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

APPENDIX 11

HUMAN HEALTH AND ECOLOGICAL RISKS

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April 2019

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The human health and ecological risk assessments conducted for the 2002 Record of Decision (ROD) for the Hudson River PCBs Superfund Site (Site) were evaluated for this five-year review to determine if the assumptions and data used in the original assessments were still appropriate. This appendix discusses the evaluations and results that are included in this Second Five-Year Review Report.

1 HUMAN HEALTH RISKS

1.1 Summary of Human Health Risk Assessment Supporting the 2002 ROD

Following a peer-review of its 1999 Human Health Risk Assessment (HHRA) for the Site, in November 2000 the United States Environmental Protection Agency (EPA) issued a Revised HHRA. The revised HHRA addressed peer-review comments. The November 2000 HHRA evaluated both cancer risks and non-cancer health hazards to young children, adolescents and adults posed by PCBs in the Upper and Mid-Hudson River. Polychlorinated Biphenyls (PCBs) were identified as the only chemical of concern (COC) for the Site.

Risk Conclusions for Upper Hudson – Deterministic Assessment Results

The 2000 HHRA found that ingestion of fish contaminated with PCBs resulted in the highest lifetime cancer risks. The cancer risks and non-cancer hazards that served as the basis for the decision were based on the Reasonable Maximum Exposure (RME). 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, exposure duration, etc.). 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 2000 HHRA, is 1x 10^{-3}, or one in 1,000. The total cancer risk of 1 x 10^{-3} is composed of risks to the adult (6 x 10^{-4} or six in 10,000), to the adolescent (4 x 10^{-4} or four in 10,000), and to the young child (4 x 10^{-4} or four in ten thousand). The cancer risks to the RME individual exceed the risk range established under the National Contingency Plan (NCP) of 1 x 10^{-6} to 1 x 10^{-4} (one in a million to one in ten thousand). Consistent with the 1996 document "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures" (EPA, 1996), RME cancer risks associated with the dioxin-like PCBs were evaluated and found to be comparable to those from total non-dioxin like PCBs.

EPA's evaluation of non-cancer health effects in the 2000 HHRA (EPA 2000e) involved comparing the average daily exposure levels (dose) to determine whether the estimated exposures exceed the Reference Dose (RfD). The ratio of the site-specific calculated dose to the RfD for each exposure pathway and receptor age group were summed to calculate the Hazard Index (HI) for the exposed individual. An HI of 1 is the reference level established by EPA above which concerns relating to noncancer 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 generally 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} and a calculation of noncancer 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 = 1.

Risk Conclusions for Mid-Hudson River

Ingestion of fish contaminated with PCBs resulted in the highest lifetime cancer risks. Consistent with the approach used in the Upper Hudson described above, the cancer risk was 7×10^{-4}, or 7 in 10,000 increased risk of developing cancer. The RME cancer risks associated with the dioxin-like PCBs are comparable. The total cancer risk of 7×10^{-4} is comprised of risks to the adult (3×10^{-4} or three in 10,000); to the adolescent (2×10^{-4} or two in 10,000); and the risk to the young child (2×10^{-4} or two in ten thousand). The cancer risks to the RME individual exceed the risk range established under the NCP of 1×10^{-6} to 1×10^{-4}. Consistent with the 1996 *Reassessment of the Carcinogenicity of PCBs*, RME cancer risks associated with the dioxin-like PCBs were evaluated and found to be comparable to those from total PCBs (EPA 1996).

The evaluation of noncancer health effects followed the same process as that for the Upper Hudson. An HI of one (1) is the reference level above which concerns relating to noncancer health effects must be evaluated. Ingestion of fish resulted in the highest HI values. The RME HI was 53, 37, and 34, for the young child, adolescent, and adult, respectively.

Estimated deterministic RME and central tendency cancer risks relating to PCB exposure in sediment and water while swimming or wading, or from inhalation of volatilized PCBs in air by residents living near the river in the Mid-Hudson were not evaluated due to low PCB concentrations present in the Mid-Hudson River.

Toxicity Assessment

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

- 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 including a reduced ability to fight infections (Aroclor 1254) and reduced birth weights (Aroclor 1016)

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 the files were developed.

