FINAL THIRD FIVE-YEAR REVIEW COMMENT RESPONSE FOR THE

HUDSON RIVER PCBS SUPERFUND SITE

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LIST OF ABBREVIATIONS AND ACRONYMS

BERA	Baseline Ecological Risk Assessment
CAG	Community Advisory Group
CSM	Conceptual Site Model
EPA	see USEPA
FOCH	Friends of Clean Hudson
FS	Feasibility Study
FTN	flow-temperature-normalized
FYR	Five-Year Review
g/m^2	grams per meter squared
GE	General Electric Company
GRTS	Generalized Random Tessellation Sampling
HHRA	Human Health Risk Assessment
HQ-OSRTI	EPA Headquarters' Office of Superfund Remediation and Technology Innovation
HUDTOX	Upper Hudson River Toxic Chemical Model; a mechanistic, numerical chemical fate and transport model for water and sediment
IARC	International Agency for Research on Cancer
IC	Institutional Control(s)
IRIS	Integrated Risk Information System
LWA	length-weighted average
MCL	maximum contaminant level
mg/kg	milligram per kilogram
mg/kg-ww	milligram per kilogram wet weight
MM&AM	Monitoring, Maintenance and Adaptive Management
MNR	Monitored Natural Recovery
MPA	Mass Per Unit Area; typically expressed as grams per square meter (g/m2)
ng/L	nanograms per Liter

NLOM	non-lipid organic matter
NOAA	National Oceanic and Atmospheric Administration
NYS	New York State
NYSDEC	New York State Department of Environmental Conservation
NYSDOH	New York State Department of Health
OM&M	Operations, Maintenance, and Monitoring
OU	Operable Unit; an officially designated portion of a CERCLA site for investigation and remediation purposes
PCB	Polychlorinated Biphenyl
ppm	parts per million
ppt	parts per trillion
RAO	Remedial Action Objective
RI/FS	Remedial Investigation and Feasibility Study
RME	Reasonable Maximum Exposure (Exposed)
ROD	Record of Decision
RS	River Section
RSA	Recovery-Sediment-Area
SEDC	Supplemental Engineering Data Collection
SEMD	Superfund and Emergency Management Division
Site	Hudson River PCBs Superfund Site
SME	subject matter experts
SSAP	Sediment Sampling and Analysis Program
TEF	toxic equivalency factors
TPCB	Total PCB
Tri+ PCBs	PCBs containing three or more chlorines
UHR	Upper Hudson River
USEPA	United States Environmental Protection Agency
Yrs	years

I. INTRODUCTION

1.1 The Third Hudson River PCBs Superfund Site Five Year Review

The purpose of the Third Five-Year Review (FYR) for the Hudson River Polychlorinated Biphenyls (PCB) Superfund Site is to determine if the Superfund cleanup remedy is functioning as intended and is protective of human health and the environment. Superfund law requires that five-year reviews be performed when a cleanup action leaves hazardous substances on a site at levels that do not allow for unlimited use and unrestricted exposure. These reviews are required every five years from the start of construction of the cleanup action.

The third Hudson River PCBs Superfund Site FYR was led by United States Environmental Protection Agency (EPA) Project Director, Gary Klawinski. Participants also included other EPA staff within EPA Region 2's Superfund and Emergency Management Division (SEMD) and EPA Headquarters' Office of Superfund Remediation and Technology Innovation (HQ-OSRTI), as appropriate.

1.2 FYR Public Outreach and Engagement

Throughout the five-year review process, EPA provided various opportunities for public participation. Before the initiation of the formal public comment period for the third FYR, EPA established a team that included representatives of the state agencies, federal agencies, natural resource trustees, Community Advisory Group (CAG) members, and EPA subject matter experts; and held five-year review team meetings. Additionally, EPA provided updates on the FYR process and report to stakeholders represented by the Site's CAG.

Although EPA does not typically seek public comment on a FYR report, EPA initiated a formal public comment period with the release of the draft FYR report on July 10, 2024. The comment period was originally set to end on October 8, 2024. As requested by the Friends of Clean Hudson (FOCH), EPA extended the public comment period until November 7, 2024.

As mentioned above, EPA hosted five FYR team meetings and two follow-up meetings. EPA discussed the purpose, scope and findings of the ongoing FYR and answered questions from the FYR team members during those meetings:

- Team Meeting #1: December 14, 2022 to discuss FYR purpose, process, considerations and summary of the last FYR.
- Team Meeting #2: January 18, 2023 to discuss OU1 and OU2 water column data and caps.
- Team Meeting #3: February 1, 2023 to discuss OU2 fish.
- Team Meeting #4: March 1, 2023 to discuss OU2 sediment.

- Team Meeting #5: March 15, 2023 to discuss follow-up items from prior meetings and a wrap up.
- Follow-up meetings were held on September 5, 2024 and October 2, 2024.

EPA reviewed and considered all comments received during the public comment period. By the close of the comment period, EPA has received approximately 1,800 discrete submissions of comments. Of the 1,800 submissions, approximately 1,400 submissions are based on five form letters, approximately 250 submissions are modified from the form letters, and approximately 150 were unique letters. These unique letters include primary comments from four parties (FOCH, National Oceanic and Atmospheric Administration (NOAA), New York State Department of Environmental Conservation (NYSDEC), and General Electric Company (GE)), six town/county resolution letters, one letter from select members of U.S. Congress, and other unique letters from individuals or organizations.

All comments submitted to EPA during the public comment period were reviewed and carefully considered. To ensure a complete and comprehensive evaluation and response to the FYR comments, all comment documents were reviewed and catalogued. To manage the comments, each comment letter was divided into segments that each captured a unique theme or topic with respect to the FYR process or report. The segments were organized for content and then assigned to review by subject matter experts (SMEs). All unique segments were identified and were individually adopted as a "master comment," or were consolidated with other similarly themed segments (addressing similar issues) into a single master comment. EPA prepared a response for each master comment.

A quality assurance program was implemented to verify that the full body of segments were reviewed and categorized appropriately. All segments identified to be within the scope of the FYR report and/or process were consolidated into master comments. The quality assurance program was also used to verify that these topics were accurately represented in the master comments and the responses are technically complete. EPA received some comments and opinions that were outside the scope of the FYR report and process. For example, there were comments referencing the Lower Hudson River and the Upper Hudson River Floodplain which were not part of this FYR. These comments are not addressed as part of the master comments and responses. As indicated during the FYR process, EPA is available to discuss these out-of-scope comments further as needed.

Responses were informed by and drawn from:

- material presented in the third FYR report
- previous project reports and other literature
- the experience of other remedial projects and individuals

- EPA policy
- technical analyses that were performed specifically to address comments or questions raised during the public comment period.

Comments were numbered and then grouped into 6 categories. The first category relates to OU1 and categories 2 through 6 are related to OU2, as follows:

1. Ownership, sampling, risk assessment
2. EPA should determine the remedy is not protective
3. Risks not evaluated sufficiently
4. Remaining PCBs and their importance
5. Fishing advisories and restrictions
6. Data collection and analysis

Table 1 below contains a list of all comments and their corresponding section in this document.

Table 1. FYR Master Comment Response List

Comment Number	Comment Title	Response Found in Section
1a	The remedy is not protective	2.2 EPA should determine the remedy is not protective
1b	Quantitative criteria are necessary to determine remedy performance	2.2 EPA should determine the remedy is not protective
2	Additional in-river work is necessary	2.4 Remaining PCBs and their importance
3a	Current data should be compared to ROD predictions - Comparison of current concentrations	2.2 EPA should determine the remedy is not protective
3b	Current data should be compared to ROD predictions - Recovery is different than ROD projected	2.2 EPA should determine the remedy is not protective
4a	The ROD forecast should be revised if the model assumptions are not being met - Re-evaluate ROD assumptions	2.4 Remaining PCBs and their importance
4b	The ROD forecast should be revised if the model assumptions are not being met - high-flow events and their relationship to the recovery of the river	2.4 Remaining PCBs and their importance
5	Fish data analysis method	2.6 Data collection and analysis

Comment Number	Comment Title	Response Found in Section
6a	Fish are not meeting ROD targets - Human health	2.3 Risks not evaluated sufficiently
6b	Fish are not meeting ROD targets - Ecological targets	2.3 Risks not evaluated sufficiently
7a	The need for more years of data despite slower recovery in existing data	2.2 EPA should determine the remedy is not protective
7b	Sediment data show little recovery	2.2 EPA should determine the remedy is not protective
7c	Fish recoveries vary by species and confounded by lipids	2.2 EPA should determine the remedy is not protective
8	Remaining PCBs in river	2.4 Remaining PCBs and their importance
9	Sediment monitoring (top 12 inches vs. 2 inches)	2.4 Remaining PCBs and their importance
10	Sediment PCB concentrations remained high	2.4 Remaining PCBs and their importance
11	CSM - relationship of sediment, water, fish	2.4 Remaining PCBs and their importance
12	Human health and ecological risks associated with exposure to PCBs	2.3 Risks not evaluated sufficiently
13	Habitat related concerns	2.6 Data collection and analysis
14	OU1 Remnant Deposits	2.1 Ownership, sampling, risk assessment
15	Concerns regarding fish consumption advisories	2.5 Fishing advisories and restrictions
16	Special studies	2.6 Data collection and analysis
17	Water column data analysis	2.6 Data collection and analysis
18	Pre- and post-dredging data comparison	2.6 Data collection and analysis
19	EPA should use arithmetic mean rather than geometric mean	2.6 Data collection and analysis
20	Independent third-party review	2.6 Data collection and analysis

II. MASTER COMMENTS AND RESPONSES

2.1 Ownership, sampling, risk assessment

2.1.1 Comment 14: OU1 Remnant Deposits

Comment

Commenters indicated that the EPA's progress on addressing PCB contamination at the Remnant Deposits sites along the Hudson River (Operable Unit 1 or OU1), has been slow. The key issues mentioned by the commenters are the unresolved land ownership disputes hindering the implementation of institutional controls and the lack of data to assess the risk posed by these sites. Commenters suggested that EPA should prioritize resolving ownership issues, implementing effective controls, and gathering necessary data to protect human health and the environment. Additionally, a comprehensive risk assessment for OU1 is needed to evaluate the adequacy of the existing remedial work.

