Third Five-Year Review Report for the Hudson River PCBs Superfund Site

APPENDIX 5

HUMAN HEALTH AND ECOLOGICAL RISKS

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THIRD FIVE-YEAR REVIEW REPORT FOR THE HUDSON RIVER PCBs SUPERFUND SITE

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1 INTRODUCTION

This appendix provides a review of the human health and ecological risk assessments conducted for the Site and evaluates if the assumptions and data used in the original assessments are still appropriate (EPA, 2000a, 2000b). The results of this appendix are summarized in the main text of this Third Five-Year Review Report.

The U.S. Environmental Protection Agency (EPA) is addressing the Hudson River PCB Superfund Site (Site) in five discrete components known as operable units (OUs). This Five-Year Review (FYR) addresses OUs for which a remedy has been selected and where identified contamination has been left behind; therefore, OU1 (Remnant Deposit) and OU2 (Upper Hudson River [UHR] river sediments) are addressed as part of this FYR and this appendix. Section 1 of the FYR main text discusses the status of the other Site OUs.

2 HUMAN HEALTH RISK ASSESSMENT

This section provides an overview of the human health risk assessment (HHRA) conducted for the Site.

2.1 Summary of Risk Determination for Remnant Deposits OU1

When the Remnant Deposit remedy was selected in 1984, guidance on risk assessment was in its early development at EPA. As a result, a risk assessment was not conducted, and a total polychlorinated biphenyl (PCB) concentration of 5 milligrams per kilogram (mg/kg) was used to determine areas to be addressed and cleaned up. The remediation of the Remnant Deposits involved capping concentrations greater than 5 mg/kg with a buffer zone extending at least 5 feet beyond the 5 mg/kg concentration boundary. The cap system consists of a soil cover, a geosynthetic clay liner, and a topsoil and vegetative layer. Ongoing inspections and maintenance are necessary/required into perpetuity.

2.2 Summary of the OU2 HHRA Supporting the 2002 ROD

The OU2 remedy called for selective dredging followed by monitored natural recovery (MNR) to achieve several remedial action objectives (RAOs) including the objective of 0.05 mg/kg PCBs in fish fillets. This objective was supported by the HHRA that was conducted for the 2002 Record of Decision (ROD) for the Site (EPA, 2002). Following a peer review of its 1999 HHRA (EPA, 1999a) for the Site, in November 2000, the EPA issued a Revised HHRA. The Revised HHRA addressed peer-review comments and identified PCBs as the primary contaminant of concern (COC) for the Site. This conclusion is supported by fish data collected by the New York State Department of Environmental Conservation (NYSDEC) at the Site, which showed other contaminants present at low levels relative to health concerns or below detection limits (Sloan, 1999). Other contaminants analyzed by NYSDEC included: total dichlorodiphenyltrichloroethane (DDT), total chlordane, total endrin, total endosulfan, dieldrin, aldrin, mirex, total heptachlor, total hexachlorobenzene, toxaphene, methoxychlor, individual polycyclic aromatic hydrocarbons (PAHs), cadmium, mercury, dioxins, and dibenzofurans. The Revised HHRA evaluated both cancer risks and non-cancer health hazards to young children, adolescents, and adults posed by current and future potential exposures to PCBs in the Upper and Mid-Hudson River (EPA, 2000b). Exposure pathways evaluated during the HHRA included ingestion of fish, ingestion and dermal contact with sediment and surface water through recreational activities, and inhalation of volatilized PCBs.

The Revised HHRA found that ingestion of fish contaminated with PCBs resulted in the highest increased (i.e., over background) lifetime cancer risks and non-cancer hazards. Risks for other pathways (e.g., ingestion and dermal contact with sediment or surface water, and inhalation) were below target risk levels.

The Revised HHRA used both a "deterministic" risk assessment, and a Monte Carlo or probabilistic assessment pursuant to the Agency's guidance on a Probabilistic Analysis (PRA) for risk assessment (EPA, 1997b). The approaches for these risk assessments and results are summarized in the sections below: exposure assessment, toxicity information, deterministic risk results, and Monte Carlo risk results. This section concludes with a summary of the RAOs that were derived using the Revised HHRA.

Exposure Assessment for Fish Ingestion

Fish ingestion is the primary route of exposure to PCBs in the UHR. Key assessment inputs are the fish ingestion rate and the duration of exposure.

The 1991 New York Angler survey (Connelly et al., 1992) was selected as the primary source of information for the deterministic and Monte Carlo assessments for analysis of the fish ingestion pathways. The fish ingestion rate included in the deterministic and PRA represents the amount of fish an individual consumes on average within the year, annualized such that it is expressed in units of grams of fish consumed per day (g/day). The deterministic risk assessment used an ingestion rate of 31.9 g/day representing the 90th percentile ingestion rate from the Connelly et al. 1992 study with appropriate adjustments for adolescents and young children consumption rates. The entire distribution of fish ingestion rates was used in the Monte Carlo Analysis (MCA, described below) to represent the variability of fish consumption patterns among the angler population.

Assumptions for exposure duration included an evaluation of population mobility data from the U.S. Census Bureau for the five counties surrounding the UHR and fishing duration data from the 1991 New York Angler survey to determine the length of time an angler fishes in the UHR (i.e., exposure duration). The exposure duration for fish ingestion was 12 years for the central tendency or average exposure estimates (total of 6, 3, and 3 years for adult, adolescent, and young child exposures, respectively), 40 years for the Reasonable Maximum Exposure (RME) exposure estimate for cancer (total of 22, 12, and 6 years for adult, adolescent, and young child exposures, respectively). The exposure duration of seven years for the RME estimate for non-cancer health assessment was selected because it is an exposure period for chronic non-cancer health effects that yields a high-end average daily dose (ADD) based on the modeled decline in PCB concentration with time.

The exposure point concentration (EPC) for fish was based on an average concentration of what a typical angler is expected to commonly catch and consume throughout the UHR over the exposure period. To calculate this value, a species-weighted average concentration was developed based on modeling results for bass, bullhead, and perch across all three river sections, accounting for how frequently these fish are expected to be caught and the length of each river section. Hudson River PCB fish data with congener-specific results were used to determine what fraction of the Total PCBs in fish are associated with each dioxin-like PCB congener (discussed below).

