges from 0 (0%) to 1.0 (100%) of the variance that is explained by the regression model). For example, if the slope is significant (p = 0.01), but the regression model only explains a small proportion of the variance in the congener concentration [dependent variable] (as indicted by the r^2-value), one might not select the regression model as an adequate predictive tool.

RESPONSE 824:

Please refer to the response to General Issue 5. Three criteria were considered in selecting regression models for use in the risk assessment: sample size, r^2 values, and p-values. Regression models based on the largest sample size available were selected regardless of p-values or r^2 values. Almost all models had p-values lower than 0.05, and the few exceptions were not among the selected regression models. Some regression models, based on a smaller data set, had higher r^2 values than the corresponding regression model based on a larger data set. Even in these cases, EPA believes that the regression model based on the larger data set should be selected because the larger data set is likely to be more representative of floodplain conditions than the smaller data set.

- Suggest clarifying and adding rationale for not using a specified prediction limit (*e.g.,* 95% upper prediction limit) for obtaining an estimate of the dependent variable value (*i.e.,* congener concentration). Given the stated purpose of the regression models, use of this metric is (a) directly relevant to the use of the regression models, (b) provides a measure of confidence/assurance that the "actual" congener concentration is no greater than the predicted concentration, and (c) accounts for the fact that the further away from the mean, the less reliable are the estimates of the independent variable (this is because of the uncertainty about the true slope of the regression model).

RESPONSE 825:

Please refer to the response to General Issue 5.

- It is recommended that the reader be clearly informed that predictions from these regressions are best applied over the range of tPCB concentrations considered in the regression analyses. Predicting congener concentrations outside the range of the regression models (*i.e.,* outside the bounds of the data set) is problematic.

RESPONSE 826:

Please refer to the response to General Issue 5.

- To further ensure the clarity and transparency of the proposed use of the regression models, it is recommended that an example calculation be added to Attachment 2 that shows how the regression results are used to derive a congener concentration (including the use of the TEQ).

RESPONSE 827:

Please refer to the response to General Issue 5.

Specific Comments

- Page 2, lines 18-27 (bullet #4): It is suggested that the 4th bullet, *Used Only Reach 5 Data*, be moved to the #1 or #2 bullet position under METHODS as it is a key [first-cut] exclusion of the data.

RESPONSE 828:

The requested change will be made.

- Page 2, lines 12-13 (bullet #3): A reference should be added for the statement: "This additional cleanup step is not needed for other dioxin-like PCB congeners and does not affect the ir quantification." This reference will further support exclusion of these data from the regression analyses.

RESPONSE 829:

The requested change will be made.

- Page 2, lines 28-32 (last bullet): Further clarification is needed as to why Aroclor concentrations quantified by GERG were not used. The method used by GERG should be specified and the rationale why this method is not comparable to Method 8082 should be provided. Method 8082 is the method "more commonly used to analyze soils samples from the site" (Last Bullet, Lines 31-32, Page 2). Were methods (other than Method 8082 and those used by GERG) used to quantify Aroclors at the site?

RESPONSE 830:

Please refer to the response to General Issue 5.

- Page 2, line 38: It is stated that for PCB congeners other than PCB77, PCB81, PCB126, and PCB169, there was "consistency" between (a) regression models based on 2002 data and (b) models based on pre-2002 and 2002 data. Regression models for PCB congeners PCB77, PCB81, PCB126, and PCB169 are based on 2002 data only). This "consistency" rationale is provided to support the use of regression models for PCB77, PCB81, PCB126, and PCB169 based on 2002 data only. The meaning of "consistency" (*e.g.,* consistency based on model predictions, r^2-values, other parameters?) needs to be defined and why this consistency is sufficient to support the use of regressions based on a small data set further clarified. Results of power analyses may also provide helpful supporting information.

RESPONSE 831:

Please refer to the response to General Issue 5.

- Page 4, lines 7-13, Table 2: Please clarify why was the tPCB concentration of 10 mg/kg used to illustrate the comparability of predicted congener concentrations using the two regression models. It appears that 10 mg tPCB/kg is near the midpoint for most of the tPCB ranges for the "2002 data only" model. Differences between predictions using the two models tend to be minimized using midpoints as compared to a concentration near either end of the tPCB range (see spread of 95% confidence intervals).