Exposure Assessment

The 1991 New York Angler survey (Connelly et al., 1992) was selected as the primary source of information for the deterministic and Monte Carlo exposure analysis of the fish ingestion pathways probabilistic analysis (PRA) for the Upper Hudson River anglers because the climate and characteristics of other New York waterbodies are more likely to be similar to the Upper Hudson River than other non-New York surveys that were evaluated in the HHRA. Further reasoning for selecting the New York Angler survey is the fact that it reasonably matches the demographics of the Upper Hudson angler population that was surveyed in an independent study (Barclay 1993). 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). Upper Hudson River anglers were defined as all individuals who would consume self-caught fish from the Upper Hudson River at least once per year in the absence of fish consumption advisories. Only non-zero ingestion rates were included in the analysis (42.7% of the responses indicated the anglers did not consume the fish they caught). The deterministic risk assessment used an ingestion rate of 31.9 grams/day representing the 90th percentile ingestion rate from the Connelly et al. 1992 study with appropriate adjustments for adolescents and young children. The entire distribution of fish ingestion rates was used in the Monte Carlo Analysis (MCA, described below) to represent variability of fish consumption patterns among the angler population.

Exposure assumptions for exposure duration included an evaluation of population mobility data from the U.S. Census Bureau for the five counties surrounding the Upper Hudson River and fishing duration data from the 1991 the New York Angler survey to determine the length of time an angler fishes in the Upper Hudson River (*i.e.*, exposure duration). Standard EPA default factors at the time of the HHRA were used for angler body weight. Future concentrations of PCBs in fish were derived from forecasts which were then grouped by fish species and averaged over species for the entire Upper Hudson River, and a separate evaluation was conducted for the Mid-Hudson. Other exposure assumptions were obtained from the EPA Standard Default Exposure Assumptions applicable at the time (EPA, 1989a, b) and the 1997 Exposure Factors Handbook (EPA, 1997d) or professional judgment where appropriate.

Monte Carlo Analysis

In addition to the “deterministic” risk assessment discussed above, a Monte Carlo or probabilistic assessment was conducted pursuant to the Agency’s guidance on PRA for risk assessment (EPA, 1997c). 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 noncancer health hazards. The MCA included a distribution of cancer risks and noncancer health hazards for the fish ingestion pathway. The MCA was specific to the exposure assessment portion of the HHRA.

The Monte Carlo base case scenario is the one from which point estimate exposure factors for fish ingestion used in the deterministic HHRA were drawn. Thus, the point estimate RMEs and the Monte Carlo base case estimates can be compared. Similarly, the point estimate central tendency (average) and the Monte Carlo base case midpoint (50th percentile) are comparable. For cancer risk, the point estimate RME for fish ingestion (1×10^{-3}) falls approximately at the 95th percentile from the Monte Carlo base case analysis. The point estimate central tendency value (3×10^{-5}) and the Monte Carlo base case 50th percentile value (6×10^{-5}) are similar. For noncancer health hazards, the point estimate RME for fish ingestion (104 for young child) falls between the 95th and 99th percentiles of the Monte Carlo base case. The point estimate central tendency HI (12 for young child) is approximately equal to the 50th percentile of the Monte Carlo base case HI of 11. That the deterministic and Monte Carlo risk estimates were closely aligned provided additional confidence in the deterministic risk results used to support the remedy decision.

1.2 Evaluation of Human Health Risks for Question B for the Second Five-Year Review

Remnant Deposits (OU1)

There have been no changes in the physical conditions of Remnant Deposits 2 through 5 that would change the protectiveness of the remedy. The cap system on the Remnant Deposits prevents exposure to the capped sediments, and perimeter fencing prevents access to the sites. Posted signage provides an additional barrier to exposure. The Remnant Deposits have limited access based on location in addition to perimeter fencing. The ongoing procedures to inspect and re-establish the fencing where appropriate should continue as a barrier to exposure.

The Town of Moreau is considering whether to construct a passive park (i.e., a park that would use portions of Remnant Deposit sites 2 and/or 4). Likely use would consist of passive recreation activities such as hiking and cycling over the area. Details of the passive use and any additional design measures on the OU1 area would need to be developed in close consultation between EPA, New York State (NYS), and the parcel owners. Consideration would need to be given to the fences (i.e. institutional control [IC]) on the area that limit use of the area. If the fences are modified in the development of passive use of the parcel, additional engineering controls may be necessary. As noted above, the IC needs be maintained to ensure that future use of the Remnant Deposits does not compromise the integrity of the cap system or result in unsafe exposures.