Other exposure assumptions including body weight were obtained from the EPA Standard Default Exposure Assumptions applicable at the time (EPA, 1989a, 1989b) and the 1997 Exposure Factors Handbook (EPA, 1997c), or the risk assessor's professional judgment was used where appropriate.

Toxicity Assessment

PCBs are a group of 209 individual chemicals known as congeners. Each congener is a specific chlorinated biphenyl compound. PCBs were manufactured and sold as mixtures of congeners known as Aroclors. While PCBs can be analyzed as either Aroclors or as individual congeners, typically the toxicity of PCBs is evaluated as a mixture because the available toxicological literature is generally for exposure to one of the Aroclors and not individual congeners. However, a subset of PCB congeners are considered to be dioxin-like. These dioxin-like congeners are typically evaluated separately in addition to the mixtures. The Revised HHRA used toxicological information from two sources: EPA's Integrated Risk Information System (IRIS) for PCB mixtures (EPA, 1999b) and values published by the World Health Organization (WHO) for the dioxin-like PCBs available in 1998. The 1998 WHO/International Program on Chemical Safety (IPCS) Toxicity Equivalency Factors (TEFs) were used to calculate cancer risks for dioxin-like PCBs and results were discussed in the risk characterization (Van den Berg et al., 1998). Additional details related to TEFs are provided below.

Office of Solid Waste and Emergency Response (OSWER) Directive 9285.7-53, Human Health Toxicity Values in Superfund Risk Assessment, outlines a process for selecting toxicity values for use in the HHRA (EPA, 2003). The toxicity hierarchy identifies IRIS as a Tier 1 source of toxicity information. The IRIS PCB toxicity values identified in the Revised HHRA are considered Tier 1 toxicity criteria. IRIS identifies PCBs as (EPA, 2000b):

- A probable human carcinogen and known animal carcinogen - consistent with Superfund guidance, chemicals classified as known, probable, or possible human carcinogens are all evaluated in the HHRA for carcinogenic effects; and
- Having non-cancer health effects observed in laboratory animal studies such as reduced birth weight (Aroclor 1016) and impaired immune function, distorted finger and toenail beds, and occluded meibomian glands located in the eyelid (Aroclor 1254).

The basis for the systemic toxicity values (non-cancer) were studies of Aroclors 1016 and 1254 in Rhesus monkeys following a thorough review of the literature that existed when they were developed. For the non-cancer hazard calculations for exposure to fish tissue, the oral Reference Dose (RfD) for Aroclor 1254 was used because the distribution of PCBs in fish tissue tends to have a higher degree of chlorination (Tri+ PCBs), which better corresponds to the higher chlorination level of Aroclor 1254.

A subset of PCB congeners is considered to be dioxin-like, that is, they are structurally similar to dibenzo-*p*-dioxins, bind to the aryl hydrocarbon receptor, and cause dioxin-specific biochemical and toxic responses (reviewed in EPA, 1996). The carcinogenic potency has been estimated for these dioxin-like PCB congeners relative to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD). Dioxins, furans, and dioxin-like PCBs have been associated with numerous adverse health effects, including cancer, developmental and reproductive effects, as well as immunotoxicity. However, dioxin-like PCB congeners are responsible for only part of the carcinogenicity of a Total PCB mixture. The calculation of cancer risks specifically for dioxin-like PCBs (using the 1998 WHO/IPCS TEFs) allows for the ability to account for potentially higher relative concentrations of dioxin-like congeners in environmental mixtures, particularly in fish, due to bioaccumulation of more persistent congeners.

At the time of the Revised HHRA, EPA did not have a publication documenting TEFs for use in EPA risk assessments, including dioxin-like PCBs. Therefore, TEF values published by the WHO in 1998 were appropriately used in the risk assessment to evaluate 12 dioxin-like PCB congeners. The evaluation of dioxin-like PCBs was conducted separately from the evaluation of Total PCBs.

Deterministic Risk Assessment Results

The Revised HHRA found that ingestion of fish contaminated with PCBs resulted in the highest increase (i.e., over background) in lifetime cancer risks and non-cancer hazards. Fish tissue was observed to contain PCBs with a higher degree of chlorination relative to other media (e.g., sediment, surface water). As discussed above, the non-cancer toxicity values used for fish ingestion in the HHRA were for Aroclor 1254. As described in more detail below, risks for other pathways (e.g., ingestion and dermal contact with sediment or surface water, and inhalation) were below target risk levels. Accordingly, the cancer risks and non-cancer hazards associated with the RME scenario for fish ingestion served as the basis for the RAOs provided in the ROD (EPA, 2002).

The RME is defined as the highest exposure that could reasonably be expected to occur for a given exposure pathway at a Site and is intended to account for both uncertainties in the contaminant concentration and variability in exposure parameters (e.g., exposure frequency and exposure duration). The estimate of increased risk to the RME individual developing cancer averaged over a lifetime (childhood through adulthood over 40 years), based on the exposure assumptions in the Revised HHRA, was 1×10^{-3}, or one in 1,000. The total cancer risk of 1×10^{-3} is composed of risks to the adult (6×10^{-4} or six in 10,000), to the adolescent (4×10^{-4} or four in 10,000), and to the young child (4×10^{-4} or four in 10,000). The cancer risks to the RME individual exceed the risk range established under the National Contingency Plan (NCP) of 1×10^{-6} to 1×10^{-4} (one in 1,000,000 to one in 10,000; EPA, 1991).

Cancer risks associated with dioxin-like PCBs were evaluated consistent with the 1996 document "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures" (EPA, 1996). The Site fish data with congener-specific results were used to determine what fraction of the Total PCBs in fish are associated with each dioxin-like congener. These fractions were then multiplied by the high-end Total PCB exposure point concentration used in the risk assessment, to determine the high-end (RME) EPC for each dioxin-like congener. These EPCs were then multiplied by the corresponding 1998 WHO/IPCS TEFs (Van den Berg et al., 1998) to generate a dioxin equivalent (Toxicity Equivalent Quotient; TEQ) for each dioxin-like congener.