Response

As stated in the Draft Third FYR, the remedy for the Remnant Deposits sites is functioning as intended by the 1984 Record of Decision (ROD). Water column Tri+ PCB concentrations immediately downstream of the Remnant Deposits at the Rogers Island monitoring station during the post-dredging period (2016 to 2021) have averaged approximately 0.87 nanograms per liter (ng/L) or parts per trillion (ppt). This concentration is below the anticipated concentration of 2 ng/L described in the 2002 ROD. The low PCB concentrations in the river immediately downstream of the Remnant Deposits suggests that the area is not a significant source of PCBs to the river.

EPA acknowledges the need to resolve landownership at the Remnant Deposit sites. In order for the remedy to be protective in the long-term, an institutional control needs to be implemented to ensure that the future use of the Remnant Deposits areas does not compromise the integrity of the cap system or result in exposures. EPA, in coordination with NYSDEC, is in the process of determining ownership of the Remnant Deposits Site properties so that institutional controls, such as an environmental easement, can be established.

There is limited risk of exposure at the Remnant Deposits sites because the perimeter fencing and cap limit site access and contain residual contamination under the caps. The final cap design for the Remnant Deposits included a sand/fill bedding layer, a gas collection/venting system, a composite layer (consisting of a reinforcing geotextile and low permeability bentonite clay layer), a sand drainage layer, a topsoil layer, and a vegetative cover. In-place containment of the formerly exposed Remnant Deposits (Remnant Deposits 2, 3, 4, and 5) was completed in 1991. The capping system limits ecological and human health exposure. As a result, a risk assessment is not necessary for the Remnant Deposits sites.

As discussed in Section 5.2, the sections of this former river bottom that remain uncapped are limited and are being evaluated under the floodplain Remedial Investigation and Feasibility Study (RI/FS) to determine if any further work is necessary in these areas.

2.2 EPA should determine the remedy is not protective

2.2.1 Comment 1a: The remedy is not protective

Comment

Commenters asserted that the risks posed by PCB exposure in the Upper Hudson are still well above the acceptable range, for both cancer and non-cancer health effects, as well as ecological risk, and that the remedy is thus not protective. The commenters' assertions are based on the following claims:

- *Ongoing Risks:* Human health and ecological risks remain well above the "acceptable risk range."
- *Missed Fish Tissue PCB Targets:* The dredging remedy has missed or will miss the fish tissue interim targets. The first fish tissue interim target of 0.4 mg/kg Total PCB (TPCB) has not been achieved nearly 10 years after dredging was completed, and recovery rates indicate that the second target of 0.2 mg/kg TPCB is unlikely to be met within the anticipated timeframe.
- *Minimal Declines in PCB Concentrations:* PCB concentrations in fish and sediment are not declining as anticipated. Sediment data show minimal recovery in the top two inches, and fish PCB concentrations have not declined as expected across most species and locations. Neither fish nor sediment are recovering at the rates needed to achieve the targets EPA projected in the 2002 ROD, and residual PCB contamination in sediment continues to hinder progress.

Based on these claims, commenters stated that the remedy's outcomes were inconsistent with modeling analysis and expectations presented in the ROD. They concluded that the remedy is not protective and urged EPA to declare the cleanup as "not protective."

Response

The 2002 ROD selected environmental dredging in certain areas to address PCB-contaminated sediment in the Upper Hudson River (UHR), followed by monitored natural recovery (MNR). As EPA indicated in the ROD, after the dredging, PCB concentrations in fish tissue would decrease over decades before reaching the remedial goals. As required by the ROD, Institutional Controls

(ICs) in the form of fishing advisories and restrictions are in place to control human exposure pathways that could result in unacceptable risks until the remedial goals for human health are achieved. Therefore, PCB concentrations in fish above the targets and remedial goals alone do not warrant a "not protective" determination. A critical factor needed for the protectiveness determination is a reliable calculation of the rate of decline in post-dredging fish tissue PCB levels. Once a rate of decline can be established, EPA will determine if the targets and goals will be achieved within reasonable expectations of the ROD. It is important to note that specific timeframes for achieving the fish targets and remediation goals are not established in the ROD Remedial Action Objectives (RAOs). The timeframes to reach the targets that are discussed in the ROD were specifically developed for the remedy selection process so that EPA could compare remedial alternatives. The targets that are included in the RAO were intended to provide perspective regarding the potential for New York State Department of Health (NYSDOH) to relax fish consumption advisories as concentrations declined to certain target levels. The ROD also does not specify anticipated rates of recovery post-dredging. While modeling was performed to support remedy selection and rates of decline and timeframes can be calculated from this modeling, direct comparison to these model results is not appropriate and is discussed in more detail in the Second FYR.

As discussed in this FYR, EPA has evaluated the data collected on the Upper Hudson River project and has determined that rates of decline in fish, water and sediment cannot be established until more data has been collected. The year-to-year variability in fish and water data during the pre-dredging period was evaluated using a moving window analysis (See Section 5.1.7) and indicates that a minimum of eight years (2016-2023) of data is necessary before a trend in the data can be reliably estimated. Once eight or more years of data have been collected, EPA will evaluate the data to determine if a reliable rate of decline can be established.

It is important to note that while sufficient years of data may exist to overcome some of the year-to-year variability, additional data are necessary before EPA can be confident in the calculated rates of decline. The post-dredging water, fish and sediment sampling programs (Operations, Maintenance, and Monitoring [OM&M]) were designed to detect a 5 percent annual rate of decline over a 10-year period. Therefore, it should be noted that it may take up to 10 years (2026) of data before EPA can be confident in the rates of decline. This 10-year time period is consistent with findings from the NYSDEC Cumberland Bay (Wilcox Dock) Site in Lake Champlain (see Appendix 8 of the Second FYR report, Figures A8-5.1 and A8-5.2) (EPA, 2019a) and studies such as the Great Lakes research (Gewurtz et al., 2011), which concluded that more than 10 years of data is needed for estimating fish recovery time trends.

For further details, refer to Comment 7a on the importance of long-term data to reduce variability and improve trend accuracy, Comment 7b on the sediment recovery and Comment 7c on the fish recovery.

2.2.2 Comment 1b: Quantitative criteria are necessary to determine remedy performance

Comment

Commenters indicate that EPA should establish, in this FYR, clear and quantitative criteria that will be used by EPA in determining protectiveness over the next few years. The commenters stressed that these criteria should be based on the ROD and the expectations of remedy performance at the time of remedy selection.

Commenters questioned how EPA changed its expectation of remedy performance from 7 to 9 percent decline per year to 5 percent decline per year, without modifying the ROD.

Commenters also asked EPA to clarify the meaning of the phrase "reasonably consistent" regarding ROD projections, as used in the Third FYR. They requested that EPA clarify how "reasonably consistent" is to be determined, specifically in terms of recovery rates and the timeframes to achieve the thresholds set in the ROD. For example, what rates of decline would EPA determine to be "reasonably consistent?"

Overall, commenters called for transparent and quantitative criteria to evaluate remedy performance and to ensure accountability in EPA's decision-making. Commenters opined that these criteria are important for determining whether the remedy is performing as anticipated or if additional remedial actions or even a ROD amendment might be necessary.

Response

When evaluating whether the remedy is performing reasonably consistent with the ROD expectations, EPA will use multiple lines of evidence, looking closely at the available data related to the recovery of the fish, water, and sediment, as well as information from special studies. EPA's evaluation will incorporate all available data and conduct evaluations at various levels of detail including overall, by river section, by reach, as well as species-specific recovery. This type of technical evaluation involves many considerations, and it is not feasible to define specific criteria at the time of the ROD before design data and remedy performance information are available. EPA will continue to adaptively manage the project and adjust data collection and evaluations based on the conditions observed in the data. EPA will continue to monitor the recovery of the river and progress towards the achievement of the ROD goal of 0.05 mg/kg in fish tissue, which will be protective of human health and ecological receptors.

It is important to note that the ROD RAOs do not include specific time requirements for achieving interim fish targets and remediation goals and it does not specify anticipated rates of recovery post-dredging. While modeling was performed to support remedy selection, and rates of decline and timeframes can be calculated from this modeling, direct comparison to these model results is not appropriate. The ROD model was designed and calibrated to be used for a specific purpose, to compare the relative performance of various remedial alternatives. The model was not devised to yield output data that could serve as absolute predictions of tissue and sediment recovery rates. Inevitably, model predictions differ from actual observations due to natural variability, localized exposure differences, and uncertainties in factors such as prey availability, lipid content and exposure pathways. Additionally, differences between the assumptions made in representing the remedy at the time of ROD and the actual implementation of the remedy have introduced further variability, as outlined in Appendix 8 of the Second FYR (EPA, 2019a) and Response to Comment 3 of this FYR.

As stated above, the ROD does not specify anticipated post-dredging recovery rates. A 7 to 9 percent recovery rate is consistent with the observed rates of recovery for sediment during pre-dredging period, but this rate of decline is not expected to be the same for the post-dredging period. As concentrations decrease over time, it is expected that rates of decline will slow down. This expected reduction in recovery rate was understood at the time of the ROD and reflected in the modeling results. For example, during the first 10 years post-dredging, the model predicted an average annual rate of decline for brown bullhead in River Section (RS) 2 of 5.8 percent, whereas the final 10 years of the modeling run had an average annual rate of decline of 0.8 percent.

