

Changes/Additions to the Human Health Risk Assessment Report

Volume 1 - HHRA Report

Section 1: Introduction

This expanded introductory section includes:

- A more detailed description of the GE/Housatonic River Site and its regulatory history.
- A description of each reach in Rest of River including current uses of the floodplain and the river.
- A description of potential future uses of the properties evaluated and the information sources and methodology for making these determinations.
- A description of the populations and demographics of the communities in the Housatonic River Area (HRA).
- Estimates of the number of individuals who participate in hunting, fishing and outdoor recreational activities in the HRA.
- A summary of the MDPH Exposure Study for the HRA, including PCB serum measurements.
- A summary of the ATSDR health consultation including its comparison of cancer rates in the HRA with the rest of Massachusetts.

Section 2: Conceptual Site Model and Strategy for the Human Health Risk Assessment

This new section includes new or expanded information on the following:

- An incomplete exposure pathway for a construction worker was added to the Conceptual Site Model (CSM), which is otherwise unchanged. The description of the CSM, particularly the fate and transport of PCBs in the river and floodplain, was expanded.
- The strategy for evaluating the 26 exposure scenarios in a geographical area the size of the HRA is described in a new subsection.
- A description of the screening level risk assessments for air and surface water is provided.
- An expanded description is provided of the how the sediment and floodplain soil were divided into exposure areas.
- The screening level risk assessments for direct contact exposure with soil and sediments, and the more detailed evaluations for exposure areas that were retained for further evaluation, are described.

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- Additional detail is provided on the strategies for selecting exposure frequencies, exposure durations, intake rates, and other exposure parameters for each exposure scenario, and in some cases, individual exposure areas, and the implications regarding the appropriate methodology for combining exposure areas and exposure scenarios to determine total risk from the site.

Section 3: Hazard Identification

This new section provides an overview of the data available for the HHRA, including specifically:

- An overview of both the systematic and discrete sampling programs for floodplain soils in Reaches 5-9.
- A description of sediment sampling programs in Massachusetts and Connecticut.
- A summary of the chemical analyses conducted on the soil and sediment samples, including a discussion of the methods used for quantifying PCBs.
- A summary of the sampling and analysis programs for air, surface water, and biota (fish, waterfowl, frogs, grass, squash, corn, and fiddlehead ferns).

Section 4: Toxicity Assessment.

This section, which was Section 2 of Volume 1 in the draft HHRA, has been revised and expanded to include the following:

- Definitions of EPA toxicity values (RfDs, CSFs) including expanded discussion of the uncertainty associated with the toxicity values.
- A detailed discussion of the uncertainty associated with cancer slope factors, including the cancer slope factor for PCB. There is also an enhanced discussion of the uncertainty associated with the CSF for dioxin.
- A detailed discussion of the uncertainty associated with the RfD for PCBs, including the quality of the study on which the RfD is based, uncertainty factors included in the RfD methodology, and the applicability of an RfD based on Aroclor 1254 to represent the toxicity of PCB mixtures in the HRA.
- A summary of toxicity studies on PCBs and dioxins published after the public review draft, including recent animal bioassays published by the National Toxicology Program.
- A revised approach to assessing cancer risk from TEQ and total cancer risk, in which the risks due to PCBs and TEQ are not summed.
- An update on the referral of EPA's evaluation of dioxin toxicity to the National Academy of Sciences.

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Section 5: Screening Assessments for Air and Surface Water

This new section includes:

- A discussion of air monitoring data used in conducting the screening assessment for air. It also includes a comparison of the monitoring results with screening risk level benchmarks.
- Minor revisions to the description of the screening assessment for surface water.

Section 6: Phase I Direct Contact Risk Assessment.

This section, which was Section 3 of the draft has been revised to include the following:

- Expanded discussion of the future land use and its impacts on the Phase 1 screening results.
- Expanded discussion of the development of screening risk-based concentrations (SRBCs).

Section 7: Phase 2 Direct Contact Risk Assessment.