RESPONSE 832:

Please refer to the response to General Issue 5.

- Figure 1: It appears that the 95% confidence intervals provided in Figure 1 are related to the slope. If this is true, for clarity, suggest specifying on the regression plots that the "associated 95% confidence intervals" are related to the slope and not related to predicted values from the regression (*i.e.,* prediction limits).

RESPONSE 833:

Please refer to the response to General Issue 5.

ATTACHMENT 3: APPROACH TO SPATIAL WEIGHTING OF CONTAMINANT CONCENTRATIONS IN THE HOUSATONIC RIVER FLOODPLAIN

- Whereas inverse-distance weighting (IDW) is the geostatistical approach selected for spatial weighting, the document states that different approaches (e.g., kriging) were evaluated. Although I do not question that IDW may be the best approach, information should be provided on how this determination was made. A discussion on the strengths and limitations of IDW (in general and versus other approaches [e.g., kriging]) would be useful.

RESPONSE 834:

The discussion of spatial weighting in the revised HHRA will be expanded to include a discussion of kriging, a comparison of kriging to IDW, and a more detailed description of how and why the IDW approach was selected.

- How the habitat mapping was used in focusing the spatial weighting lacks transparency. Was it only used to define separate areas that were spatially weighted separately, or was it also somehow factored into the weighting (which could have been done if it wasn't--

especially if these are tied to topography as indicated)? Also, how were the separate areas combined (if at all) to obtain the overall concentration map.

RESPONSE 835:

The discussion of spatial weighting in the revised HHRA will be expanded to provide more detail on how the habitat mapping was used in conjunction with IDW to obtain the final spatially weighted PCB concentrations in the floodplain.

- Whereas IDW doesn't accommodate anisotrophy (direction), kriging does. Since this is a river floodplain, it seems as though the direction of contamination would be a factor to consider in geostatistics. Kriging would have allowed this. Was anistrophy considered in selecting IDW (vs. Kriging) in selecting a spatial weighting approach?

RESPONSE 836:

Because of the meandering nature of the river in the PSA floodplain, the direction from the river to a particular cell in the spatially weighted grid was a less important consideration for determining a spatially weighted PCB concentration in that cell than the physical and hydrological conditions in a location, which are integrated and expressed by the habitat type present at the location. In addition, because of the meandering of the river and the configuration of adjacent wetlands and backwaters, the hydrology of the river when it goes out of bank is not consistent with the concept of anisotropy. This concept will also be discussed in greater detail in the expanded discussion of the spatial weighting approach to be included in the revised HHRA.

ATTACHMENT 4: CALCULATION OF EXPOSURE POINT CONCENTRATIONS:

- Whereas the approach, methods and discussion presented in this section appears to be thorough and accurate, the presentation is cumbersome and lacks transparency. It does not follow a straightforward path, and tends to be redundant. A flowchart of the process would improve transparency. For example, although the decisions on what methods to use in conjunction with a specific type of data distribution, a discussion of how distributions are determined in the first place would improve transparency of the methods.

RESPONSE 837:

Attachment 4 will be revised to reflect the Reviewer's comments and recommendations. As indicated in the response to General Issue 4.A, a flowchart will be added to illustrate the process.

ADDITIONAL COMMENTS

GENERAL COMMENTS ON VOL. I, HHRA

Holly Hattemer-Frey

The HHRA does not address historical exposures to residents living in or near the affected area but appropriately focuses on current and potential exposures only. While addressing past exposures will not affect the calculation of clean up goals, it is an important aspect of evaluating total risk to exposed individuals and should be addressed in some fashion in the HHRA. Measured fish concentrations used to calculate current and future exposures could underestimate risks to individuals who may have consumed fish from the Rest of River area over past decades. I recommend that some discussion of past exposures via fish consumption be included as part of the Uncertainty Analysis.

RESPONSE 838:

Please refer to the response to General Issue 1.C.