EPA has not stated a specific annual rate of decline to assess the remedy performance; the 5 percent annual rate of decline is associated with the design of the long-term monitoring program. EPA has designed the long-term monitoring program for fish, water, and sediment to detect a 5 percent annual rate of decline with 80 percent power and 95 percent confidence in 10 years. The selection of the 5 percent rate of decline was also informed by the analyses conducted during the Second FYR, which evaluated pre-dredging fish and sediment data and found a wide range of recovery rates depending on species and location. Furthermore, as PCB concentrations decrease over time, the rate of decline is expected to slow down. Based on these findings, a 5 percent annual decline was deemed a reasonable and practical metric upon which to design the OM&M sampling program.

2.2.3 Comment 3a: Current data should be compared to ROD predictions - Comparison of current concentrations

Comment

Commenters requested that the post-remedy monitoring data should be compared to the ROD model forecast. Specifically, many commenters questioned the effectiveness of the remedy because the fish concentration missed the first fish target within the ROD model-predicted timeline. Commenters requested information regarding the “progress” of the remedy and suggested the FYR should demonstrate the continuous decline of PCB concentrations post-dredging such that they are approaching the ROD predictions. Some commenters pointed out that the post-remedy conditions were different from the ROD model assumptions, such as post-dredging sediment concentrations are higher than the residual Tri+ PCB sediment concentrations assumed in the ROD model (i.e., 0.25 ppm for cohesive areas and 0.5 ppm for non-cohesive areas), and they speculated that may be the reason why the first fish target was missed. Some commenters further suggested that the water column Tri+ PCB load should be compared to the ROD model forecast and the MNR values. A commenter questioned which years were considered as the time for establishing equilibrium post-dredging and noted that a comparison to the ROD forecast should still be presented with the consideration of equilibrium time.

Response

Comparisons of the PCB concentrations in water column and fish against the ROD RAOs and targets are presented in Sections 5.1.5.1 and 5.1.5.3, and Appendices 1 and 3 of the Third FYR. Although there are no quantitative remedial goals in the ROD for sediment, understanding sediment concentrations is an important part of river recovery and post-dredging data and analysis are presented in Section 5.1.5.2 and Appendix 2.

Statements regarding the effectiveness of the remedy are premature at this time. As discussed in this FYR, there are not enough sets of annual data available since the completion of dredging to establish rates of decline in fish with statistical confidence which is a critical component to evaluating effectiveness. Calculations of rates of recovery at this time could yield inaccurate and misleading results. It is important to note that there are no ROD specific timeframes for achieving the fish targets and goals established in the ROD. Furthermore, the ROD does not specify anticipated rates of recovery post-dredging. While modeling was performed to support remedy selection and rates of decline and timeframes can be calculated from this modeling, direct comparison to these model results is not appropriate and discussed in detail in the Second FYR.

The post-dredging data have shown positive progress toward meeting the ROD RAO expectations. Although the modeling conducted by EPA and discussed in the ROD projected that the 0.4 and 0.2 mg/kg interim targets would be achieved within 5 and 16 years, respectively, actual conditions during dredging did not, and were not expected to, coincide in every way with conditions as understood when the ROD modeling was conducted. It should also be noted that dredging started later than the model considered. Furthermore, short-term and localized increases and subsequent decreases in fish tissue PCB concentrations anticipated in the Feasibility Study (FS) and ROD (and observed between 2009 and 2016) were not directly reflected in the long-term fish tissue forecasts presented in support of remedy selection. For these reasons, direct comparisons of observed data to ROD forecasts should be performed carefully with the various factors taken into consideration.

EPA indicated in the Second FYR (EPA, 2019a) that model predictions were likely to differ from actual observations due to: 1) variability in actual exposures; 2) highly localized exposures; 3) the importance of sediment versus water exposure pathways, which can vary over time due to prey availability and natural variability in exposure conditions; 4) uncertainty and variability in lipid content of fish and prey items; 5) uncertainty and variability in consumption of specific prey items and PCB concentrations in prey; and 6) measurement uncertainty (including allowing for differences in sampling programs and analytical methods). As a result, while the ROD estimated post-dredging fish tissue recoveries, the full range of specific impacts and the timing of such delays on each fish species or population could not reasonably have been predicted.

The ROD anticipated at least a year of equilibration in the system in response to the dredging and related activities. An accurate determination of the time to reach specific ROD targets and goals requires information on the rate of decline following dredging. Post-dredging equilibration over several years has been observed in other remedial sites. For example, as described in Section 2.7 of Appendix 8 of the Second FYR (EPA, 2019a), Cumberland Bay (Lake Champlain, NY) fish tissue PCB levels were observed to require several years to recover in the wake of a removal action (NYSDEC, 2012). At the Cumberland Bay (Wilcox Dock) Site, the Wilcox Dock remediation was implemented by NYSDEC in 1999 and 2000 and fish tissue concentrations for two species, including rock bass and yellow perch, began to stabilize after several post-dredging years. Overall, these observations suggest that some time is required for remedial sites to undergo equilibration before it is reasonable to expect the post-dredging trend to be determined.

The assumption of 0.25 mg/kg residual sediment concentration was made in the ROD model to represent the bed condition immediately following backfill. This assumption was made based on a review of the outcomes at other Superfund sites and was considered reasonable at the time of the ROD (EPA, 2002). However, EPA acknowledged in the Second FYR Comment Response document (EPA 2019b) that the ROD model was never intended to accurately predict post-dredging conditions or accurately predict specific years when certain concentrations would be met. Nonetheless, the reduction in surface sediment concentrations as a result of dredging was consistent with expectations in the ROD. Overall percentage reductions on an area-weighted average basis for the 0–2-inch surface sediment were more than 80 percent for all river sections, as presented in Appendix 4 of the Second FYR report (EPA, 2019a).

Similarly, because the ROD model was never intended to accurately predict post-dredging conditions, comparison of ROD-forecasted water column Tri+ PCB load to current measurements is not technically justified. HUDTOX simulations of remedial alternatives required an assumed long-term series of daily future flows, so for the RI/FS, a representative series was constructed from prior years' flow records. This was appropriate because actual flows cannot be known in advance, but differences between simulated and actual outcomes on any given date may significantly affect predicted results. As discussed in this FYR, PCB loads transported in the water column are dominated by storm events. The timing, duration and intensity of the storm can be different from the predicted flows assumed for the ROD projections. In this FYR, the flow-temperature-normalized (FTN) PCB flux was estimated (Figure A1-19 of Appendix 1). By removing variability in the water column Tri+ PCB loads introduced by flow and seasonality, the results indicate FTN Tri+ PCB loads to the Lower Hudson River are decreasing.

2.2.4 Comment 3b: Current data should be compared to ROD predictions - Recovery is different than ROD projected

Comment

Commenters noted that the recovery of fish and sediment is slower than anticipated in the ROD and EPA has changed their expectation of remedy performance. Specifically, commenters noted that the anticipated rate of decline (7 to 9 percent per year) is not observed, and the remedy has failed to reach the key remediation targets in the time frame predicted in the ROD. Consequently, commenters asked EPA to take steps to re-evaluate the UHR remedy and determine whether further sediment remediation is required to meet the ROD goals.

Response

Statements regarding the effectiveness of the remedy are premature at this point in time. As discussed in this FYR, there are not enough sets of annual data available since the completion of dredging to establish rates of decline in fish, water or sediment with statistical confidence which is a critical component to evaluating effectiveness. Any estimate of rates of decline with the existing data set could yield misleading results.

The ROD does not specify anticipated rates of recovery post-dredging. Modeling was performed to support remedy selection and rates of decline can be calculated from this modeling. However, direct comparisons to these models are not appropriate since there are differences between the assumptions made in representing the remedy at the time of ROD and the actual implementation of the remedy which have introduced further variability, as outlined in Appendix 8 of the Second FYR (EPA, 2019a). A 7 to 9 percent recovery rate is consistent with the observed rates of recovery for sediment during pre-dredging period, but this rate of decline is not expected to be the same for the post-dredging period. As concentrations decrease over time, it is expected that rates of decline will slow down. This expected reduction in rate of decline was understood at the time of the ROD and reflected in the modeling results. For example, during the first 10 years post-dredging, the ROD model predicted an average annual rate of decline for brown bullhead in RS 2 was 5.8 percent, whereas the final 10 years of the modeling run had an average annual rate of decline of 0.8 percent.

2.2.5 Comment 7a: The need for more years of data despite slower recovery in existing data

Comment

Commenters questioned EPA's need for "eight or more years" of data, based on a statistical test(s) that was not included in the ROD. They asserted that if the remedy's performance results in minimal or no decline in fish PCB concentrations, use of this test would never result in EPA having enough data to detect a statistically significant percentage annual decline in fish PCB concentrations with 95% confidence and 80% power. They also questioned why EPA's monitoring program was designed to detect a 5 percent annual decline, which is slower than the 7 to 9 percent decline anticipated in the ROD. Furthermore, they asked EPA to explain why the 2021 sediment program was not designed to collect data with the statistical power and confidence needed to compare to 2017 results, delaying the protectiveness decision.

Commenters asserted that EPA used the moving window analysis to avoid evaluating (and presenting) the current trends. Commenters argue that waiting for an additional one or two years of data is unlikely to alter the trends observed in the current data. They urge EPA to use the available data to evaluate trends.

Response

The commenter implies that EPA needs sufficient data to detect a trend with 95% confidence and 80% power. However, as discussed in comment 1b, EPA has not defined the exact metrics that will be used to establish a rate of decline. EPA will use multiple lines of evidence, looking closely at the recovery of the fish, water, sediment and special study data. This type of technical evaluation involves many considerations, and it is not appropriate to define specific criteria ahead of time. Additionally, EPA anticipates conducting multiple statistical analyses to gain a thorough understanding of the data and associated trends.