In 1984, when the Remnant Deposits remedy was selected, guidance on the development of risk assessment was only beginning at EPA and, as a result, a risk assessment was not conducted. The selection of a value of 5 milligrams per kilogram (mg/kg) as the basis for determining areas for capping is, however, consistent with a potential recreational use of the property using current risk assessment methods. Currently, 1 mg/kg is the concentration associated with a residential property assuming exposures to a young child 1 to 6 years of age exposed 350 days/year for six years with an oral Reference Dose for Aroclor 1254 of 0.00002 mg/kg-day. Considering the less frequent exposures of an adolescent trespassing on the property, capping of all PCB concentrations greater than 5 mg/kg, and the differences in bodyweight between a young child and adolescent, the value is protective.

In-River Sediments (OU2)

There have been no changes in the physical condition of the Site since the last five-year review that would change the protectiveness of the remedy. Since the last five-year review, dredging in the Upper Hudson River was completed. The cleanup goal for the Hudson River of 0.05 mg/kg in fish remains protective of human health since there have been no significant changes to the toxicity and exposure assumptions used in the original risk assessment. Monitoring of PCB concentrations in fish continues and ICs in the form of fish consumption advisories implemented by NYSDOH continue to inform the public about the health risks associated with consumption of fish from the Hudson River.

Exposure

Since the last five-year review exposure assumptions were updated with the release of the 2014 OSWER Directive # 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 (WIR) for the young child and adult, and other parameters. These changes do not change the conclusions of the risk assessment or the protectiveness of the remedy.

The fish ingestion rate used in the 2000 HHRA represented a site-specific ingestion rate. This rate is consistent with the 2011 Exposure Factors Handbook (EPA 2011b) recommendation to use site-specific information to develop ingestion rates.

The fish ingestion rate used in the HHRA represented 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). Upper Hudson River anglers are defined as all individuals who would consume self-caught fish from the Upper Hudson River 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 for sustenance (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 Upper Hudson River anglers. The 2000 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. The same fish ingestion rate was used for the Mid-Hudson. There are no new studies of fish consumption that call for the development of a fish ingestion rate that would change the overall conclusions of the HHRA.

Toxicity

OSWER Directive 9285.7-53 (EPA 2003) outlines a process for selecting toxicity values for use in the 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. 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 identify plans to update cancer toxicity values for PCBs.
- The noncancer toxicity values used in the HHRA were also obtained from IRIS. At the current time, the IRIS agenda identifies the noncancer toxicity values as being scheduled for update. The update will evaluate systemic toxicity (e.g., noncancer health effects) including the oral RfD and inhalation RfC. Any changes in the IRIS noncancer toxicity values will be evaluated in the next five-year review.

Dioxin-like PCBs. 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). Several investigators have estimated the carcinogenic potency of these dioxin-like PCB congeners relative to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (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. EPA has set a CSF of 150,000 $(mg/kg\text{-}day)^{-1}$ for TCDD, based on liver and respiratory tumors in chronically-exposed rats (EPA, 1997a) based on the cancer assessment in EPA 1996).

The 2012 Five Year Review discussed the update to the dioxin-TEFs for dioxin-like PCBs (EPA 2010f). Since that time, the IRIS program issued a noncancer toxicity value for dioxin and this value along with dioxin Toxicity Equivalence Factors can be used in the assessment of dioxin-like PCBs. The updated reference dose for dioxin is 7×10^{-10} mg/kg-day. A comparison of the results from the original risk assessment with those calculated with the updated reference dose for the dioxin-like PCBs show that RME non-cancer hazards associated with the dioxin-like PCBs are comparable to those from total PCBs, indicating the dioxin-like PCBs do not enhance the risks from PCB exposure (EPA 1996).

Cleanup Levels

There are no Applicable or Relevant and Appropriate requirements (ARARs) or to be considereds (TBCs) for PCBs in fish and sediment. EPA determined that 0.05 mg/kg (wet weight in fish fillets) is an acceptable risk-based PCB concentration for Hudson River fish based on an annual consumption of 51 half-pound meals per year by an adult. Other target concentrations are 0.2 mg/kg PCBs in fish fillet, 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 who consumes one half-pound meal every two months. These targets of higher concentrations in fish represent points at which fish consumption advisories and fishing restrictions might become less stringent (*e.g.,* the “eat none” advisory for the Upper Hudson may be relaxed as conditions improve).

With respect to the fish consumption advisories, the New York State Department of Health (NYSDOH) continues to reach out to both people who fish the Hudson and to their family members. Appendix 13 provides a summary of the NYSDOH outreach and other activities from 2009 to 2016. NYSDOH continues to work with partners to inform anglers along the 200-mile site of the advisories. 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 Hudson River, 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 in programs with students and youth groups. Since 2009, NYSDOH project partners have reached over 5,000 school children and nearly 3,000 adults through environmental programs. Each spring Transport of Rockland County has collaborated in posting the health advice in English and Spanish on public buses with an annual ridership of nearly three million people.