I recommend that population risk estimates be calculated to provide risk managers with additional information. The purpose of population risk estimates is not to discount individual risks, nor am I saying that remediation decisions should be based on population risk estimates. For a large, complicated site such as this one, however, population risk estimates may provide useful information for risk managers. EPA made a comment during one of the meetings that it was difficult to get an idea as to the number of people living in or area the affected area. I believe census data could be useful here.

RESPONSE 839:

Please refer to the response to General Issues 1.A and 1.B. Population data will be provided in the revised HHRA as a context for the risk assessment; however, only individual risks will be calculated.

The issue of whether or not subsistence fishing occurs in the Rest of River area needs to be finalized. Claims that subsistence fishing does not occur are weak given the many rebuttal arguments offered in other public comments on the HHRA.

RESPONSE 840:

Please refer to the response to General Issue 3.C. EPA has made several unsuccessful attempts to contact the Schaghticoke tribe regarding the issue of subsistence angling, and will continue these efforts in the future. EPA will evaluate the need to include a subsistence angler as a future potential exposure scenario in the revised HHRA.

Overall, I find Vol 1 (the volume summarizing the HHRA) too sparse. While I appreciate the effort to summarize the risk assessment process in the HHRA and leave the technical details to the appendices, there are several areas lacking in detail. For example, there needs to be some discussion of how COPCs were identified in the HHRA.

RESPONSE 841:

Volume I of the revised HHRA will be expanded in several areas, including more discussion and clarity on the selection of COPCs. Please refer to the responses to General Issues 1 (all subsections), 2 (all subsections), and 5.C.

The Site History section of Vol IV, Appendix C (Consumption of Fish) is superior to the site history information included in the HHRA. I recommend that this section replace the current Site History section of the HHRA (Vol I).

RESPONSE 842:

The revised HHRA will include an expanded Site History section in Volume I and in the appendix reports. EPA will look to the Site History section in the Consumption of Fish (Volume IV, Appendix C) for guidance in this regard.

SPECIFIC COMMENTS ON VOL. I, HHRA

Page 1, lines 24-25: The text does not present clear evidence that all PCBs present in the Rest of River Study Area originate from the GE facility. The report needs to clarify that there are no other PCBs sources upstream.

RESPONSE 843:

This clarification will be made in the revised HHRA.

Page 1-5 to 1-6, Appendices A & B: The text states that the Phase I screening-level evaluation was based on direct contact to PCB-contaminated soil and sediments only, while Phase II evaluated PCBs, PCDDs, PCDFs. It is not clear at this point why other COPCs were not included in the Phase I and II screening assessments.

RESPONSE 844:

This clarification will be made in the revised HHRA. The focus of Phase 1 Direct Contact Assessment was to determine areas with elevated levels of PCBs, the primary COPC, based on site-specific data and site history, and to eliminate areas where PCB concentrations were below conservative risk-based concentrations. Evaluation of these data showed that the tPCB concentrations from the site were substantially greater than other COPCs from a risk perspective. Therefore, tPCBs were used as an indicator contaminant in performing the risk screening in Phase 1. In the Phase 2 evaluation, analytical data for all contaminants were subjected to a COPC selection process, as presented in Appendix B, Section 2.5. The process resulted in the elimination of all contaminants other than PCBs, PCDDs, and PCDFs.

Page 1-7, lines 4-6: The text states that this report was prepared according to EPA policies and procedures using guidance documents listed in Table 1-1. Table 1-1 also lists MA Dept of Environmental Protection (MDEP) guidance documents. Suggest adding MDEP to the first sentence or deleting reference to it from Table 1-1.

RESPONSE 845:

This clarification will be made in the revised HHRA.

Page 2-3, lines 22-23: "… where as toxicity values for noncancer effects associated with oral exposures are known as reference doses (RfDs)." This statement is misleading since there are inhalation references doses as well.

RESPONSE 846:

This clarification will be made in the revised HHRA.

Page 2-4, line 23: Recommend changing the "likelihood that an individual *will* develop cancer" to *may* develop cancer. CSFs are not used to predict a certainty of cancer but a probability.

RESPONSE 847:

Language consistent with that used in guidance (EPA, 1989b), specifically "the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen," will be incorporated into the revised HHRA.