This section, which was Section 4 of the draft, has been updated to reflect the revisions described in the summary of changes to Volume III, Appendix B, below.

Section 8: Fish and Waterfowl Consumption.

This section, which was Section 5 of the draft, has been updated to reflect the revisions described in the summary of changes to the Volume IV, Appendix C, below.

Section 9: Risks from Agriculture Product Consumption

This section, which was section 6 of the draft, has been updated to reflect the revisions described in the summary of changes to the Volume V, Appendix D, below.

Section 10: Integrated Risk Characterization and Major Findings

This is a new section that includes the following:

- Strategies and examples for combining risks from multiple pathways.
- New graphics indicating the relative contributions of consumption and direct contact exposure pathways to total tPCB cancer risk.

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- A discussion of TEQ exposure due to contamination in the HRA based on a comparison of HRA-related exposure pathways with levels of TEQ intake in a typical American diet.
- Estimates of breast milk concentrations in nursing women who consume fish or waterfowl from the Primary Study Area or dairy products from cows fed grain and other feeds grown on floodplain soils. These estimates are compared with tPCB concentrations measured in breast milk in several other populations.
- A summary of the major findings regarding cancer risk and non-cancer hazard for the exposure pathways that were evaluated quantitatively beyond a screening level assessment.

Attachment 2: Congener vs. tPCB Regression Analyses for Floodplain Soil

This attachment was expanded to include:

- An addendum providing documentation for regression model development, including 4 regression models and associated residual diagnostics plots for each congener:
- Box-and-whisker plots with summary statistics for data used to construct each regression model, with justification for log-transformation.
- More detailed information about laboratory methods.
- Discussion about the applicability of regression models to downstream reaches, given the spatial heterogeneity of congener composition of PCBs in floodplain soils and soil characteristics.
- A quantitative uncertainty analysis of PCB-126 exposure on a hypothetical commercial dairy farm to illustrate uncertainty in regression models.
- Discussion about the prediction of dioxin and furan concentrations from Aroclor data.
- An explanation of how TEQ was calculated using regression models.
- A discussion of regression model predictions at different assumed tPCB concentrations.
- Additional details of regression model selection criteria and their application.

Attachment 7: Summary of Analytical Methods

This is a new attachment describing chemical analytical methods for PCBs.

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Volume II (Appendix A)

Phase 1 Direct Contact Risk Assessment

No changes were made to this volume.

Volume III (Appendix B)

Phase 2 Direct Contact Risk Assessment

The following information has been added and/or expanded upon in the sections indicated:

Section 1: Introduction

- Description of the Consent Decree.

Section 4: Exposure Assessment

- Discussion of current and future land uses (Sections 4.2.2 and 4.2.3, respectively).
- Discussion of how exposure areas were determined (Section 4.3.5).
- Flow chart showing the EPC calculation method (Figure 4-2).
- Description of accessibility classifications and development of new use-weighting factors (Section 4.4.1.1.1).
- Description of the FI term (Section 4.5.1.3).
- Description of the dermal absorption factor (Section 4.5.1.4).
- Description of the incidental ingestion rates (Section 4.5.2.3).
- Description of the soil-to-skin adherence factors (Section 4.5.2.4.2).
- Discussion of the general recreation EFs (Section 4.5.3.2.1).
- Discussion of the angler EFs (Section 4.5.3.6.1).
- Discussion of the waterfowl hunter EFs (Section 4.5.3.7.1).

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Section 5: Point Estimate Risk Characterization

- Description and evaluation of the current and future land uses at each exposure area and subarea.
- Delineation of areas with tPCB concentrations greater than 50 mg/kg on EA figures.

Section 6: Probabilistic Risk Characterization

This is a new section describing the Probabilistic Risk Assessment for direct contact.