The 95% confidence and 80% power metrics relate specifically to the design of the OM&M program. The OM&M program was designed to detect a 5 percent annual decline over 10 years with 95% confidence and 80% power. EPA will have about 10 years of post-dredging data in 2027, at which time EPA will be able to determine with statistical confidence whether the rate of decline exceeds or falls below 5 percent. If a trend greater than 5 percent cannot be established, EPA will conclude that the trend is less than 5 percent. EPA will use all the available data to inform its decision regarding the rate of decline.

The ROD does not specify anticipated post-dredging recovery rates. A 7 to 9 percent recovery rate is consistent with the observed rates of recovery for sediment during pre-dredging period, but this rate of decline was not expected to be the same for the post-dredging period. As concentrations decrease over time, it is expected that rates of decline will slow down. This expected reduction in recovery rate was understood at the time of the ROD and reflected in the modeling results. For example, during the first 10 years post-dredging, the model predicted an average annual rate of decline for brown bullhead in RS 2 of 5.8 percent, whereas the final 10 years of the modeling run had an average annual rate of decline of 0.8 percent.

EPA has designed the long-term monitoring program for fish, water and sediment to detect a 5 percent annual rate of decline with 95% confidence and 80% power in 10 years. The selection of the 5 percent rate of decline was informed by the analyses conducted during the Second FYR, which evaluated pre-dredging fish and sediment data and found a wide range of recovery rates depending on species and location. Furthermore, as PCB concentrations decrease over time, the rate of decline slows down. Based on these findings, a 5 percent annual decline was deemed a reasonable and practical metric to design the OM&M sampling program. However, it is important to note that EPA has not stated a specific annual rate of decline to assess the remedy performance. When EPA has sufficient data to properly evaluate whether the remedy is performing reasonably consistent with the ROD expectations, EPA will use multiple lines of evidence, looking closely at the recovery of the fish, water, sediment and special study data. See EPA's Response to Comment 1b for more information on evaluating the remedy effectiveness.

The moving window analysis conducted as part of this FYR, using pre-dredging data, demonstrates the need for at least eight or more years of data to accurately account for year-to-year variability (Section 5.1.7). EPA also conducted a moving window evaluation using 30 years of simulated data to assess the comparability of short-term trends (spanning just 7 or 10 years within the overall 30-year simulation) to the long-term trend (derived from the entire 30-year simulated dataset). These simulations assumed a 5 percent annual decline and incorporated actual variance and sample sizes from the OM&M post-dredging fish samples.

The results, summarized in the table below, show the proportion of short-term trends (spanning 7 or 10 years) that fall within ±50% of the long-term trend (30 years). The analysis revealed that 76% to 93% of trends based on 10 years of data aligned with the long-term trend range, compared to only 49% to 70% of trends based on only 7 years of data. These findings emphasize the importance of long-term datasets in producing reliable and accurate trend analyses.

Table 7a-1 Proportion of short-term trends (spanning 7 or 10 years) that fall within ±50% of the long-term trend (30 years)

Window Length (yrs)	RS 1			
	Brown Bullhead	Smallmouth Bass	Yellow Perch	Pumpkinseed
7	64%	57%	61%	49%
10	89%	83%	86%	76%

Window Length (yrs)	RS 2			
	Brown Bullhead	Smallmouth Bass	Yellow Perch	Pumpkinseed
7	59%	65%	70%	58%
10	86%	90%	93%	83%

Window Length (yrs)	RS 3			
	Brown Bullhead	Largemouth Bass	Yellow Perch	Pumpkinseed
7	65%	57%	66%	70%
10	88%	84%	91%	93%

Commenters also questioned why sediment sampling in 2021 did not replicate the sample size of 2017, so that EPA would have enough data to assess the rate of decline in five years. For a given population of PCB data, the precision of recovery rate estimates varies with the sample size, the frequency of monitoring, the duration of the monitoring program and the variability of the sample data. Of these parameters, the precision of the recovery estimates is the most sensitive to the duration of the monitoring period, followed by the number of samples collected in the first and last monitoring time step. EPA's analyses demonstrate that restricting the assessment to a five-year period would require substantially more samples than were collected in 2016/2017 to detect recovery rates in the 3 to 8 percent range, and the level of effort to collect those samples would not be reasonable. There would also be significant uncertainty to achieve such a measurement in a 5-year program. Therefore, the OM&M program is designed over a 10-year time frame. This is consistent with findings from Gewurtz et al. (2011), which highlight the necessity of at least 10 years of data to accurately detect trends, as shorter datasets are more prone to variability and can lead to premature or inaccurate conclusions. Similarly, Wagner et al. (2022) concluded that "Monitoring for short time periods (e.g., 5 years) was inadequate for detecting regional temporal trends, regardless of the number of sites sampled or the magnitude of the annual declines." These findings underscore the importance of long-term monitoring to ensure reliable and robust trend analyses.

2.2.6 Comment 7b: Sediment data show little recovery

Comment

Commenters concluded that post-dredging monitoring data indicated minimal decline in PCB concentrations in surface sediments in the Upper Hudson River. Commenters stressed that this lack of sediment recovery was linked to the slower-than-anticipated declines in fish PCB concentrations, raising concerns about the remedy's effectiveness and its ability to achieve the targets for PCBs in fish.

Response

Commenters' assertion that there has been minimal recovery of surface sediment PCB concentrations is based on data from only two monitoring periods: 2016/2017 and 2021. The OM&M program is explicitly designed to assess long-term trends over a 10-year period to account for the year-to-year variations. Additional data from the next scheduled monitoring in 2026 will be essential to determine the progress of recovery; therefore, it is premature to assess surface sediment concentration trends at this time. EPA anticipated that overall conclusions about sediment recovery may not be able to be made after only two sampling events spanning 5 years.

EPA remains committed to assessing sediment and fish PCB concentrations and will integrate the findings from the ongoing OM&M program with additional lines of evidence to comprehensively evaluate remedy performance. Refer to the findings of the moving window analysis in Section 5.1.7 of this FYR and responses to Comment 7a for further details on the importance of long-term data and the statistical basis for EPA's approach.

2.2.7 Comment 7c: Fish recoveries vary by species and confounded by lipids

Comment

Commenters expressed concern about the apparent lack of recovery in the post-dredging fish tissue PCB concentrations, particularly when evaluated on a lipid-normalized basis. Two of the four fish species monitored (yellow perch and yearling pumpkinseed) show little to no recovery post-dredging on a wet weight or lipid-normalized basis. The other two species (black bass and bullhead) show evidence of a decline in some reaches on a wet weight basis, but much lower to no decline on a lipid-normalized basis. Commenters asserted that the apparent decline in tissue PCB concentrations for these two species is due to declining lipid levels, and therefore cannot continue to trend downward, as there are currently very low lipid concentrations in bass and bullhead with little room for further declines in lipid content. Additionally, high lipid measurement errors for black bass, bullhead and yellow perch (>15% error) and temporal fluctuations in lipid can introduce further uncertainty into trend estimates.

Commenters mentioned that the rate of decline to date in total PCB tissue concentrations is not sufficient to meet the ROD's long-term fish tissue PCB targets. Commenters emphasized the need for EPA to better address confounding factors in evaluating the rate of recovery and provide a clearer assessment of recovery progress.

Response

The commenters' assessment that fish tissue rates are declining slowly or not at all (when lipid-normalized data are evaluated) is based on only six years of data. As outlined in EPA's response to Comment 7a, a minimum of eight or more years of data is necessary to account for year-to-year variations and to establish reliable recovery trends. Short duration datasets could produce inaccurate conclusions. EPA has observed variability in recovery rates across species and River Sections and is designing special studies to help understand these differences. This variability highlights the inherent complexity of evaluating PCB recovery in fish populations, further emphasizing the need for long-term data and the consideration of multiple factors influencing fish recovery rates. It should be noted that although certain species of fish appear to have minimal to no recovery, there are species that appear to have declined since dredging ended. This is different for different species at different locations.

EPA acknowledges the importance of considering lipid content in accurately assessing post-dredging rates of decline in fish tissue PCB concentrations, as it helps distinguish between changes driven by exposure reduction and those influenced by fluctuations in lipid content. However, as discussed in the response to Comment 5, the lipid-normalization approach has limitations. In addition, various uncontrollable factors such as age, sex, size, gill surface area, habitat, temperature variations and flow can influence fish PCB levels from year to year. These inherent and significant variabilities mean that, even with sufficient data for trend analysis, long-term rates of decline are likely to fluctuate. It appears one commenter used an average lipid content in fish to draw conclusions about the lack of recovery; such an approach may not be detailed enough for this site given, in part, the low level and nonlinear nature of the data.

EPA is exploring advanced approaches to address lipid measurement error, lipid within-year variability, lipid temporal trend and other confounding factors in recovery assessments. These approaches aim to provide a more comprehensive understanding of recovery dynamics. This may include the collection of additional parameters as outlined in the fish special studies described in Section 6.1 of this FYR. The results from EPA's evaluation will be included in the FYR addendum to be published no later than 2027.

2.3 Risks not evaluated sufficiently

2.3.1 Comment 6a: Fish are not meeting ROD targets - Human health

Comment

Commenters expressed concerns that the fish are not meeting the targets outlined in the 2002 ROD. Commenters stated that the observed recovery rates are inconsistent with the expectations and modeling presented in the ROD. The first interim target for PCB concentrations in fish (0.4 mg/kg), which should have been reached five years after dredging, has not been met. Additionally, the post-dredging sediment recovery rates are insufficient to allow the ongoing natural recovery in fish to reach the second preliminary remediation target of 0.2 mg/kg of PCB in fish within 16 years after dredging completion. Due to the slow recovery, human health risks remain above acceptable levels, posing a continued threat. PCB levels in the Upper Hudson River are not declining at the anticipated rate, jeopardizing the long-term health of the human populations. The commenters argued that EPA must acknowledge the unmet targets, reassess the situation, and take necessary steps to ensure the effectiveness of the remediation.