Table 2-3: It would be helpful if the common names were listed for the PCBs congeners as well as the chemical formula. Also, it is not clear what the number before the colon means.

RESPONSE 848:

The number before the colon is the IUPAC number, which is typically used as the common name for the PCB congener. The revised HHRA will clarify this table by putting "PCB-" before the IUPAC number.

Section 2.2.2.1: It is inferred that there were no PCB congeners present in any media for which a TEQ value was not available. If this is true, it needs to be stated. If not, how these PCB congeners were handled in the TEQ calculations needs to be explained.

RESPONSE 849:

Section 2.2.2.1 provides the methodology by which TEQ was calculated. As indicated in this section, TEQ was calculated by multiplying the concentrations of individual dioxin, furan, and PCB congeners by their respective toxic equivalency factor (TEF) values and summing the weighted values. There were numerous samples, primarily of soil and sediment, in which the chemical analysis was for tPCBs by Aroclor, but individual congeners were not quantified. Therefore, TEQ would not have been calculated, except in the part of the analysis that incorporated the congener regression equation.

Page 2-8, lines 20-21: "TEQ concentration estimates … were based on measured congener data. Please clarify if congener-specific data were measured for PCDDs, PCDFs, and PCBs. Lines 23-25 seem to imply that congener-specific data were collected for PCBs only. This section needs a clearer and more extensive discussion of how concentrations for PCDDs, PCDFs, and dioxin-like PCBs were estimated using regressions analyses.

RESPONSE 850:

Page 2-8, lines 20-21, refer to fish tissue data. For fish tissue samples collected by EPA in the Massachusetts portion of the river, congener-specific data were available for PCBs, dioxins, and furans. Lines 23-25 refer to soil data. For approximately 10% of the soil samples, congener data were available, including PCBs, dioxins, and furans. The text will be clarified in the revised HHRA.

Page 2-20, lines 1-2: Agree with the use of an oral absorption factor of 100% for PCBs.

Page 2-20, lines 10-12. The specific EPA document that recommends a dermal absorption rate of 14% for PCBs need to be cited here (along with the Wester et al., 1993 study).

RESPONSE 851:

The additional reference (RAGS E, Dermal Guidance) will be included in the revised HHRA.

Section 2.4.2 is very repetitive to Section 2.2.3.2 and can be deleted.

RESPONSE 852:

This section will be included only once in the revised HHRA.

Section 3.3: Inherent to the discussion of the calculation of the EPC (95% UCL) based on whether the data were lognormally or normally distributed is the assumption that the distribution of the data has been determined. The text should include information on how the distribution of different data sets was determined and what the results were.

RESPONSE 853:

The specific statistical tests used to determine normality and lognormality were described in the Section 2.2 of Appendix A, Volume IIA. They were not included in Volume I because EPA believed that this level of detail was inappropriate for the integrated summary volume. A section discussing the EPC calculation will be included in the revised HHRA (Volume I), as discussed in General Response 4.A. This section will also specify the statistical tests used to determine normality and lognormality.

Table 3-1: Please give more details either here or in the text as to how the exposure frequencies of 84 and 56 days were developed (e.g., days/week times weeks/year).

RESPONSE 854:

The text of Appendix A, Phase I Direct Contact Screening Risk Assessment (p. 2-7), provides the basis for the exposure frequencies. Specifically, 84 and 56 days represent 3 and 2 days/week, respectively, for 7 months (28 weeks) of the year. In the Housatonic River Area, soil contact is judged to occur between April and October.

Tables 3-1 through 3-7: References for the sources of the parameters used to calculate SRBCs (e.g., skin absorption factors, soil and sediment ingestion factors, etc) should be cited here. Also, it is not clear if the values used for the various exposure parameters were upper-bound or 50th percentile values. For example, Table 3-3 notes that the soil adherence factors used were 50th percentile values. Similar information needs to be provided for the other exposure parameters used to calculate SRBCs.

RESPONSE 855:

The revised HHRA, Volume I, will include additional details regarding the derivation of the screening risk-based concentrations (SRBCs).