NYSDOH also conducted fish consumption surveys along the 200 miles of the Hudson River that included 1,332 participations. The short fish consumption surveys were conducted by NYSDOH and their partners (*e.g.,* Cornell Cooperative Extension (CCE) staff) to better understand how individuals learned about the fish consumption advice and how this information is being applied. NYSDOH learned that many people who fish in the Hudson also fish in other waters. The popularity of striped bass is also clear from the survey results. The CCE staff, conducting surveys at health clinics, food banks and a variety of community settings in Dutchess, Columbia, Greene, Orange and Ulster Counties, found three-quarters of the people surveyed since 2014 are women under 50 years. The survey highlighted that some people are unaware of the advisories and continue to consume fish from the Hudson.

Based on the results of the survey, and discussions with participants, NYSDOH:

- Developed displays specific to striped bass to help people understand the message.
- Updated brochures emphasizing how individuals can reduce their exposure to contaminants. For example, NYSDOH's newest brochures for the Hudson Valley Region, for each of the thirteen counties that border the Hudson River in the project area, NYSDOH includes local alternatives of New York State Department of Environmental Conservation (NYSDEC) public access water bodies where the whole family can catch fish that are acceptable for consumption.
- NYSDOH developed a series of county maps that show NYSDEC public access waters with the health advisories overlaid. The maps serve to highlight the waters with the general advisory - waters where the whole family can eat up to four fish meals a month. NYSDOH utilizes local events, where these maps help people see fishing locations other than the Hudson if their intent is to eat the fish rather than fish for recreation. This fishing season, through social service providers in Albany and Rensselaer counties, NYSDOH plans to reach out to families at homeless shelters and other community spaces, to promote eating fish from healthier waters than the Hudson.

EPA will continue to work with NYSDOH to improve awareness of fish advisories for the Hudson River and share information on NYSDOH's work with the community.

Remedial Action Objectives

Based on EPA's evaluation of the HHRA data and assumptions as discussed in this appendix, the human health remedial action objectives (RAOs) identified in the 2002 ROD are still valid and appropriate for the Site.

2 ECOLOGICAL RISKS

2.1 Summary of Baseline Ecological Risk Assessment Conducted for 2002 ROD

The Baseline Ecological Risk Assessment (BERA), completed in 2000, evaluated multiple assessment endpoints across several trophic levels of the Hudson River aquatic environment. The results of the BERA supported EPA's decision that a remedial action was necessary to reduce unacceptable risks to ecological receptors, specifically by reducing the concentration of PCBs in fish. The risk-based remedial goal for the ecological exposure pathway is a range from 0.3 to 0.03 mg/kg PCBs in fish (largemouth bass, whole body), based on the Lowest Observed Adverse Effect Level (LOAEL) and the No Observed Adverse Effect Level (NOAEL) for consumption of fish by the river otter. This remedial goal was selected in the 2002 ROD and is considered protective of all the ecological receptors evaluated because the river otter was calculated to be at greatest risk from PCBs at the Site. The previous five-year review (2012) indicated that the exposure assumptions and toxicity data were still valid. These factors, along with the remedial goals and RAOs were evaluated as part of this five-year review. The remainder of this section answers two critical questions related to the current protectiveness and validity of the selected remedy, specifically:

- Is the remedy functioning as intended by the decision documents; and
- Are the (a) exposure assumptions, (b) toxicity data, (c) cleanup levels, and (d) rRAOs used at the time of the remedy still valid?

Question A. Is the remedy functioning as intended by the decision documents?

2.2 The remedy is functioning as intended although ecological remedial goals have not yet been achieved, consistent with modeling analyses and expectations presented in the Feasiblity Study (FS) and ROD. Evaluation of Ecological Risks for Question B of the Second Five-Year Review

(a) *Exposure Assumptions:* The exposure assumptions that were used in the BERA were evaluated during this five-year review to determine if they were still valid. Five exposure parameters were evaluated: body weight, food ingestion rates (FIRs),WIRs, sediment ingestion rates (SIRs), and home range. The RAOs in the 2002 ROD were based on risk calculations for female river otters and female mink from the BERA (EPA 2000d). Since that time, many exposure parameters and toxicity reference values (TRVs) have been updated by the EPA Superfund Headquarters Environmental Response Team (ERT) and used for BERA. This literature search and review (last update, November 2016) focused on exposure parameters cited for female piscivorous mammals. The only exception is the wet weight FIR for the mink. The BERA used the average ingestion rate for both sexes in the risk calculations Average or mean exposure parameters were used in the risk calculations and in this comparison.