The cancer risk for an RME scenario associated with fish ingestion of dioxin-like congeners was 1.5×10^{-3} which was comparable to the total cancer risk for total non-dioxin-like PCBs. EPA's evaluation of non-cancer health effects in the Revised HHRA (EPA, 2000b) involved comparing the average daily exposure levels (dose) to determine whether the estimated exposures exceed the RfD used to evaluate non-cancer health effects. The ratio of the Site-specific calculated dose to the RfD for each exposure pathway and receptor age group was summed to calculate the Hazard Index (HI) for the exposed individual. HI of 1 is the reference level established by EPA above which concerns relating to non-cancer health effects are further evaluated. Ingestion of fish resulted in the highest HI values. The RME HI was 104, 71, and 65, for the young child, adolescent, and adult, respectively.

Estimated RME and central tendency cancer risks relating to PCB exposures in sediment and water while swimming or wading, or from inhalation of volatilized PCBs in air by residents living near the river, are much lower than those for fish ingestion, falling mostly at the low end, or below, the cancer risk range of 1×10^{-4} to 1×10^{-6}. At the time of the assessment, the cancer risks from exposure to volatilized PCBs under residential exposure assumptions were below 1×10^{-6} (one in 1,000,000), and a calculation of non-cancer hazards from exposure to PCBs in air for a resident, developed after the HHRA was completed, was also below the goal of protection of HI of 1. At the time of the HHRA, non-cancer toxicity data was not available to evaluate dioxin-like PCBs.

Monte Carlo Risk Analysis Results

In addition to the "deterministic" risk assessment discussed above, an MCA or probabilistic assessment was conducted pursuant to the Agency's guidance on PRA for risk assessment (EPA, 1997b). The purpose of the MCA was to estimate a probability distribution of PCB exposure among members of the angler population and to quantify the extent to which important sources of uncertainty affect the precision of these estimates. When combined with the toxicity information for PCBs, the range of PCB exposure is translated into a range of cancer risks and non-cancer health hazards. The MCA included a distribution of cancer risks and non-cancer health hazards for the fish ingestion pathway.

The results of the deterministic analysis for the average (Central Tendency Exposure [CTE]) and RME scenarios were compared to the MCA results to assess the consistencies and inform the degree of conservatism associated with the deterministic results. The deterministic and Monte Carlo risk estimates were closely aligned, which provided additional confidence in the deterministic risk results used to support the remedy decision. For cancer risk, the point estimate RME for fish ingestion (1×10^{-3} or one in 1,000) falls approximately at the 95th percentile from the

Monte Carlo base case analysis. The point estimates central tendency value (3 x 10^{-5} or three in 100,000) and the Monte Carlo base case 50^{th} percentile value (6 x 10^{-5} or six in 100,000) are similar. For non-cancer health hazards, the point estimate RME for fish ingestion (104 for young child) falls between the 95^{th} and 99^{th} percentiles of the Monte Carlo base case which is generally the target range for remedial decision-making. The point estimate central tendency HI (12 for young child) is approximately equal to the 50^{th} percentile of the Monte Carlo base case HI of 11.

Remedial Action Objectives

The RAOs to reduce the cancer risk and non-cancer health hazard for people eating fish from the Hudson River by reducing the concentration of PCBs in fish was derived using the inputs (toxicity and exposure values) from the HHRA.

EPA established the RAO of 0.05 mg/kg (wet-weight [ww] in fish fillets) as an acceptable risk-based PCB concentration for Hudson River fish based on an annual consumption rate of 51 half-pound meals by an adult.

The ROD also established target PCB concentrations in fish fillets of 0.2 mg/kg PCBs, which is protective at a fish consumption rate of one half-pound meal per month, and 0.4 mg/kg PCBs in fish fillet, which is protective of the average angler, or CTE individual, who consumes one half-pound meal every two months. These targets were developed as milestones to assess the recovery of fish in the UHR and are not the overall project goal of 0.05 mg/kg, or one fish meal per week for an adult. It was also anticipated that the targets would be achieved in fish in different areas of the river at different times during the recovery.

2.3 Evaluation of Human Health Risks for Question B for the Third FYR

"Are the exposure assumptions, toxicity data, cleanup levels, and remedial action objectives (RAOs) used at the time of the remedy selection still valid?"

The following sections address the current validity of the exposure assumptions, toxicity information, cleanup levels, and RAOs for the Site. The RAOs and cleanup levels are discussed in the first section, and for each OU separately.

2.3.1 Ongoing Validity of the RAOs and Cleanup Levels for OU1 and OU2

The validity of the RAOs and cleanup levels for OU1 and OU2 are still valid and appropriate for the Site as discussed below.

Remnant Deposits (OU1)

When the remedy for the Remnant Deposits was selected in the 1984 ROD, guidance on risk assessment was in its early development at EPA, as a result, a risk assessment was not conducted. The selected remedy included an in-place cover system, perimeter fencing, and signage. The OU1 remedy was completed in 1991 covering soil/sediment with PCB concentrations greater than 5 mg/kg, long-term monitoring of the cap is ongoing, and repairs are conducted as needed.

The cap system on the Remnant Deposits prevents human exposure to the capped sediments, and perimeter fencing limits human access to the deposits. There have been no changes in the physical conditions of Remnant Deposits 2 through 5 that would change the protectiveness of the current capping remedy. The Remnant Deposits are inspected semiannually to identify and address any issues (i.e., maintenance of the vegetative cover, access roadways, diversion ditches, culverts, vent pipes, and Site security).