Section 7: Uncertainty Analysis

- Description of EPA guidance on uncertainty and variability including discussion of PRA methods/approaches.
- Discussion of uncertainty associated with the toxicity assessment (Section 7.2.3).
- Discussion of uncertainty associated with the risk characterization, including the TEQ cancer risk (Section 7.2.4).
- New section on quantitative treatment of uncertainty (Section 7.3).

Section 8: Risk Summary

- Description of the probabilistic methods/approaches.
- Summary of the probabilistic results.
- Discussion comparing the probabilistic and point estimate results.

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Volume IV (Appendix C)

Fish and Waterfowl Consumption Risk Assessment

The following information has been added and/or expanded upon in the sections indicated:

Section 1: Introduction

- Information on the definition of the site according to the Consent Decree.
- Description of newly designated catch and release fishing areas in Massachusetts.

Section 2: Hazard identification

- Data from reference areas for both fish and waterfowl.
- Discussion of analytical methodology for quantifying tPCBs in the various datasets.
- Data for pesticides based on GC/MS (SIM) methods which indicates interference of PCBs with pesticide analysis leading to overestimates of pesticide concentrations.
- Rationale for elimination of pesticides as COPCs for fish and waterfowl.
- Discussion of temporal trends in contaminant concentrations in fish tissue.
- Description of the selection of fish data relevant to human risk assessment (to include in the EPC calculation in Section 4).
- Discussion of anticipated lack of concentration differences in dark vs. white meat in waterfowl.

Section 3: Dose-Response Assessment

- Definitions of EPA toxicity values (RfDs, CSFs), including discussion of the uncertainty associated with the toxicity values.
- Description of revised approach to assessing cancer risk from TEQ and total cancer risk, in which the risks due to PCBs and TEQ are not summed.
- Update on the referral of EPA's evaluation of dioxin toxicity to the National Academy of Sciences.

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Section 4: Exposure Assessment

- Inclusion of nursing infant (breast milk exposure) and in utero exposure as subpopulations/exposure routes of concern.
- Description of the number and biomass of fish species in the PSA.
- Estimate of the number of ducks resident in the PSA.
- Information regarding the Schaghticoke Tribal Nation including consumption patterns and traditional cooking methods.
- Discussions of the basis for each parameter in the fish consumption exposure assessment, including adult and child consumption rates, fraction ingested, cooking loss, and exposure duration.
- Modifications of exposure parameters used in the point estimate calculations of ADD from fish consumption including the use of the central tendency estimate of cooking loss in the RME calculation.
- Modification of the ED used to calculate the point estimate ADD based on RME adult duck consumption in order to maintain consistency with the ED used for fish consumption.
- Discussion on the reasonableness of the meal size estimate for waterfowl consumption.

Section 5: Point Estimate Risk Characterization

The changes made in this section reflect cancer risks and noncancer hazards based on revised exposure parameters.

Section 6: Probabilistic Risk Characterization

The changes made in this section reflect cancer risks and noncancer hazards based on revised exposure parameters and distributions.

Changes to probabilistic risk analysis of fish consumption:

- EPCs for TEQ and trout were revised.
- EF distributions were created for the second tier model and the microexposure model, respectively.
- Uncertainty due to household size and extent of sharing was included in the probability bounds analysis.
- Fraction ingested (FI) parameter added to all models.
- Cooking loss distributions revised for all models based on reanalysis of literature.
- CSF TEQ risk calculations were removed.
- Discussion of interpreting MCA and PBA with respect to decision making was expanded.

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- Graphs to summarize the sensitivity analysis results were included.
- The discussion of model uncertainty was expanded.
- Many figures were changed to log-scale to improve readability.

Changes to probabilistic risk analysis of waterfowl consumption:

- Figures summarizing the sensitivity analysis results were added.
- The proposed CSF TEQ results were added.