Table 1 illustrates the effect on the calculated Average Daily Dose (ADD) and hazard quotient (HQ) of substituting each ERT exposure parameter individually in the risk calculations for the parameters used in the 2000 BERA. The effect of using all ERT parameters instead of the 2000 BERA parameters is also shown.

Body Weight

The body weights for mink and river otter used in the 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 NYSDEC. 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 ERT 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 are from various states and regions within the United States. As different studies report body weights using different statistical measures (means, medians, ranges), the ERT "average" is the midpoint of all reported body weights. For mink, 34 papers that cited mink body weights were reviewed and incorporated into the ERT "average." For river otter, 25 papers that cited adult body weights were reviewed and incorporated. All of the original papers cited inEPA 1993 were included in this review.

The body weight used by ERT for female mink (0.816 kilograms [kg]) is slightly (1.7%) lower than the value used in the BERA (0.83 kg). The body weight for female otters used by ERT is 5% higher than the value used in the BERA (7.72 kg vs. 7.32 kg).

For the mink, use of a lower body weight would result in a slightly higher calculated ADD, and slightly higher calculated HQs (i.e., a more conservative risk estimate). Use of a higher body weight for otter would result in a lower calculated ADD and HQ (a less conservative risk estimate).

Food Ingestion Rates, kg/day wet or dry weight

The wet weight (ww) FIRs for mink used in the BERA came from Bleavins and Aulerich (1981). Dry weight (dw) FIRs were estimated using allometric equations from Nagy (1987).

For mink, ERT reviewed ten laboratory studies that reported daily food consumption rates. Six laboratory studies or animal care guidelines were reviewed to estimate daily food consumption for river otters. Dry weight FIRs were either reported in the study or calculated using moisture contents cited in EPA (1993) for the listed dietary components.

The ww FIR used by ERT for female mink (0.233 kg/day) is substantially higher (43%) than the value used in the BERA (0.132 kg/day). The ww FIR for female otters used by ERT is 31% higher than the value used in the BERA (1.31 versus 0.9 kg/day, respectively). For both species, use of a higher ww FIR would result in a higher ADD and HQ and a more conservative risk estimate. For mink, the calculated HQs using the ERT ww FIR would be almost twice as high as the HQs from the BERA.

The dw FIR used by ERT for female mink (0.074 kg/day) is higher (20%) than the value used in the BERA (0.059 kg/day). The dw FIR for female otters used by ERT is

7% lower than the value used in the BERA (0.328 versus 0.353 kg/day, respectively). For mink, use of a higher dw FIR would result in a higher ADD (more conservative). For otter, the calculated ADD and HQs using the ERT dw FIR would be slightly lower (less conservative) than the ADD and HQ calculated using the BERA FIR.

Water ingestion Rates

TheWIRs used for mink and otter in the BERA and for otter used by ERT were calculated using the allometric equation for mammals developed by Calder and Braun (1983):

$$WIR = 0.099 * BW^{0.90}$$

where WIR = water ingestion in liters per day (L/day) and BW = body weight in kilograms.

Because the female river otter body weight used by ERT is slightly higher than the body weight used in the BERA, the ERT calculated WIR for otters (0.62 L/day) was slightly higher (4%) than the WIR used in the BERA (0.59 L/day).

For mink, ERT uses WIRs measured in two laboratory studies. The WIR used in the BERA (0.084 L/day) is 21% higher than the WIR used by ERT, 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

Measured SIRs have not been reported for either mink or otter. The BERA assumed a SIR of 1% of the food ingestion rate for both mink and river otter. Because sediment concentrations are typically reported on a 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).

ERT calculates a SIR based upon 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 BERA for mink is 80% greater than the ERT SIR estimate, and the SIR used for river otter is 84% greater than the ERT estimate. Use of a higher SIR in the 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 BERA reported home range sizes for both species in units of kilometers (km) stream length. ERT 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 ERT home range value for mink, reported in units of stream length, is 35% higher than the value in the BERA (2.93 versus 1.9 km, respectively), while the ERT home range value for river otter (19.7 km) is almost twice as large as the 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.