The cleanup value of 5 mg/kg at the Remnant Deposits was not based on a risk assessment therefore it is not possible to evaluate if the exposure assumption and toxicity values are still applicable. However, any soils contaminated with PCBs that remain outside the capping system in the low-lying areas near the river are being evaluated under the floodplain Remedial Investigation and Feasibility Study (RI/FS) being done as OU4 of the Site to determine if there is an increased risk to human health and if any further work is necessary in these areas. Given the overall status of the Remnant Deposits and that all non-covered PCB soils will be assessed under OU4, the 5 mg/kg threshold remains appropriate.

Cleanup Levels for In-River Sediments (OU2)

OU2 consists of the in-river sediments in the UHR. This 40-mile section of river is immediately downstream of OU1 and runs from Fort Edward, NY to Waterford, NY. The 2002 ROD selected targeted environmental dredging to address PCB-contaminated sediment in the UHR, as well as MNR of PCB contamination that remains in the river after dredging. Dredging occurred between 2009 and 2015 which removed 2.63 million cubic yards of sediment which were dewatered and transported by rail for disposal. Long-term monitoring is being conducted to track the recovery of the river over time.

There have been no changes in the physical condition of the Site since the second FYR that would change exposure or toxicity assumptions for the Site. The cleanup goal for the Hudson River of 0.05 mg/kg in edible fish tissue that was developed as the RAO for the Site (as described in the prior section) remains protective of human health since there have been no significant changes to the toxicity and exposure assumptions used in the original risk assessment, as described further below. Monitoring of PCB concentrations in fish continues and catch and release fishing restrictions are in place for the UHR to reduce human exposure to fish tissue until the cleanup goal for fish tissue is achieved. It is illegal to possess a fish from the UHR area.

2.3.2 Ongoing Validity of Exposure Assumptions and Toxicity Data

Exposure Assessment

Since the Revised HHRA was completed, exposure assumptions were updated with the release of the 2014 OSWER Directive No. 9200.1-120 (Human Health Evaluation Manual, Supplemental

Guidance: Update of Standard Default Exposure Factors [EPA, 2014]). Updates include changes in exposure assumptions for body weight for the adult, skin surface area for the adult and child, drinking water ingestion rate for the young child and adult, and other parameters. These updates do not change the conclusions of the risk assessment (EPA, 2000b) or the protectiveness of the fish tissue cleanup level concentrations in the RAO because the changes are small enough that they do not materially alter the conclusions of the HHRA.

The exposure duration was based in part on population mobility data from the U.S. Census Bureau for the five counties surrounding the UHR and fishing duration data from the 1991 New York Angler survey (Connelly et al., 1992) for this area to determine the length of time an angler fishes in the UHR.

Chapter 11 of the Exposure Factors Handbook regarding fish consumption was updated in 2011 but the modifications do not affect the fish consumption rates in the HHRA (EPA, 2011). The fish ingestion rate used in the Revised HHRA represented a Site-specific ingestion rate for UHR anglers. This rate is consistent with the 2011 Exposure Factors Handbook (EPA, 2011) recommendation to use Site-specific information to develop ingestion rates. Chapter 10 of the Exposure Factors Handbook regarding fish consumption has not been updated since the second FYR.

The fish ingestion rate used in the Revised HHRA represented the amount of fish an individual consumes on average within the year, annualized such that it is expressed in grams of fish per day (g/day) of fish consumed. UHR anglers are defined as all individuals who would consume self-caught fish from the UHR at least once per year in the absence of fish consumption advisories. The population in question therefore includes a range of infrequent to frequent anglers, who may fish for sport (recreational) or as a food source. Based on a review of the available literature and consideration of a number of scientific issues relevant to fish ingestion rates, a probability distribution of fish consumption rates was determined using data from the 1991 New York Angler survey (Connelly et al., 1992) to represent UHR anglers. The Revised HHRA (Chapter 2, Section 2.4.1 and Chapter 3, Section 3.2.1) provides a detailed analysis of the evaluation of fish ingestion rates. There are no known newer studies of fish consumption that call for the development of a fish ingestion rate that would change the overall conclusions of the HHRA.

Exposure to PCBs in fish continues to be the exposure pathway of concern, with fish tissue concentrations remaining above the ROD remedial goal of 0.05 mg/kg. Therefore, fishing restrictions (as described further below) remain appropriate to limit exposure.

Status of Fish Advisories

With respect to the fish consumption advisories, the New York State Department of Health (NYSDOH) continues to reach out using a community-based approach to both people who fish the Hudson River and their family members. Appendix 8 provides a summary of the NYSDOH outreach and other activities conducted since the time of the second FYR. NYSDOH continues to work with its partners to inform anglers along the 200-mile Site of the fishing advisories and restrictions. NYSDOH's partners include recreational fishing associations, marina and boating community representatives, nutrition educators, neighborhood associations and community group leaders, food pantry and community food networks, environmental justice advocates, environmental educators and non-profits, immigrant support networks, local health and municipal officials, environmental conservation officials, parks and recreation officials, health care provider representatives, housing authorities and schools and youth programs. Connecting at the local level, these partners work with NYSDOH to promote awareness of the health advice, help NYSDOH learn more about who is eating fish from the UHR, and develop educational tools and outreach activities. Grantees work in a variety of settings, from fishing locations on the river to nutrition programs, clinic waiting rooms, community events, food pantries, and programs with students and youth groups. The 2017 Summary of the Outreach activities is provided at: https://www.health.ny.gov/environmental/outdoors/fish/hudson_river/docs/2017_hrfa_update.pdf (NYSDOH, 2017).

As addressed in Appendix 8, EPA will continue to work with NYSDOH to improve awareness of fish advisories for the Hudson River and share information on NYSDOH's work within the community. NYSDOH and EPA's outreach activities related to the fish consumption advisories for the Lower Hudson River and restrictions for the UHR for the Site are funded by the responsible party – General Electric Company. That funding is expected to continue into the foreseeable future.

Status of Toxicity Information

OSWER Directive 9285.7-53 (EPA, 2003) outlines a process for selecting toxicity values for use in an HHRA. The directive provides a hierarchy of human health toxicity values generally recommended for use in risk assessments under the Superfund program. EPA followed this toxicity hierarchy in evaluating potential changes in toxicity values.