Section 5.4.1, page 5-11, lines 23-26. Please provide a reference for the statement that EPA found no evidence of subsistence fishing in MA and CT reaches of the Housatonic River.

RESPONSE 856:

Please refer to the response to General Issue 3.C and Response 840.

Sections 5.5.1.1, 5.6.1.1, Table 5-7, and Table 5-15: Cancer risks are reported for tPCBs and TEQ risks from excess dioxin-like PCBs and dioxin/furan congeners only in Sections 5.5.1.1, 5.6.1.1, Table 5-7, and Table 5-15 despite the fact that Section 5.2.1.3 (pages 5-7 to 5-8) lists 14 COPCs for fish? It needs to be clarified that tPCB risks only are reported because the relative contribution from other COPCs was very low (about 1% or less).

RESPONSE 857:

This clarification will be made in the revised HHRA.

Table 6-4: I disagree with setting BCFs for various compounds to zero because the compound was not detected in soil.

RESPONSE 858:

The BCFs were set to zero because the compounds were not detected in biota tissue. In these cases where a value could not be calculated, table entries will be changed from zero to a note indicating that a value is not available. Also, the report will be modified to demonstrate that use of BCFs based on ½ detection limits or the detection limits for these congeners would not result in appreciable changes in risk estimates.

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APPENDIX A
LIST OF PUBLIC COMMENTS ON THE HHRA

Table A-1

Summary of Comments on the HHRA

Commenter and Affiliation	Date	Comment Summary
David R. Bailey, CityForest Corporation	June 24, 2003	Specific question regarding derivation of the 2-ppm cleanup level for residential soil
Patrice Mullin, President and Treasurer, Berkshire Foundation	June 19, 2003	Specific questions and concerns regarding primarily the risks due to consumption of agricultural products
Dr. Peter L. deFur and Ms. Tamara Pirkle, Environmental Stewardship Concepts	July 31, 2003	Various issues including exposure, toxicity, risk estimates, and uncertainties – refer to the EPA Housatonic River website for details.
Ernest T. Galliford	July 1, 2003	Cleanup costs should be shared by the government and companies involved. Woods Pond should be drained, excavated, and the dam removed.
General Electric Company	July 28, 2003	Specific technical comments on numerous aspects of the HHRA – refer to the EPA Housatonic River website for details.
Judith A. Herkimer, Director, Housatonic Environmental Action League, Inc. Attachments: Hartford Courant Article (Jan. 8, 1993) Northeast Generation Company Letter (December 27, 1999)	July 31, 2003	Various issues related to the river in Connecticut, including primarily questions about cultural practices and potential subsistence fishing in Connecticut, and the potential for deposits of PCBs in sediment behind large dams in Connecticut.
Timothy Gray, Director, Housatonic River Initiative Attachments: HRI Comments on the ATSDR Public Health Assessment Declaration of Independence from PCBs	July 31, 2003	Concerns regarding additional sampling, particularly for waterfowl in Connecticut. Additional concerns relate to the areas of fishing, particularly subsistence fishing, and the consumption of frogs and turtles. The risk due to existing body burden and multiple exposure pathways should be evaluated. Volatilization and the air pathway should be evaluated.
Dr. Peter L. deFur, Technical Advisor, Housatonic River Initiative	July 31, 2003	Primary technical comments presented in deFur and Pirkle (above). This submittal presents a series of questions to be considered by the Peer Review Panel, including data in Connecticut, tribal practices, neurological effects of PCBs, and the use of a weight-of-evidence approach.
David Mackey	July 20, 2003	Active remediation has the potential for making the situation worse and should not be undertaken.

Table A-1

Summary of Comments on the HHRA (Continued)

Commenter and Affiliation	Date	Comment Summary
Susan J. Steenstrup, Project Coordinator, Special Projects, Bureau of Waste Site Cleanup, Massachusetts Department of Environmental Protection	July 31, 2003	Detailed technical comments on various aspects of the HHRA, including statistical approaches and exposure assumptions – refer to the EPA Housatonic River website for details.

Note: The text of these comments is presented on the EPA Housatonic River website: http://www.epa.gov/ne/ge/