Summary of Evaluation of Exposure Assumptions: The values associated with the five exposure parameters used to estimate risk for piscivorous mammals (mink and river otters) have been refined since the competition of the BERA for the 2002 ROD. Some of the parameters have increased, while others have decreased. Use of the currently recommended ERT values for body weight, WIR, and SIR would have almost no impact on the calculated LOAEL HQs for both mink and otter. Conversely, the ERT ww FIR is higher for both mink and river otter, and the ERT dw FIR is higher for mink.

Use of these ERT exposure parameters would result in a more conservative estimate of risk (higher ADD and calculated HQ).

(b) *Toxicity Data:* The toxicity data that were used in the BERA were evaluated during this five-year review to determine if they were still valid. The 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 0.044 mg/kg-BW/day used in the 2000 BERA was from Restum et al. (1998). ERT uses a LOAEL TRV of 0.033 mg/kg-BW/day reported in a more recent study (Bursian et al. 2013). Use of a lower TRV results in a more conservative estimate of risk. EPA evaluated the relationship between LOAELs and NOAELs in studies that reported both values. Sixteen studies were reviewed to derive the TRV used in the mink dietary exposure calculations (see Table 2). Two of the studies reported measured LOAELs and NOAELs, whereas the remaining 14 studies estimated the NOAEL by using a 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 as opposed to the higher 10-fold difference that was used as a conservative default ratio when estimating a NOAEL in the final BERA. This suggests a factor of 3 may be an appropriate adjustment for estimating the NOAEL. To summarize, EPA's review of recent toxicity data suggests that the LOAEL and NOAEL toxicity values used in the original BERA could be revised to 0.033 and 0.011 mg/kg/day, respectively.

(c) *Remedial Goals:* Remedial goals were identified in the 2002 ROD to reduce ecological risk in piscivorous mammals using the mink and river otter as surrogate receptors. The risk-based remedial goal from the ROD for the ecological exposure pathway is a range from 0.3 to 0.03 mg/kg PCBs in fish, as measured by whole-body largemouth bass, based on the LOAEL and NOAEL for consumption of fish by the river otter. The ecological remedial goal is considered to be protective of all the ecological receptors evaluated because it was developed for the river otter, the piscivorous mammal and ecological receptor calculated to be at greatest risk from PCBs at the Site. 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 for the mink, a species known to be sensitive to PCBs. Utilizing the refined 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. Specifically, the recalculated remedial goal range for largemouth bass consumed by the river otter would be 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 would be 0.34 to 0.11 mg/kg PCBs in fish compared with 0.7 to 0.07 mg/kg PCBs in fish in the final BERA. Thus, refinement of the toxicity values and exposure parameters would result in risk-based ranges of PCBs in largemouth bass and spottail shiner that would be 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 does not affect the protectiveness determination of the selected remedy with respect to ecological receptors.

(d) *Remedial Action Objectives (RAOs) for Ecological Receptors:* Consumption of fish contaminated with PCBs remains the primary route of exposure for upper trophic level wildlife species, and the river otter and mink are still considered the most sensitive wildlife species. Therefore, the RAO to reduce the risks to ecological receptors by reducing the concentration of PCBs in fish is still valid.

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APPENDIX 11

HUMAN HEALTH AND ECOLOGICAL RISKS

Tables

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April 2019

Table 1. Comparison of Use of Various Exposure Parameters and Toxicity Reference Values on Risk Estimates for Female Mink and River Otters

Exposure Parameter Source	NOAEL (mg/kg/day)	HQ NOAEL	LOAEL (mg/kg/day)	HQ LOAEL	Concentration in Sediment (mg/kg d.w.)	Sediment Ingestion Rate (kg/day dw)
Female Mink, fish conc 0.7 mg/kg ww						
Hudson River BERA, 34% fish	0.0044	**9.4**	0.044	0.9	5.0	0.00059
Hudson River BERA, 34% fish	0.0044	**1.7**	0.044	0.2	5.0	0.00059
All ERT parameters, 34% fish	0.0033	**10.2**	0.033	**1.0**	5.0	0.00012
All ERT parameters, 34% fish	0.0033	**1.2**	0.033	0.1	5.0	0.00012
All ERT parameters, 34% fish, NOAEL AF = 3	0.011	1.0	0.033	0.3	5.0	0.00012
Exposure Parameter Source	NOAEL (mg/kg/day)	HQ NOAEL	LOAEL (mg/kg/day)	HQ LOAEL	Concentration in Sediment (mg/kg d.w.)	Sediment Ingestion Rate (kg/day dw)
Female Otter, fish conc 0.3 mg/kg ww						
Hudson River BERA	0.0044	**8.4**	0.044	0.8	5.0	0.00353
Hudson River BERA	0.0044	**1.4**	0.044	0.1	5.0	0.00353
All ERT parameters	0.0033	**10.4**	0.033	**1.0**	5.0	0.00055
All ERT parameters	0.0033	**1.1**	0.033	0.1	5.0	0.00055
All ERT parameters, NOAEL AF=3	0.011	**1.1**	0.033	0.4	5.0	0.00055