- The IRIS cancer toxicity information used in the HHRA meets the Tier I toxicity criteria for the Superfund program (EPA, 2000b). The IRIS chemical file identifies PCBs as a probable human carcinogen (B2 classification). Superfund guidance states that chemicals classified as known, probable or possible human carcinogens are all evaluated for carcinogenic risk when a Cancer Slope Factor (CSF) necessary to calculate cancer risk is available. PCBs for this Site were evaluated for carcinogenic risk as per this guidance. The IRIS Agenda that lists chemicals being assessed under the IRIS Program does not currently identify plans to update cancer toxicity values for PCBs.
- The non-cancer toxicity values used in the HHRA were also obtained from IRIS. At the current time, the IRIS Agenda identifies the non-cancer toxicity values for PCBs as being scheduled for an update. The schedule for those updates is not available at this time. The

update will evaluate systemic toxicity (e.g., non-cancer health effects) including the evaluation of oral RfDs and inhalation Reference Concentrations (RfC).

- In March 2015, EPA invited the public to provide input and participate in discussions about problem formulation, preliminary assessment materials, and draft IRIS assessments for PCBs. During problem formulation, the IRIS Program was looking for input from the scientific community and the general public as it framed the specific scientific issues that were the focus of the update to the systematic review of potential health hazards of PCBs (effects other than cancer).
- EPA subsequently released the Systematic Review Protocol For The Polychlorinated Biphenyls (PCBs) Noncancer IRIS Assessment (Preliminary Assessment Materials) (Report) for public review and comment (EPA, 2019b). . The IRIS Program Outlook website indicates that the release of the public comment draft of the revised assessment is planned for Fiscal Year 2024 with external review anticipated in Fiscal Year 2025.
- Currently, the IRIS webpage identifies PCBs as Step 1 in the update process. IRIS Program updates for PCBs and other chemicals are available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=309645 (EPA, 2019c). Any changes in the IRIS non-cancer toxicity values will be evaluated in the next FYR, as available.

PCBs were synthesized as mixtures of congeners into commercial mixtures known as Aroclors, and the composition of commercially produced PCB mixtures can vary from mixtures humans are currently exposed to in the environment. Most health effect studies of PCBs in animals have been conducted using commercial mixtures, typically Aroclors. Therefore, EPA is evaluating methods to compare environmental mixtures to the standard Aroclor mixtures to determine the degree to which the mixtures are similar in their ability to cause health effects and whether they are "sufficiently similar" for risk assessment applications. These methods are not yet part of the risk assessment process and are still under development and review through the IRIS Program's update of non-cancer toxicity values for PCBs. EPA will continue to track the development of these tools including non-cancer toxicity values and evaluate their use for the Hudson River.

Dioxin-like PCBs

The toxicity information for dioxin-like congeners is based on TEFs. TEFs are unitless factors that are applied to the concentrations of dioxin-like compounds so that the concentrations of these chemicals can then be used along with the 2,3,7,8-TCDD toxicity values. EPA has set a CSF of 150,000 $(mg/kg\text{-}day)^{-1}$ for 2,3,7,8-TCDD, based on liver and respiratory tumors in chronically exposed rates (EPA, 1997a, based on the cancer assessment in EPA, 1996). An oral RfD for non-cancer was posted on the IRIS database in 2012 and is discussed below (EPA, 2012).

To calculate the risk associated with dioxin-like PCBs the fraction of dioxin-like PCBs in the fish sample must be known. The Revised HHRA utilized the Phase 2 fish data from the UHR to determine the proportion of each dioxin-like PCB. The fractions of each dioxin-like PCB utilized for the HHRA were compared to congener fish data from the post-dredging period (2018 to 2021) to determine if the fraction of dioxin-like PCBs has changed since the HHRA was completed. This review established that there was not a substantial shift in the fraction of dioxin-like PCBs. These new fractions were used to confirm that they would not impact the calculation.

The Revised HHRA evaluated dioxin-like PCBs for increased cancer risks. As discussed in the first FYR, the TEFs for dioxin-like PCBs were updated in 2010 (EPA, 2010). A comparison of the results from the Revised HHRA with those calculated with the revised TEFs for the dioxin-like PCBs (and the post-dredging data) show that cancer risks associated with the dioxin-like PCBs are still comparable to those for Total PCBs, indicating the dioxin-like PCBs do not enhance the risks from Total PCB exposure (EPA, 1996).

Non-cancer risks associated with dioxin-like PCBs were not evaluated as part of the Revised HHRA because an appropriate non-cancer toxicity value was not available. However, the IRIS Program issued a non-cancer toxicity value for 2,3,7,8-TCDD in 2012 with the updated TEFs; therefore, non-cancer risks were also evaluated in the first FYR based on the approach used in the Revised HHRA (EPA, 2012). The RfD derived for TCDD was 7×10^{-10} mg/kg-day. Separate calculations of non-cancer hazards for dioxin-like PCBs were performed as summarized in the second FYR Report (EPA, 2019). A comparison of the non-cancer hazards calculated for PCBs in the original risk assessment in 2000 with those calculated with the new 2,3,7,8-TCDD RfD and the revised TEFs for the dioxin-like PCBs (as well as the post-dredging data) show that RME non-cancer hazards associated with the dioxin-like PCBs are comparable to or lower than those from Total PCBs, indicating the dioxin-like PCBs do not enhance the risks from Total PCB exposure (EPA, 1996).

Dioxin is not listed on the IRIS Agenda for update. In addition, the EPA Risk Assessment Forum’s (RAF) dioxin TEF document titled “Recommended Toxicity Equivalence Factors (TEFs) for HHRA of 2,3,7,8-Tetrachlorodibenzo-p-dioxin and Dioxin-Like Compounds” was last updated in 2010 (EPA, 2010). EPA will evaluate if updates to the TEFs are necessary and any updates will be addressed in the next FYR.

3 ECOLOGICAL RISK ASSESSMENT

This section provides an overview of the Baseline Ecological Risk Assessment (BERA) conducted for the Site and its conclusions.