Some commenters indicated the ROD does not describe gradual improvement over more than five decades. Instead, the ROD specifically identified two targeted fish PCB concentrations, intended to represent when NYSDEC may consider reducing fish consumption advisories.

Response

The remedial action was implemented consistent with the expectations of the ROD as discussed in the 2nd FYR (Section 5.1.1.2 and Appendices 8 and 9 of the 2nd Five Year Review, EPA 2019a), and while human health goals have not yet been achieved, progress is being made toward the RAOs presented in the ROD. As discussed in Section 5.1, EPA acknowledges that the first target was not achieved within the five-year time period, however, overall concentrations are declining and are approaching the first target. As discussed in Section 5.1 and Comment 7a, EPA needs additional years of data before a rate of decline can be calculated, at which time EPA can determine when the 1st and 2nd targets are expected to be reached and if they are reasonably within expectations of the ROD. As discussed in Comments 5, 7a, and 7c, this evaluation will be comprehensive and include evaluation on a species and reach level, in addition to the overall species-weighted-average concentration. For further details, refer to Comment 7a on the importance of long-term data to reduce variability and improve trend accuracy, Comment 7b on the sediment recovery, and Comment 7c on the fish recovery.

As discussed in the Second FYR Comment Responses, EPA stated that the remediation goal for protection of human health with regard to fish consumption was attainment of 0.05 mg/kg in fish fillet (species-weighted average concentration) in fish of the Upper Hudson. As indicated in the ROD, the interim target levels of 0.4 and 0.2 mg/kg are not remediation goals but interim targets to be achieved along the way to the final remediation goal, the achievement of which could be used by the State as a basis to reevaluate the fish advisories and potentially relax some fishing restrictions. The modeling conducted by EPA and discussed in the ROD projected that the 0.4 and 0.2 mg/kg interim targets would be achieved within 5 and 16 years, respectively. However, actual conditions during dredging did not, and were not expected to, match up in every way with conditions as understood when the ROD modeling was conducted. Therefore, direct comparisons of observed fish tissue concentrations to ROD forecasts need to be carefully considered. It should also be noted that dredging began later than the model contemplated. Also, short-term and localized increases and subsequent decreases in fish tissue PCB concentrations were anticipated in the FS and ROD (and observed between 2009 and 2016) but were not directly reflected in the long-term fish tissue forecasts presented in support of remedy selection. For these reasons, direct comparisons of observed data to ROD forecasts need to be done carefully with the various factors taken into consideration (EPA 2019b). Further, when looking at the targets more closely, they are specified not just for the entire UHR but also for each river section. Some of those timeframes are in the future and it is plausible they will be achieved. For example, the first target of 0.4 mg/kg are projected to occur in RS 1 and 2 about 15 years after dredging. It is also important to note that the second target for the whole upper river was anticipated to also occur in the future (16 years after dredging).

EPA will continue to use the interim targets to track progress toward the remediation goal. At this time, EPA does not have sufficient data to determine if the various interim targets will be achieved within EPA's expectations. As stated above, as EPA obtains more years of fish data, the Agency will be better able to assess progress toward the interim targets and the final remediation goal.

Natural recovery is ongoing within the UHR, and these processes are expected to result in the river eventually reaching the long-term remediation goal for the protection of human health with regard to fish consumption (0.05 mg/kg PCBs in species-weighted fish fillet). EPA acknowledged in the ROD that the consumption advisories are not fully effective in that they rely on voluntary compliance in order to prevent or limit fish consumption. EPA will continue to work with New York State (NYS) to ensure the ongoing maximum effectiveness of the advisories including supporting the project outreach program.

EPA disagrees with the statement that the ROD does not describe gradual improvement over more than five decades and only focuses on the two targeted fish PCB concentrations. In Table 11-2 of the ROD, the Species-Weighted Fish Fillet Average PCB Concentration (mg/kg) is projected through the year 2067 and shows gradual improvement over time.

2.3.2 Comment 6b: Fish are not meeting ROD targets - Ecological targets

Comment

Commenters are concerned with the ecological risks still present in the Upper Hudson River. Commenters noted that despite dredging efforts, ecological risks remain significantly above EPA's acceptable risk ranges and are projected to persist for the foreseeable future. Commenters are concerned that little progress has been made in approaching or attaining RAOs for river otter and mink.

Commenters stated that there is limited data available for evaluating ecological risk. While EPA plans to collect additional data on spottail shiner, this approach is time-consuming and may not provide sufficient information for a timely assessment. Alternatively, existing data on pumpkinseed, a common forage fish, could be used to evaluate ecological risk more promptly. Pumpkinseed data is readily available and can provide valuable insights into the current state of contamination and the effectiveness of the dredging project. Additionally, one commenter suggested that ecological receptors should be compared to the recalculated risk-based goal of 0.2 to 0.07 mg/kg wet weight in largemouth bass for river otter and 0.34 to 0.11 mg/kg wet weight in spottail shiner for mink.

Response

The remedial action was implemented consistent with the expectations of the ROD, and while ecological goals have not yet been achieved, progress is being made toward RAOs presented in the ROD. At this time, EPA does not have sufficient data to determine if the RAOs will be achieved within EPA's expectations. As EPA obtains more years of fish data, the Agency will be better able to assess progress toward the remediation goals and the anticipated timeframes for achieving them.

EPA is planning to implement several special studies that will provide insights into the progress towards the achievement of the RAOs. The 2002 ROD specifies two targets for protection of ecological resources: 1) largemouth bass based on a whole-body largemouth bass of the size range typically consumed by river otter (4 to 7 inches), and 2) spottail shiner as representative of forage fish of the size range typically consumed by mink (less than 4 in in length). During the post-dredging period, largemouth bass samples of a size larger than typically consumed by river otter have been analyzed on a fillet basis. EPA identified the lack of PCB data on appropriately sized whole-body largemouth bass as a data gap. To address this data gap, EPA is planning to have whole-body largemouth bass that is representative of the size targeted by river otter collected in 2025. This data will provide information on the risk exposure for river otter and allow for an evaluation of time trends in estimated PCB concentrations.

Additionally, during the post-dredging period, the sampling program has focused on collection of a variety of forage fish species, including spottail shiner. EPA modified the forage fish collection program in 2021 to focus solely on spottail shiner. This is intended to reduce uncertainty in time trends (e.g., avoids uncertainty introduced by combining different species) and a direct comparison to the ROD RAO can be made. The frequency of spottail shiner collection will be implemented such that time trends can be further established.

To address comments regarding pumpkinseed fish use in risk evaluation, pumpkinseed PCB concentrations were compared to spottail shiner ecological risk target values. Comparing pumpkinseed to spottail shiner ROD ecological targets is a logical approach, especially considering the limited spottail shiner data and that pumpkinseed is a forage fish consumed by mink. It should be noted that spottail shiner is the species that is referenced in the ROD RAO. Therefore, spottail shiner concentrations are the basis for determining whether the respective ROD

RAO is achieved and whether progress is being made toward achieving the RAO (EPA 2002). Appendix 3 of this FYR has been updated and Figure A3-8 shows the comparison of pumpkinseed to the ROD ecological targets for spottail shiner. In the post-dredging period, approximately 27 percent of pumpkinseed data are below the 0.7 mg/kg-ww criterion and no results are below the 0.07 mg/kg-ww criterion.

Additionally, in Appendix 3 of the FYR, Figure A3-9B compares spottail shiner results to both the ROD Ecological Risk Target PCB Concentrations (0.7 to 0.07 mg/kg-ww) and the Refined Ecological Risk Target PCB Concentrations (0.34 to 0.11 mg/kg-ww). Figure A3-10 compares largemouth bass results to both the ROD Ecological Risk Target PCB Concentrations (0.3 to 0.03 mg/kg-ww) and the Refined Ecological Risk Target PCB Concentrations (0.2 mg/kg-ww to 0.07 mg/kg-ww).

2.3.3 Comment 12: Human health and ecological risks associated with exposure to PCBs

Comment

Commenters questioned the toxicity values for PCBs for both human health and ecological receptors. They also stated that fish ingestion rates incorporated in the human health risk assessment may be outdated and need to be updated. Some commenters requested that EPA identify PCBs as probable human carcinogens and evaluate the current associated health risks. A few commenters requested EPA assess risks related to the use of the Hudson River for drinking water.

a. Commenters indicated that toxicity values for PCBs for both human health and ecological receptors may be outdated. Commenters contend EPA should update the Integrated Risk Information System (IRIS) database to include recent data on PCB toxicity and update the human health risk assessment based on updated information in IRIS for dioxin-like PCBs and potential risks from inhalation. Commenters noted EPA classifies PCBs as probable human carcinogens, while the International Agency for Research on Cancer (IARC) has listed PCBs as a known human carcinogen since 2013. Commenters asserted that EPA should also discuss the updates to mammalian toxic equivalency factors (TEFs) for the ecological risk assessment (Van den Berg 2006; DeVito et al. 2024) relative to mink and river otter target levels and updates to fish TEFs (Doering et al. 2023).

b. Commenters focused on the fish ingestion rates incorporated in the human health risk assessment with specific reference to fish consumption rates for subsistence versus recreational anglers. Commenters questioned if the reasonable maximum exposure (RME) scenario is representative of subsistence anglers and if updated consumption rates are based on National Cancer Institute methods.

c. Commentors noted that the Hudson River serves as a drinking water source and requested more information on applicable or relevant and appropriate requirements (ARARs) for both drinking and surface water.

d. Commenter stated the FYR should include the current health risks. Another commenter focused on an apparent lack of decline in fish and surface sediments leading to potential continued elevated human health and ecological risks.