Section 7: Uncertainty Analysis

- Discussion of the uncertainties associated with the hazard identification and the basis for EPCs including analytical methods; identification of COPCs; lack of available of data for individual congeners and certain fish species in Connecticut reaches; parts of fish consumed and consumer species preference in the fish EPC calculation; the impact of the length of the river in each exposure area; the impact on the parts of waterfowl eaten on the waterfowl EPC; and the impact of the fall migration on the waterfowl EPC.
- Inclusion of a bounding estimate for risk for consumption of waterfowl in Connecticut.
- Discussion of the uncertainties associated with the parameters incorporated into exposure assessment.
- Discussion of the uncertainties associated with the CSFs and RfDs for PCBs and TEQ that were used in the dose-response assessment, and the uncertainty regarding combining cancer risks from PCBs and TEQ.
- Expanded risk characterization that included risk estimates based on strong species preferences for fish, different parts of fish consumed, and traditional Schaghticoke food preparation methods.

Section 8: Risk summary.

- Cancer risks and noncancer hazards updated to reflect the revised point estimate and PRA risk calculations.
- Discussion of the comparison of point estimate and PRA risk estimates.
- Discussion of the impact of model assumptions.

Appendix C.7: Use of Probability Bounds Compared to 2-dimensional Monte Carlo

New appendix that evaluates variability and uncertainty associated with the risk of fish consumption in the PSA with a two-dimensional Monte Carlo simulation, and compares the results with uncertainty characterized using probability bounds.

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Volume V (Appendix D)

Agricultural Product Consumption Risk Assessment

The following information has been added and/or expanded upon in the sections indicated:

Section 1: Introduction

- Description of the Consent Decree.
- Description of the site, including figures defining river reaches.

Section 2: Hazard identification

- Discussion and table regarding tPCB concentrations on current and potential future agricultural land and the fraction of these areas in the floodplain (Section 2.2.1).
- Discussion of potential future exposure pathways (Section 2.1.2).
- Discussion about data usability and validation (Section 2.3.1).

Section 3: Dose-Response Assessment

- Summary of changes made to Section 4 of HHRA Volume I.

Section 4: Exposure Assessment

- Figures to clarify method used to predict COPC concentrations in foods (Figures 4-1 and 4-2).
- PCB congener BCF data for poultry (Section 4.4.2.2.4).
- Table summarizing model inputs used for each scenario (Table 4-11).
- Rationale for use of a non-parcel-specific approach (Section 4.1).
- Predicted food concentrations for the range of tPCB concentrations detected on current and potential future agricultural lands.
- Discussion of and tables summarizing soil-to-plant transfer factors from the literature (Tables 4-5 and 4-6; Sections 4.3.2, 4.3.3, 4.3.4).
- Comparison of TFs to screening model results (Section 4.3.2).
- Comparison of predicted to measured milk concentrations (Attachment D.2).

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- Summary of new COPC concentration data for the U.S. milk supply (Section 4.5.1).
- Adjusted garden produce consumption rates to account for regional variability (Section 4.6.2.2.3).
- Description of exposure duration data (Section 4.6.2.7).

Section 5: Point Estimate Risk Characterization

- All TEQ risk calculations moved to Section 7.
- Matrix format presentation for different combinations of two agricultural model inputs: (1) tPCB EPC in floodplain soil on current or possible future agricultural parcels, and (2) fraction of cultivated land or pasture that is in the floodplain.
- Sensitivity analysis incorporated into new Section 6.

Section 6: Probabilistic Risk Characterization

This is a new section describing the Probabilistic Risk Assessment for agricultural product consumption.

Section 7: Uncertainty Analysis

- TEQ risk estimates (Section 7.2.4.1).
- Sensitivity analyses to show how TEQ risk predictions would change with the use of screening level TFs and BCFs based on detection limits for those congeners for which BCFs were assumed to be zero (Sections 7.2.2.1.1, 7.2.2.1.2, and 7.2.4.2).
- Discussion of uncertainties associated with the Dose-Response assessment (Section 7.2.3).
- Summary of quantitative treatment of uncertainty (Section 7.3).

Section 8: Risk Summary

- Summary and comparison of results from the point estimate and probabilistic risk characterizations.