3.1 Summary of Ecological Risk Determination for OU1

When the remedy for OU1 was selected in the 1984 ROD, guidance on the development of a risk assessment was in early development at EPA. As a result, a risk assessment was not conducted. The cap system is protective of ecological receptors as it prevents direct exposure to PCBs in those areas. Any areas that are not covered by the cap system are being evaluated as part of the Floodplain RI/FS – OU4.

3.2 Summary of BERA Conducted for 2002 ROD

EPA issued a Revised BERA in November 2000 that addressed peer-review comments received on the 1999 draft document. The Revised BERA evaluated multiple assessment endpoints across several trophic levels of the Hudson River aquatic environment, and consistent with the HHRA, PCBs were the only contaminant group identified as a potential concern. The results of the Revised BERA supported EPA's decision in the 2002 ROD that remedial action was necessary to reduce unacceptable risks to ecological receptors and establish RAOs for the protection of ecological receptors. The principal components of the Revised BERA and relevant RAOs are summarized below. This summary includes an evaluation of the ecological exposure assumptions and toxicity data used in the Revised BERA and the development of ecological remediation goals.

3.2.1 Revised BERA

The Revised BERA consisted of the following four components: problem formulation, exposure assessment, toxicity assessment, and risk characterization. Each is briefly described in the following sections.

Problem Formulation

The Revised BERA evaluated current and future ecological risks in the UHR. Ecological receptors considered included animals and plants living in or near the river, such as invertebrates, fish, amphibians, water-dependent reptiles, birds, and mammals, which could be exposed to PCBs directly and/or indirectly through the aquatic food web. Receptors were selected to be representative of various feeding preferences, predatory levels, and habitats (aquatic, wetland, shoreline). Receptors of concern included the benthic macroinvertebrate community, fish (seven species), aquatic-dependent birds (five species), and mammals (four species). A number of federal and state-listed threatened and endangered animal and plant species are known or could utilize

Hudson River habitats and the Revised BERA selected the bald eagle (*Haliaeetus leucocephalus*) to quantify exposures and risks to top trophic-level piscivorous bird species.

Assessment endpoints included benthic community structure (aquatic benthos are a key food source for local fish and wildlife), which is a food source for local fish and wildlife, sustainability (survival, growth, and reproduction) of local forage fish populations, local piscivorous fish populations and local omnivorous fish populations, and protection (survival and reproduction) of insectivorous bird and mammal populations, waterfowl populations, piscivorous bird and mammal populations and omnivorous mammal populations. Various information including literature dose-response data, Site-specific analytical results for surface water, sediment and biological tissue, exposure models, and available field surveys were used to evaluate the assessment endpoints. Because PCBs bioaccumulate in the environment through bioconcentration and biomagnification processes, the Revised BERA emphasized indirect exposure at various levels of the food chain to address PCB-related risks at higher trophic levels.

Exposure Assessment

Complete exposure pathways and exposure parameters (e.g., body weight, prey ingestion rate, home range) used to calculate the concentrations or dietary doses to which the receptors of concern could be exposed to were obtained from EPA references, scientific literature, and directly from researchers. Contaminant fate and ecological exposure models (HUDTOX and FISHRAND) utilized analytical data for PCBs in river surface water, sediments, and biological tissues to estimate receptor exposures by representative wildlife species.

Effects Assessment

The risk assessment limited its focus to adverse impacts on survival, growth, and reproduction. The ecological effects assessment includes literature reviews, field studies, and toxicity tests that correlate concentrations of PCBs to effects on ecological receptors. Toxicity Reference Values (TRVs) were selected based on Lowest Observed Adverse Effects Levels (LOAELs) and/or No Observed Adverse Effects Levels (NOAELs) from laboratory and/or field-based studies reported in the scientific literature. These TRVs reflect the effects of PCBs and dioxin-like PCB congeners on the survival, growth, and reproduction of fish and wildlife species in the Hudson River. Reproductive effects (e.g., egg maturation, egg hatchability, and survival of juveniles) were generally the most sensitive endpoints for animals exposed to PCBs.

Risk Characterization

The risk characterization indicated that receptors in close contact with the UHR were above EPA's level of concern as a result of exposure to PCBs.

The Revised BERA concluded that birds and mammals that consume PCB-contaminated fish from the Hudson River, such as the bald eagle, belted kingfisher, great blue heron, mink, and river otter were at risk at the population level. PCBs may adversely affect the survival, growth, and reproduction of these species. Piscivorous mammals, represented by the river otter, were determined to be at greatest risk due to their trophic status and the predominance of fish in their diets. The risks to fish and wildlife were greatest in the UHR (in particular, the Thompson Island Pool) and decreased in relation to PCB concentrations downriver. Fragile populations of threatened and endangered species, represented by the bald eagle, are particularly susceptible to adverse effects from PCB exposure. Piscivorous fish (largemouth and striped bass) and birds and mammals that feed on emerging insects were also at risk.

PCB concentrations in water and sediments in the UHR generally exceeded standards, criteria and guidelines established to be protective of the environment. The Revised BERA concluded that other receptors including forage fish and waterfowl (other than species that predominately feed on fish) were unlikely to be affected outside the Thompson Island Pool.

3.2.2 RAOs

RAOs and cleanup levels were derived from the Site-specific risk assessment (EPA, 2000a) and were based on the most significant exposure pathway (i.e., fish consumption) and sensitive receptors (i.e., piscivorous mammals) as determined in the Revised BERA. The primary RAO applicable to ecological risk is to reduce the risks to ecological receptors by reducing the concentration of PCBs in fish.

The risk-based RAO for the ecological exposure pathway presented in the ROD is a range from 0.3 to 0.03 mg/kg PCBs in fish (largemouth bass, whole body), based on the LOAEL and the NOAEL TRVs for consumption of fish by the river otter. In addition, a range of 0.7 to 0.07 mg/kg PCBs in spottail shiner (whole fish) was developed in the ROD based on the LOAEL and NOAEL TRVs for the mink, a species known to be sensitive to PCBs. This remedial goal was considered protective of all the ecological receptors evaluated because mammalian wildlife that consume primarily fish (e.g., river otter and mink) were determined to be at greatest risk from PCBs at the Site.