Response

a. Under EPA Risk Assessment Guidance, toxicity values for human health risk assessments are based on Agency consensus as provided in the IRIS database. IRIS database updates are based on an established Agency process as described on the IRIS website (https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process). Toxicity values for PCBs as published in the EPA IRIS database have not changed since the Human Health Risk Assessment (HHRA). However, as noted in Section 6.2.1 of this FYR, EPA IRIS is in the process of updating its assessment for PCBs and once this update is finalized, EPA will evaluate any impacts to the risk assessment as part of a future FYR. As noted by a commenter, IARC (International Agency for Research on Cancer) has listed PCBs as a "known carcinogen." The designation of cancer or non-cancer risk does not impact the risk assessment or the calculation of clean-up goals. Furthermore, IARC does not calculate toxicity values, and is therefore not useful for decision making (e.g., there would be no risk calculated based on IARC because there are no calculated toxicity values).

   EPA included an evaluation of dioxin-like congeners in the Revised HHRA and further evaluated the dioxin-like congeners, including the revised TEF values and dioxin-like congener ratios in Appendix 5 of this FYR. EPA concluded the risks of dioxin-like congeners are comparable to those from Total PCBs, indicating the dioxin-like PCBs do not enhance the risks from Total PCB exposure (EPA 2000).

   As described in the Revised HHRA and summarized in Appendix 5 of this FYR, cancer risks from being exposed to PCBs through inhalation of PCBs in air were evaluated and below USEPA's levels of concern. Furthermore, IARC does not calculate toxicity values, and is therefore not useful for decision making (e.g., there would be no risk calculated based on IARC because there are no calculated toxicity values).

b. As discussed in Comment 6 of the Second FYR Comment Responses, when the ROD was developed, various consumption surveys were taken into consideration to identify consumption patterns and quantities for the risk assessment (EPA 2019b). The 1991 New

York Angler survey (Connelly et. al., 1992) was used in the development of the exposure assessments and in identifying species consumed. The Connelly survey was selected because the climate and characteristics of the New York water bodies in that study were more likely to represent Hudson River anglers than non-New York surveys. While it is understood that consumption patterns may change over time, EPA was able to assess the need to update the risk calculations based on the information currently in hand. An update to the consumption survey is not expected to increase the outcome of the risk calculations because risks are determined for the RME individual and the assumptions in the risk assessment remain appropriate and representative. The consumption rates utilized in the risk assessment for the RME individual are consistent with consumption rates used for other sites in EPA Region 2.

EPA reviewed the assumptions that were used as inputs to the risk assessment as part of this FYR, including those associated with consumption such as the species consumed. As discussed in the response to Question B in this FYR, the exposure assumptions, toxicity data, cleanup levels and RAOs used at the time of the remedy remain valid. The consideration of specific populations of fish as a food source from the river does not affect the calculation of risks for the RME individual. It does, however, highlight an opportunity for additional/updated outreach efforts to inform the public about the advisories.

c. The federal drinking water maximum contaminant level (MCL) for PCBs is 500 ng/l. Surface water samples collected from the Hudson River are consistently significantly below this threshold. Additional details about the water column concentrations can be found in Appendix 1 of this FYR.

d. The calculation of current health risks is not necessary or appropriate for this FYR. The ROD identified that there was an unacceptable risk and set clean-up goals to address that risk. As discussed in the response to Question B in this FYR, the exposure assumptions, toxicity data, cleanup levels and RAOs used at the time of the remedy are still valid. Calculation of current risks would not impact the ROD goals.

2.4 Remaining PCBs and their importance

2.4.1 Comment 2: Additional in-river work is necessary

Comment

Commenters questioned whether the cleanup levels selected in the ROD were inadequate and consequently led to the ineffectiveness of the remedy. Commenters request EPA to start the "Remedy Optimization" process and to collect data necessary for evaluating additional remedial actions, specifically contaminated areas that are causing increased fish, sediment and water PCB levels. Some commenters asked EPA to consider the dredging criteria (cleanup levels) used in RS1 for additional dredging in areas in RS 2 and RS 3. They contend that areas of elevated PCB concentrations in non-dredge areas of the river bottom in RS 2 and RS 3 could continue to contaminate the water column and fish.

Response

Statements regarding the lack of effectiveness of the remedy and the adequacy of the selected cleanup levels are premature and may not be relevant. As discussed in this FYR, there are not enough sets of annual data available since the completion of dredging to establish reliable rates of PCB contamination decline in fish. Statistical confidence is a necessary consideration when evaluating the effectiveness of the recovery. As discussed in this FYR, EPA has identified that areas with elevated PCBs could contribute to localized delays in recovery (Issue 3, Section VI of this FYR). EPA has determined that special studies are necessary to further evaluate these areas. Development of special study work plans are underway and expected to be completed in the 2025 – 2026 timeframe.

The purpose of the sediment removal program in the ROD was to reduce surface sediment concentrations and sediment inventory to reduce fish tissue concentrations. EPA evaluated both mass reduction and surface sediment reduction in the second FYR. EPA has estimated that 76 percent of the overall PCB mass from the UHR was removed by the dredging, exceeding the 65 percent reduction from dredging assumed in the ROD. The reduction in surface sediment concentrations is also within expectations in the ROD with percent reductions of 96 percent, 88 percent, and 80 percent for RS 1, RS 2 and RS 3 respectively; compared to the ROD estimate of 79 percent, 64 percent and 4.4 percent reduction for RS 1, RS 2 and RS 3, respectively (EPA 2012, 2019a).

Regarding the use of RS 1 dredge criteria for RS 2 and RS 3, EPA received similar comments in 2019 and responded to those comments (see comments 40, 47 and 58) in the Second FYR Comment Response document (EPA 2019b). As stated in the Second FYR Comment Response document, EPA agreed that more PCBs were identified and dredged than originally anticipated but disagreed with the contention that an adjustment to RS 2 and RS 3 clean up levels was needed in the remedial design to address the additional PCB inventory. The higher spatial and vertical resolution of the Sediment Sampling and Analysis Program (SSAP) dataset identified more PCB inventory and higher surface concentrations than originally anticipated in the ROD. The practical significance of the pre-design SSAP and ROD-based model concentrations difference was carefully and extensively considered and addressed in the Second FYR.

2.4.2 Comment 4a: The ROD forecast should be revised if the model assumptions are not being met- Re-evaluate ROD assumptions

Comment

Commenters assert that the ROD model might have substantially underestimated the PCB mass in pre-dredging sediment and consequently overestimated the reduction of post-dredging surface sediment and fish concentrations. Commenters also suggested that the post-dredging data show a slower-than-expected recovery, and that EPA should gather data as needed to determine whether the assumptions made between the remaining contaminated sediment and recovery in fish PCB concentrations are still valid and whether additional remediation is needed.

Response

EPA agrees there were more PCBs in the river sediment than originally estimated in the ROD; however, overall percentage PCB mass removed exceeded the ROD estimates. Overall, 76 percent of the PCB mass was removed from the Upper Hudson River, which exceeds the 65 percent removal assumed in the ROD. In addition, the goal of the sediment removal program was a percent reduction in surface sediment concentrations through removal of sediment inventory with the intention of reducing fish tissue concentrations. In other words, the fish tissue concentrations are directly linked to the surface sediment concentrations and not the total PCB inventory remaining. The reduction in surface sediment concentrations is within expectations of the ROD with percent reductions of 96, 88 and 80 percent for RS 1, RS 2 and RS 3 respectively; compared to the ROD estimate of 79, 64 and 4.4 percent reduction for RS 1, RS 2 and RS 3, respectively (EPA 2012, 2019a). Additionally, the overall amount (mass) of PCBs remaining in the river after dredging compared to the ROD estimates was slightly greater but within expectations (within less than 10% difference).

Statements regarding the effectiveness of the remedy are premature at this time. As discussed in this FYR, there are not enough sets of annual data available since the completion of dredging to establish rates of decline in fish, water or sediment with statistical confidence, which is a critical component to evaluating remedy effectiveness. Because the OM&M program is explicitly designed to assess long-term trends over a 10-year period (three rounds of sampling) to account for year-to-year variation, estimating the rate of recovery for surficial sediment PCB concentrations based on only two rounds of sampling from 2016/17 and 2021 and would be technically unjustifiable.

The ongoing collection and analysis of post-remedy sediment, surface water and fish data will be coupled with the special studies recommended in this FYR to further evaluate localized areas of elevated PCBs in sediments and associated potential impacts on uneven fish recovery. These activities will help inform EPA's understanding of sediment and fish recovery and support any additional recommendations regarding remedy performance, including any resulting refinement of the system understanding (i.e., the conceptual site model).

2.4.3 Comment 4b: The ROD forecast should be revised if the model assumptions are not being met - high-flow events and their relationship to the recovery of the river

Comment

Commenters noted EPA's statement that due to climate change, the higher frequency, magnitude and duration of high flow events could impact some of the mechanisms associated with MNR and asserted that EPA should compare the frequency, magnitude and duration of high flow events post-dredging to the framework used in the modeling to estimate the rate of natural recovery.

Response

Appendix 10 discusses potential impacts associated with climate change. Although the climate explorer indicates a likelihood of more intense rainstorms in the future, there is insufficient data to determine how this may affect river flows in the Hudson. The ROD model was never intended to accurately predict the natural recovery rate post dredging. Therefore, comparing the post-dredging frequency, magnitude, and duration of the high flow events to the ROD model forecast is not appropriate. As EPA stated in Section 2.6 of the Third FYR, "At this time, there is insufficient information to assess how climate change may affect these mechanisms as well as any potential impact, positive or negative, to the remedy. Long-term monitoring at the Site will continue as EPA assesses the effectiveness of the remedy. Monitoring data will be evaluated on a regular basis and special studies developed as needed to assess any potential climate impacts and results included in subsequent FYRs."