[1] Benthic concentration is zeroed out; RAO is based on dietary exposure to forage fish

[2] Water concentration is ARAR for surface water from the ROD; federal MCL

AF = Adjustment factor

Table 1. Comparison of Use of Various Exposure Parameters and Toxicity Reference Values on Risk Estimates for Female Mink and River Otters

Exposure Parameter Source	Dose Sediment (mg/kg/day)	Concentration in Water [2] (mg/Liter)	Water Ingestion Rate (L/day)	Dose Water (mg/kg/day)	Concentration in Fish (mg/kg w.w.)	% of diet fish
Female Mink, fish conc 0.7 mg/kg ww						
Hudson River BERA, 34% fish	0.00355	0.0005	0.084	0.0001	0.700	0.340
Hudson River BERA, 34% fish	0.00355	0.0005	0.084	0.0001	0.070	0.340
All ERT parameters, 34% fish	0.00074	0.0005	0.066	0.0000	0.340	0.340
All ERT parameters, 34% fish	0.00074	0.0005	0.066	0.0000	0.034	0.340
All ERT parameters, 34% fish, NOAEL AF = 3	0.00074	0.0005	0.066	0.0000	0.100	0.340
Exposure Parameter Source	Dose Sediment (mg/kg/day)	Concentration in Water (mg/Liter)	Water Ingestion Rate (L/day)	Dose Water (mg/kg/day)	Concentration in Fish (mg/kg w.w.)	Body Weight (kg)
Female Otter, fish conc 0.3 mg/kg ww						
Hudson River BERA	0.00000	0.0005	0.594	0.0000	0.300	7.32
Hudson River BERA	0.00241	0.0005	0.594	0.0000	0.030	7.32
All ERT parameters	0.00036	0.0005	0.620	0.0000	0.200	7.72
All ERT parameters	0.00036	0.0005	0.620	0.0000	0.020	7.72
All ERT parameters, NOAEL AF=3	0.00036	0.0005	0.620	0.0000	0.070	7.72

[1] Benthic concentration is zeroed out; RAO is based on dietary exposure to forage fish

[2] Water concentration is ARAR for surface water from the ROD; federal MCL

AF = Adjustment factor

Table 1. Comparison of Use of Various Exposure Parameters and Toxicity Reference Values on Risk Estimates for Female Mink and River Otters

Exposure Parameter Source	Concentration in benthos [1] (mg/kg w.w.)	% of diet benthos	Body Weight (kg)	Food Ingestion Rate (kg/day ww)	Dose diet (mg/kg/day)
Female Mink, fish conc 0.7 mg/kg ww					
Hudson River BERA, 34% fish	0.000	0.165	0.83	0.132	0.037850602
Hudson River BERA, 34% fish	0.000	0.165	0.83	0.132	0.00378506
All ERT parameters, 34% fish	0.000	0.165	0.816	0.233	0.033008333
All ERT parameters, 34% fish	0.000	0.165	0.816	0.233	0.003300833
All ERT parameters, 34% fish, NOAEL AF = 3	0.000	0.165	0.816	0.233	0.009708333

Exposure Parameter Source	Food Ingestion Rate (kg/day ww)	Dose fish (mg/kg/day)	Total Dose (mg/kg/day)	Reference for TRVs
Female Otter, fish conc 0.3 mg/kg ww				
Hudson River BERA	0.9	0.036885246	0.0369	Restum et al. 1998
Hudson River BERA	0.9	0.003688525	0.0061	Restum et al. 1998
All ERT parameters	1.31	0.033937824	0.0343	Bursian et al. 2013
All ERT parameters	1.31	0.003393782	0.0038	Bursian et al. 2013
All ERT parameters, NOAEL AF=3	1.31	0.011878238	0.0123	Bursian et al. 2013

[1] Benthic concentration is zeroed out; RAO is based on dietary exposure to forage fish

[2] Water concentration is ARAR for surface water from the ROD; federal MCL

AF = Adjustment factor

Table 1. Comparison of Use of Various Exposure Parameters and Toxicity Reference Values on Risk Estimates for Female Mink and River Otters