3.3 Evaluation of Ecological Risks for Question B of the Third FYR

"*Are the exposure assumptions, toxicity data, cleanup levels, and remedial action objectives (RAOs) used at the time of the remedy selection still valid?*"

The second FYR evaluated the validity of exposure assumptions, toxicity information, and ecological remediation goals for the Site. As documented in the second FYR Report, updated exposure factors were derived from a comprehensive literature search and review of field and laboratory studies that cite body weights, ingestion rates, and home range sizes for adult mink and river otters (EPA, 2019). For this FYR, a literature review was conducted, and it was determined that no new relevant literature (including PCB toxicity information for mink or river otter) has been published since the last FYR.

3.3.1 Exposure Parameters and Toxicity Data

During the preparation of the second FYR Report (EPA, 2019), The EPA Team conducted a comprehensive literature review of information available at the time pertaining to the exposure factors and toxicity data used in the Revised BERA. The literature review concluded that river otter and mink are still appropriately sensitive receptors for evaluating risks associated with PCBs, and therefore the review focused on updates to parameters used in estimating risks to the river otter and mink. This review, which was summarized in the previous FYR (EPA, 2019), included evaluating and updating the following exposure parameters for the piscivorous mammals: body weight (BW), daily water ingestion rate (WIR), daily sediment ingestion rate (SIR), daily food ingestion rate (FIR) and home range. EPA also reviewed additional relevant toxicity data for the effects of PCBs on wildlife and updated the toxicity data used in the Revised BERA. Finally, EPA determined that the methodology used in the Revised BERA to estimate ecological risk was still current.

No substantial change was identified regarding BWs, FIRs, WIRs, SIRs, or home ranges during the second FYR. Therefore, as concluded in that assessment, the exposure assumptions supporting the RAO for ecological protection remained valid. While the review was limited to piscivorous mammalian receptors, no new information has become known that would change the assumption that this trophic level remains the most sensitive to PCBs in the UHR and that remediation goals protective of them would also be protective of other ecological receptors.

The following is a summary of the exposure parameters used for the BERA and updated values based on the literature review from the second FYR that are still applicable for this review since no new literature was identified. Updated exposure parameters were derived from a comprehensive literature search and review of field and laboratory studies that cite body weights, ingestion rates, and home range sizes for adult mink and river otters. The field studies were from various states and regions within the United States.

Body Weight (kg): The body weights for mink and river otter used in the Revised BERA were derived from the 1993 Wildlife Exposure Factors Handbook (EPA, 1993), consultation with personnel from the New York Museum, and a river otter reintroduction study conducted by the NYSDEC. In addition, body weights for historic specimens collected from the Hudson River Valley Region were compared with the ranges cited in EPA (1993) to determine whether region-specific body weights fell within traditional ranges for each species.

The updated body weight used by EPA for female mink (0.816 kg) was revised slightly (1.7 percent) lower than the value used in the Revised BERA (0.83 kg). The updated body weight for female otters used by EPA was 5 percent higher than the value used in the Revised BERA (7.72 kg versus 7.32 kg). For the mink, the use of a lower body weight resulted in a slightly higher calculated ADD, and slightly higher calculated Hazard Quotients (HQs). The use of a higher body weight for otter resulted in a lower calculated ADD and HQ.

Food Ingestion Rate, kg/day wet-weight: The ww FIRs for mink used in the Revised BERA to estimate exposure to PCBs in piscivorous mammal fish prey came from Bleavins and Aulerich (1981). For mink, in the second FYR, EPA reviewed 10 laboratory studies that reported daily food consumption rates, and six laboratory studies or animal care guidelines were reviewed to estimate daily food consumption for river otters.

The ww FIR for female mink (0.233 kilograms per day [kg/day]) was substantially (43 percent) higher than the value used in the Revised BERA (0.132 kg/day). The ww FIR for female otters was 31 percent higher than the value used in the Revised BERA (1.31 versus 0.9 kg/day, respectively). For both species, the use of a higher ww FIR resulted in a higher ADD and HQ. For mink, the calculated HQs using updated ww FIR was almost twice as high as the HQs from the Revised BERA.

Water Ingestion Rates (WIR): The WIRs used for mink and otter in the Revised BERA and for otter in the second FYR were calculated using the allometric equation for mammals developed by Calder and Braun (1983).

Because the updated female river otter body weight is slightly higher than the body weight used in the Revised BERA, the updated calculated WIR for otters (0.62 liters per day [L/day]) was slightly (4 percent) higher than the WIR used in the Revised BERA (0.59 L/day).

In the second FYR, EPA selected WIRs measured in two laboratory studies for mink. The WIR used in the Revised BERA (0.084 L/day) is 21 percent higher than the updated WIR, and results in a higher ADD. However, water ingestion, especially for a highly hydrophobic contaminant class such as PCBs, has only a very small impact on risk estimates for both receptors and a negligible effect on the calculated HQ.

Sediment Ingestion Rates (SIR): Measured SIRs have not been reported for either mink or otter. The Revised BERA assumed a SIR of 1 percent of the FIR for both mink and river otter. Because sediment concentrations are typically reported on a dry-weight (dw) basis, the SIR was calculated using the dw FIR (0.00059 and 0.00353 kg sediment dw/day for the mink and otter, respectively).

In the second FYR, EPA calculated a SIR based on the amount of sediment entrained in a fish multiplied by the receptor species FIR. For mink and otter, the estimated SIRs are 0.00012 and 0.00055 kg dw/day, respectively.

The SIR used in the Revised BERA for mink is 80 percent greater than the updated EPA SIR estimate, and the SIR used for river otter is 84 percent greater than the updated EPA estimate. Use of a higher SIR in the Revised BERA results in a higher ADD and calculated HQ, resulting in a more conservative estimate of risk relative to the estimates that would result from using the updated SIRs.