EPA recognizes the potential importance of high-flow events for system recovery. EPA has used and will continue to use robust statistical analysis that considers the variability in Hudson River flows and seasonality in order to account for the impact of high-flow events on the recovery of the river. EPA also recognizes the potential importance of high-flow events for PCB resuspension and downstream transport. EPA designed a sampling program as part of the OM&M program to better characterize time-varying water-column PCB concentrations associated with high-flow events of various intensities and across different seasons. The Third FYR specifically notes that high-flow sampling is an important component, along with routine sampling, to inform the relationship between flow and PCB concentration within a given year and to estimate PCB load to the Lower Hudson River. As discussed in Comment 14 of the Second FYR Comment Response document (EPA, 2019b), concerns remain about the potential impact of high-flow events on PCB loading to the Lower Hudson River. Continued sampling is necessary to further characterize these events.

In this Third FYR, EPA analysis also shows that under high-flow conditions, post-dredging PCB loads transported in the river are much lower than corresponding pre-dredging loads, and the FTN PCB flux to the Lower Hudson River is decreasing. EPA will continue using the sampling results from the high-flow event sampling to determine robust estimates for the PCB loads that are transported to the Lower Hudson River each year. In further support of those efforts, EPA has proposed a special study to collect water samples at Rogers Island during high-flow events to better understand the impact of high flows on upstream PCB load entering OU2. Combining this information with routine sampling events and the ongoing high-flow sampling events at stations located downstream (i.e., Schuylerville and Waterford, New York) will improve EPA's understanding of the impact of high-flow events across the entire OU2 reach with respect to the factors that contribute to PCB load gains and the influence this may have on MNR rates.

2.4.4 Comment 8: Remaining PCBs in river

Comment

Commenters expressed concern that significantly more PCBs remain in the river sediment post-dredging than estimated in the 2002 ROD based on various factors, including underestimation of initial PCB mass. Commenters emphasized the need for a discussion about the uncertainty surrounding the remaining PCB mass and pointed out that the EPA has claimed the remedial action did not leave behind more PCBs than estimated in the 2002 ROD. Commenters highlighted the significant bioavailable PCB mass left behind in the surface sediments, especially in the non-dredged areas. Commenters contend the remaining PCBs in the surface sediment continue to impact fish contamination levels, limiting the ability to achieve target reductions in fish PCB concentrations. Commenters attributed the higher remaining PCB mass to the less stringent cleanup levels applied in in RS 2 and RS 3. Commenters emphasized that the success of the remedy does not depend on the percentage of PCB mass removed, but the magnitude and spatial extent of PCB mass left behind.

Response

The purpose of the sediment removal program in the ROD was to reduce surface sediment concentrations and sediment inventory to reduce fish tissue concentrations. In other words, the primary goal was not to reach a pre-determined sediment concentration or PCB mass, but rather to achieve a sufficient reduction in sediment concentrations to yield a reduction in fish tissue concentration. As stated in response to Comment 47 in the Second FYR, in the Upper Hudson River the PCBs in fish tissue are driven by PCBs in the water column (both dissolved PCBs and PCBs bound to suspended solids) and PCBs in the upper few inches of the sediment bed (EPA, 2019b). These two compartments of PCBs directly affect long-term trends in fish tissue PCB concentrations, and it is these PCB sources - and not the total PCB inventory remaining - that are the best indicators of fish exposure to PCBs. Although EPA defined surface sediment as the top 12 inches to target the dredge areas, EPA believes that a reasonable estimate of the average depth of the biologically active zone is the top 10–15 cm (4–6 inches). EPA has consistently indicated that the biologically active zone is approximately 10 cm and perhaps as great as 15 cm [6 in] deep

(EPA, 2002). In addition, modeling conducted in support of the ROD assumed that it is predominantly the PCBs present in the top 5 cm [2 inches] of the sediment that have the greatest influence on the food chain in the upper Hudson River (EPA, 2002), which was supported by pilot samples taken during the field reconnaissance in the 1990s (EPA, 2000). It is, therefore, the relative change to the 0–2-inch layer of sediment that is most important in evaluating dredging performance. The reduction in surface sediment concentrations is within expectations in the ROD with percent reduction of 96, 88 and 80 percent for RS 1, RS 2 and RS 3 respectively; compared to the ROD estimate of 79, 64 and 4.4 percent reduction for RS 1, RS 2 and RS 3, respectively (EPA 2012, 2019a).

The commenters asserted that more mass was left behind than anticipated. EPA presented calculations of mass remaining in the river, including the uncertainty, in Appendix 2 of the Second FYR report (EPA, 2019a). As described in Section 3.3 of Appendix 2 of the Second FYR report, unlike in the dredged areas, the volume of PCB-bearing sediment in the non-dredged (outside CUs) areas is less known. To estimate the PCB mass outside the CUs, the calculations integrate PCB mass on an area basis, based on the mass per unit area (MPA, g/m^2) results for cores collected outside the CUs. EPA presented two methods to estimate the PCB mass remaining in RSs 1, 2 and 3: 1) recovery correction was applied to all cores to address low sample recovery, and 2) no recovery correction was applied to cores. The first method accounts for uncertainty in the SSAP and Supplemental Engineering Data Collection (SEDC) cores and represents a likely upper bound of the mass of PCBs remaining in the Upper Hudson River. The second method represents a likely best estimate. EPA's best estimate (Method 2) of mass outside dredged areas was 41,000 kg and was only 9 percent more than the 37,500 kg of TPCB mass outside dredged areas as predicted in the 2002 ROD. Essentially, the current best estimate and the ROD prediction of PCB mass remaining in the river agree within error (EPA, 2019a). As discussed in the Second FYR, it is estimated that 76 percent of the overall PCB mass from the UHR was removed by the dredging, exceeding the 65 percent reduction assumed in the ROD.

Although EPA believes that the top 2 inches of surface are the most significant factor influencing the food chain in the upper Hudson River (EPA, 2002). EPA has calculated the percent reduction of the 0–12-inch surface sediment based on SSAP/SEDC cores due to remediation alone to further address the commenters concerns. Since not all the SSAP/SEDC cores were sectioned at 12 inches, length-weighted average (LWA) concentrations were calculated for the portion of core segments falling within 12 inches. Tables 8-1 and 8-2 show percent reduction due to remediation alone in the 0–12-inch sediment and 0–2-inch sediment, respectively. EPA's calculation showed that remediation reduced approximately 23 percent of the PCB concentrations in the 0–12-inch sediment and approximately 18 percent of those in the 0–2-inch sediment. This analysis shows that, in general, deeper sediments outside of the dredged areas tend to be less contaminated. Except for RS 3, the PCB concentrations in the 0–12-inch LWA are lower than those in the 0–2-inch. For example, in RS 1 cohesive sediment, average Tri+ PCB concentration in 0–12-inch was about 3 mg/kg, while the Tri+ PCB concentrations in the 0–2-inch was about 4 mg/kg (Tables 8-1 and 8-2, respectively). Based on this analysis, the remediation achieved a greater PCBs reduction from the 0–12-inch (23 percent) compared to the reduction in the 0–2-inch (18 percent). Additionally, the overall amount (mass) of PCBs remaining in the river after dredging compared to the ROD estimates was slightly greater but within expectations (within less than 10% difference).

Table 8-1 Area-Weighted Average Surface Concentrations (0-12- inch) Length-Weighted Average Percent Reduction based on SSAP Cores due to Remediation Alone

River Section	Sediment Type	River Bottom Area (acres)[1]		SSAP SEDC Data Remedial Design Area-Weighted Average 0-12 Length-Weighted Average Tri+ PCB Surface Concentrations2 (mg/kg)					Percent Reduction Due to Remediation Alone in 0-12 inch LWA
		Inside Dredge Boundaries	Outside Dredge Boundaries	Inside Dredge Boundary based on SSAP Cores Before Remediation	Inside Dredge Boundary After Remediation	Outside Dredge Boundary based on SSAP Cores	All Areas Before Remediation - Area Weighted Concentration	All Areas After Remediation - Area Weighted Concentration	SSAP SEDC Data Estimate
RS1	Cohesive	103	30	25	0.25	3.2	19.9	0.9	95%
	Non-cohesive	191	204	19	0.25	2.6	10.7	1.4	87%
		294	234				**13.0**	**1.3**	**90%**
RS2	Cohesive	56	77	36	0.25	6.8	19	4.0	79%
	Non-cohesive	25	305	29	0.25	6.2	8	5.8	28%
		81	382				**11**	**5.3**	**53%**
RS3	Cohesive Non-cohesive	98	3,262	13.3	0.25	4.6	4.9	4.5	7.8%
		98	3,262				**4.9**	**4.5**	**7.8%**
All River Sections All Sediment Types (Area-Weighted Average)									**22.7%**

Notes:

1. Area inside and outside dredge boundaries are based on GE Hudson dredge polygons intersected with 1992 side scan sonar coverage.

calculation is based on data only, it does not include an natural attenuation component.

Table 8-2 Area-Weighted Average Surface Concentrations (0-2- inch) Percent Reduction based on SSAP Cores due to Remediation Alone

River Section	Sediment Type	River Bottom Area (acres)[1]		SSAP Design Data Remedial Design Area-Weighted Average Tri+ PCB Surface Concentrations[2] (0-2 in) (mg/kg)					Percent Reduction Due to Remediation Alone in 0-2 inch
		Inside Dredge Boundaries	Outside Dredge Boundaries	Inside Dredge Boundary based on SSAP Cores Before Remediation	Inside Dredge Boundary After Remediation	Outside Dredge Boundary based on SSAP Cores	All Areas Before Remediation - Area Weighted Concentration	All Areas After Remediation - Area Weighted Concentration	SSAP SEDC Data Estimate
RS1	Cohesive	103	30	18	0.25	4.0	14.8	1.1	93%
	Non-cohesive	191	204	25	0.25	3.9	14.0	2.1	85%
		294	234				**14.2**	**1.9**	**87%**
RS2	Cohesive	56	77	20	0.25	7.9	13	4.7	64%
	Non-cohesive	25	305	29	0.25	8.8	10	8.1	21%
		81	382				**11**	**7.1**	**36%**
RS3	Cohesive Non-cohesive	98	3,262	5.8	0.25	3.2	3.3	3.1	4.9%
		98	3,262				**3.3**	**3.1**	**4.9%**
All River Sections All Sediment Types (Area-Weighted Average)									18.2%

Notes:

1. Area inside and outside dredge boundaries are based on GE Hudson dredge polygons intersected with 1992 side scan sonar coverage.

calculation is based on data only, it does not include an natural attenuation component.