Exposure Parameter Source	Total Dose (mg/kg/day)	Reference for TRVs
Female Mink, fish conc 0.7 mg/kg ww		
Hudson River BERA, 34% fish	0.0415	Restum et al. 1998
Hudson River BERA, 34% fish	0.0074	Restum et al. 1998
All ERT parameters, 34% fish	0.0338	Bursian et al. 2013
All ERT parameters, 34% fish	0.0041	Bursian et al. 2013
All ERT parameters, 34% fish, NOAEL AF = 3	0.0105	Bursian et al. 2013

Exposure Parameter Source
Female Otter, fish conc 0.3 mg/kg ww
Hudson River BERA
Hudson River BERA
All ERT parameters
All ERT parameters
All ERT parameters, NOAEL AF=3

[1] Benthic concentration is zeroed out; RAO is based on dietary exposure to forage fish

[2] Water concentration is ARAR for surface water from the ROD; federal MCL

AF = Adjustment factor

Table 2. Summary of Studies Conducted Evaluating Dietary Toxicity of PCBs to Mammals

Mammals									
NOAEL (mg/kg/day)	LOAEL (mg/kg/day)	NOAEL type	LOAEL: NOAEL ratio	Aroclor	Test species	Exposure Duration	Effect	Reference
0.169	0.414	Measured	2.4	Housatonic River fish	Mink	11 weeks prior to mating through weaning	Decreased kit survival and growth	Bursian et al. 2006
3.6	7.72	Measured	2.1	Aroclor 1254	Sprague-Dawley rats	Days 6 through 15 of pregnancy	Decrease in fetal weight at birth	Spencer 1982
0.0033	0.033 (0.34 µg/g diet)	Estimated		Diets containing 2.5 to 20% Hudson River fish	Mink	Two months prior to mating through	20% kit mortality at six weeks of age	Bursian et al. 2013b
0.0044	0.044	Estimated		Saginaw-Bay carp	Mink	Multigeneration	Decreased kit growth	Restum et al. 1998
0.008	0.08	Estimated		Clophen A50	Mink	Two reproductive seasons	Fewer kits per mated female, decreased kit survival	Brunstrom et al. 2001
0.01	0.1	Estimated		Aroclor 1254	Mink	6 months	Growth rate of kits	Wren et al. 1987
0.0134	0.134	Estimated		Saginaw-Bay, Lake Huron carp	Mink	12 weeks	Reduced kit survival	Heaton et al. 2001
0.014	0.14	Estimated		Aroclor 1254	mink	160 days	12.5% adult mortality	Platanow and Karstad 1973
0.0223	0.223	Estimated		Diets containing 2.5 to 20% Hudson River fish	Mink	Two months prior to mating through	20% jaw lesions	Bursian et al. 2013a
0.044	0.44	Estimated		Aroclor 1254	Mink	9 months prior to whelping through four weeks kit age	Almost complete reproductive failure (two of seven mated females whelped, one live kit produced; 8 of 8 control females whelped, 28 live kits produced)	Aulerich and Ringer 1977
0.054	0.538	Estimated		Clophen A50		2 weeks prior to mating to 4 to 6 weeks post-mating	Number of placentas with viable fetuses significantly lower in PCB-exposed group	Backlin et al. 1998
0.093	0.93	Estimated		Aroclor 1254	Oldfield mice	Three generations	Decreased fertility, growth and survival	McCoy et al. 1995
0.11	1.1	Estimated		Aroclor 1254	Mink	Six months	95% reduction in number of kits born alive	Aulerich and Ringer 1977
0.11	1.1	Estimated		PCBs	Mink	8.5 months	Complete reproductive failure	Aulerich and Ringer 1977
0.162	1.62	Estimated		Aroclor 1268	Mink	Two months prior to mating unitl kits 6 weeks old	LC20 for kit mortality	Folland et al. 2016
0.263	2.63	Estimated		Aroclor 1254	White-footed mice	Two generations	Significant decrease in number of young per litter; lower offspring weight at 4, 8 and 12 weeks of age	Linzey 1987 and 1988
	0.059			PCBs	Mink	NA	EC20, Production of surviving kits. Mink-specific dose-response curve. Results from 16 peer-reviewed papers with 50 dose groups, all of which tested reproductive toxicity of PCBs to mink.	Fuchsman et al. 2008
	0.17			PCBs	Mink	NA	EC50, Production of surviving kits. Mink-specific dose-response curve. Results from 16 peer-reviewed papers with 50 dose groups, all of which tested reproductive toxicity of PCBs to mink.	Fuchsman et al. 2008

Shading indicates non-mink mammal studies

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