Home Range: The Revised BERA reported home range sizes for both species in units of kilometers (km) of stream length. In the second FYR, EPA summarized home range sizes from nine studies for mink and eight studies for otter in units of area (square kilometers) and from three studies for mink and eight studies for otter in km stream length. The updated EPA home range value for mink, reported in units of stream length, is 35 percent higher than the value in the Revised BERA (2.93 versus 1.9 km, respectively), while the updated EPA home range value for river otter (19.7 km) is almost twice as large as the Revised BERA value (10 km).

The differences in home range sizes had no effect on risk calculations, as an area use factor of 1 (continuous spatial exposure) was used in risk calculations for both species.

Toxicity Data: The toxicity data that were used in the Revised BERA were evaluated to determine if they were still the most appropriate (EPA, 2019). As mentioned above, the review focused on available mink and otter toxicity data as no new information is available to change the assumption that piscivorous mammals remain the most sensitive ecological receptors in the Hudson River.

The Revised BERA toxicity data for the mink and river otter were compared to literature values that are currently used for evaluating exposure to mink and river otter. The LOAEL TRV of 0.04 mg/kg-BW/day used in the Revised BERA was from Restum et al. (1998). EPA used a LOAEL TRV of 0.033 mg/kg-BW/day reported in a more recent study (Bursian et al., 2013). The use of a lower TRV resulted in a higher risk estimate for a given exposure level.

EPA evaluated the relationship between LOAELs and NOAELs reported in studies that reported both values. Sixteen studies were reviewed to derive the TRV used in the mink dietary exposure calculations. Two of the studies reported measured LOAELs and NOAELs, whereas the remaining 14 studies estimated the NOAEL by using an extrapolation factor of 10. The ratios of the LOAEL to NOAEL in the two studies reporting measured toxicity values indicated a 2.1- to 2.4-fold difference compared to the higher 10-fold difference that was used as a conservative default ratio when estimating a NOAEL in the Revised BERA. This suggested that a factor of 3 was a more appropriate basis for estimating the NOAEL rather than the 10-fold factor originally assumed.

In summary, EPA's review of recent toxicity data would result in LOAEL and NOAEL toxicity values of 0.04 and 0.004 mg/kg-BW/day to 0.033 and 0.011 mg/kg-BW/day, respectively.

3.3.2 RAOs for Ecological Receptors

The supplemental evaluation conducted to support the second FYR corroborated the Revised BERA conclusion that higher trophic level piscivorous mammals were at risk, which is in accordance with expectations for highly bioaccumulative contaminants such as PCBs in aquatic food webs. In addition, there are no known substantive changes to the ecology, aquatic food web, or exposed species in the Upper Hudson as represented in the Revised BERA. Consequently, the RAO to reduce the risks to ecological receptors by reducing the concentration of PCBs in whole fish tissue is still valid.

3.3.3 Remedial Goals

Using the updated exposure parameters and toxicity values presented above, the risk-based remedial goal range for the otter and risk-based concentration range for the mink that were developed for the 2002 ROD were recalculated in the second FYR. As reported in the second FYR, the recalculated risk-based concentration range for largemouth bass consumed by the river otter is 0.2 to 0.07 mg/kg PCBs in fish compared to 0.3 to 0.03 mg/kg PCBs in fish, as reported in the ROD. The recalculated risk-based concentration range for spottail shiner consumed by the mink is 0.34 to 0.11 mg/kg PCBs in fish compared with 0.7 to 0.07 mg/kg PCBs in fish in the Revised BERA. Thus, refinement of the toxicity values and exposure factors resulted in risk-based ranges of PCBs in largemouth bass and spottail shiner that are less uncertain and bring into better focus the ranges of PCBs in fish expected to be protective of the ecological exposure pathway. The lower bounds of the updated ranges are not lower than the lower bounds for both ranges identified in the ROD, and the refinement of toxicity values and recalculation of the ecological remedial goal range for the river otter and risk-based concentration range for the mink do not affect the protectiveness determination of the selected remedy with respect to ecological receptors.

4 ABBREVIATIONS AND ACRONYMS

ADD	Average Daily Dose
BERA	Baseline Ecological Risk Assessment
BW	Body weight
COC	Contaminant of Concern
CSF	Cancer Slope Factor
CTE	Central Tendency Exposure
DDT	Dichlorodiphenyltrichloroethane
dw	dry-weight
EPA	U.S. Environmental Protection Agency
EPC	Exposure point concentration
FIR	Food Ingestion Rate
FYR	Five-Year Review
g/day	grams per day
kg/day	kilograms per day
km	kilometers
HHRA	Human Health Risk Assessment
HI	Hazard Index
HQ	Hazard Quotient
IPCS	International Program on Chemical Safety
IRIS	Integrated Risk Information System
L/day	liters per day
LOAEL	Lowest Observed Adverse Effect Level
MCA	Monte Carlo Analysis
mg/kg	milligram per kilogram
MNR	Monitored Natural Recovery
NCP	National Contingency Plan
NOAEL	No Observed Adverse Effects Levels
NYSDEC	New York State Department of Environmental Conservation
NYSDOH	New York State Department of Health

OLEM	Office of Land and Emergency Management (formerly OSWER)
OSWER	Office of Solid Waste and Emergency Response (now OLEM).
OU	Operable Unit
PAH	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
PRA	Probabilistic Risk Analysis
RAF	Risk Assessment Forum
RAO	Remedial Action Objectives
RfC	Reference Concentration
RfD	Reference Dose
RI/FS	Remedial Investigation and Feasibility Study
RME	Reasonable Maximum Exposure
ROD	Record of Decision
SIR	Sediment Ingestion Rate
Site	Hudson River PCB Superfund Site
TCDD	2,3,7,8-tetrachlorodibenzo-*p*-dioxin
TEF	Toxicity Equivalency Factors
TEQ	Toxicity Equivalent Quotient
Tri+ PCB	Sum of all measured PCB congeners with three or more chlorine atoms per molecule.
TRV	Toxicity Reference Values
UHR	Upper Hudson River
WHO	World Health Organization
WIR	Water Ingestion Rate
ww	wet-weight

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