3. This table is adapted from Table A4-5 of the Second FYR Report (EPA, 2019a)

2.4.5 Comment 9: Sediment monitoring (top 12 inches vs. 2 inches)

Comment

Commenters asserted that 0-2-inch sediment sampling substantially underestimates the mass of bioavailable PCBs, which affects EPA's ability to understand how PCB concentrations in sediment are continuing to impact PCB concentrations in fish, re-contaminating dredged areas, and contributing to loading in the Lower Hudson River. Commenters stated that the top 2-inch interval does not address the large PCB deposits documented in the bioavailable surface sediment (top 12 inches) in the areas surrounding the dredged areas in RS 2 and RS 3 during remedial design sampling. Furthermore, the 0-2-inch sediment sampling does not address the RAO on reducing the mass of PCBs in bioavailable sediments in the non-dredged areas through MNR. The shallower sampling depth underestimates the PCB-exposure potential to sediment-dwelling organisms, and those that consume them in their diet. Such sampling also prevents the comparison to target cleanup levels which were based on PCBs in the surface top 12 inches.

Commenters require that further monitoring for this site should include a broad representative sampling of the remaining bioavailable PCB contaminated sediments throughout the project area. Other commenters particularly asked EPA to include the collection of 0-12-inch samples in "areas of interest" and other non-dredged areas in RS 2 and RS 3. Such studies would be used to quantify the relationship between the remaining contaminated sediments and the trends in fish PCB concentrations.

Response

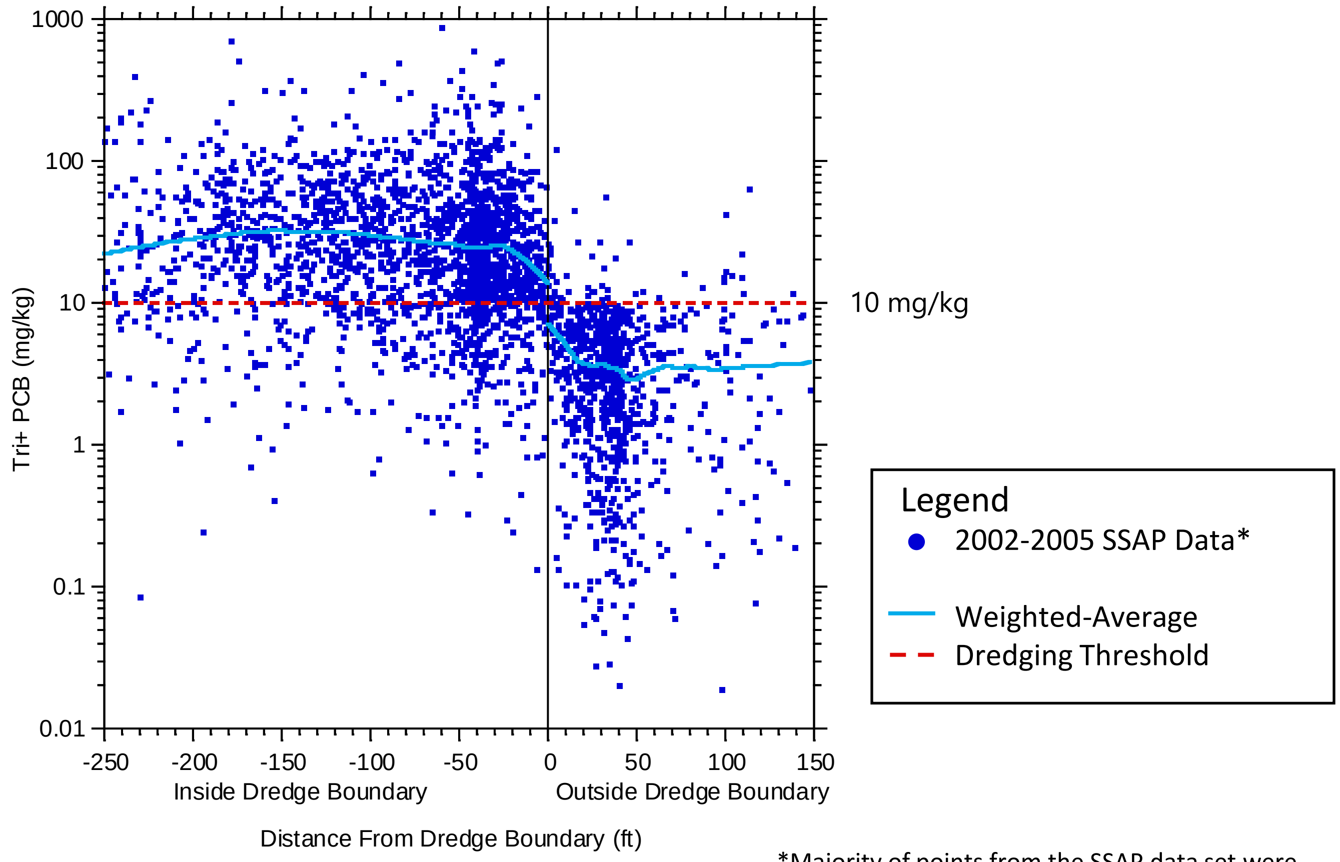
As stated in response to comment 47 in the Second FYR, in the Upper Hudson River, the PCBs in fish tissue are driven by PCBs in the water column (both dissolved PCBs and PCBs bound to suspended solids) and PCBs in the upper few inches of the sediment bed (EPA, 2019b). These two compartments of PCBs directly affect long-term trends in fish tissue PCB concentrations. Although EPA defined surface sediment as the top 12 inches for the purpose of dredge area delineation (EPA, 2006), EPA assumes that the most bioavailable PCBs in sediments are those lying at a depth up to 5 cm [2 in], but that a reduced level of bioavailability extends much deeper. This assumption is supported by the earlier Hudson River studies that found the 0–2-inch depth to be the most biologically active, although some organisms may go as deep as 12 inches (EPA 2000). In addition, fine-scale cores collected by GE in 1998 and segmented at 1 cm intervals over the top 5 cm [2 in] generally show little trend in concentration from 0 to 5 cm [0–2-in], consistent with efficient bioturbation of this zone (EPA, 2002).

The OM&M sediment sampling program focuses on monitoring this 0-2-inch zone, as it is most directly linked to fish PCB exposure. As stated in the Second FYR, understanding the rate of decline in the top two inches can also be used to estimate changes in the top foot of sediment based on relatively simple mixing calculations, so questions of exposure assessment can also be evaluated, albeit less precisely than with direct measurements of the top foot of the sediment bed (EPA, 2019a). Therefore, the commenters' suggestion about collecting 0-12-inch samples to be used to quantify the relationship between sediment and fish is not warranted. See also response to comment 11 for sediment, water and fish relationship. In addition, the OM&M sediment sampling program is based on a probability-based sample selection procedure that supports unbiased estimation of mean PCB concentrations for each river section, which considers both dredged and non-dredged areas. Hence, the sediment concentration in the "areas of interest" and other non-dredged areas in RS 2 and RS 3 can be examined from the OM&M sediment sampling results.

Commenters' concern about the presence of large PCB deposits identified in the bioavailable surface sediment (top 12 inches) in the areas surrounding the dredged areas in RS 2 and RS 3 during remedial design sampling is not supported by the SSAP data. In the Second FYR, EPA examined the variations of PCB inventory as a function of distance from the sampling location to the nearest dredged area boundaries (see comment 47 of the Second FYR, EPA 2019b). In that analysis, EPA examined PCB inventory by evaluating the maximum Tri+ PCB concentration in the top 12 inches of sediment and MPA data from the SSAP program. The results are shown in Figures 9-1 through 9-6 and discussed below. Note that in the remedial design, EPA specifically looked at two criteria for determining whether a location needed to be dredged: 1) a maximum top 12-inch interval Tri+ PCB concentration in excess of the dredging criteria of 10 mg/kg, 30 mg/kg and 30 mg/kg Tri+ PCB for RS 1, RS 2 and RS 3 respectively, and 2) a Tri+ PCB MPA value in excess of 3 g/m^2, 10 g/m^2 and 10 g/m^2 for RS 1, RS 2 and RS3 respectively. As part of applying these criteria, an adjustment was made where selected areas were allowed to remain undisturbed when the PCB inventory was buried below 12 inches or more of low-concentration sediments (less than 1 mg/kg). Figures 9-1, 9-2 and 9-3 show the results for maximum Tri+ PCB concentration, and Figures 9-4, 9-5 and 9-6 show the results for MPA data. These figures also display the threshold for removal for each river section as described above. The figures illustrate that for cores outside dredged areas in all three river sections, a very limited number of points were above the threshold for removal, confirming the successful selection of locations according to the criteria. Nearly all above-threshold locations, as well as a large number of below-threshold locations, were included in the dredged areas. GE was not required to "chase" isolated cores above the threshold, as this would likely have caused more sediment disturbance (a negative impact on the river ecosystem) with little positive gain from the removal of the isolated contaminated sediments. The orange dots shown in Figure 9-6 represent spatially isolated locations that met the "Select" criterion of an inventory greater than 10 g/m^2 underlying a minimum of 12 inches of surface sediment less than 1 mg/kg Total PCB, which were permitted to remain according to the ROD criteria.

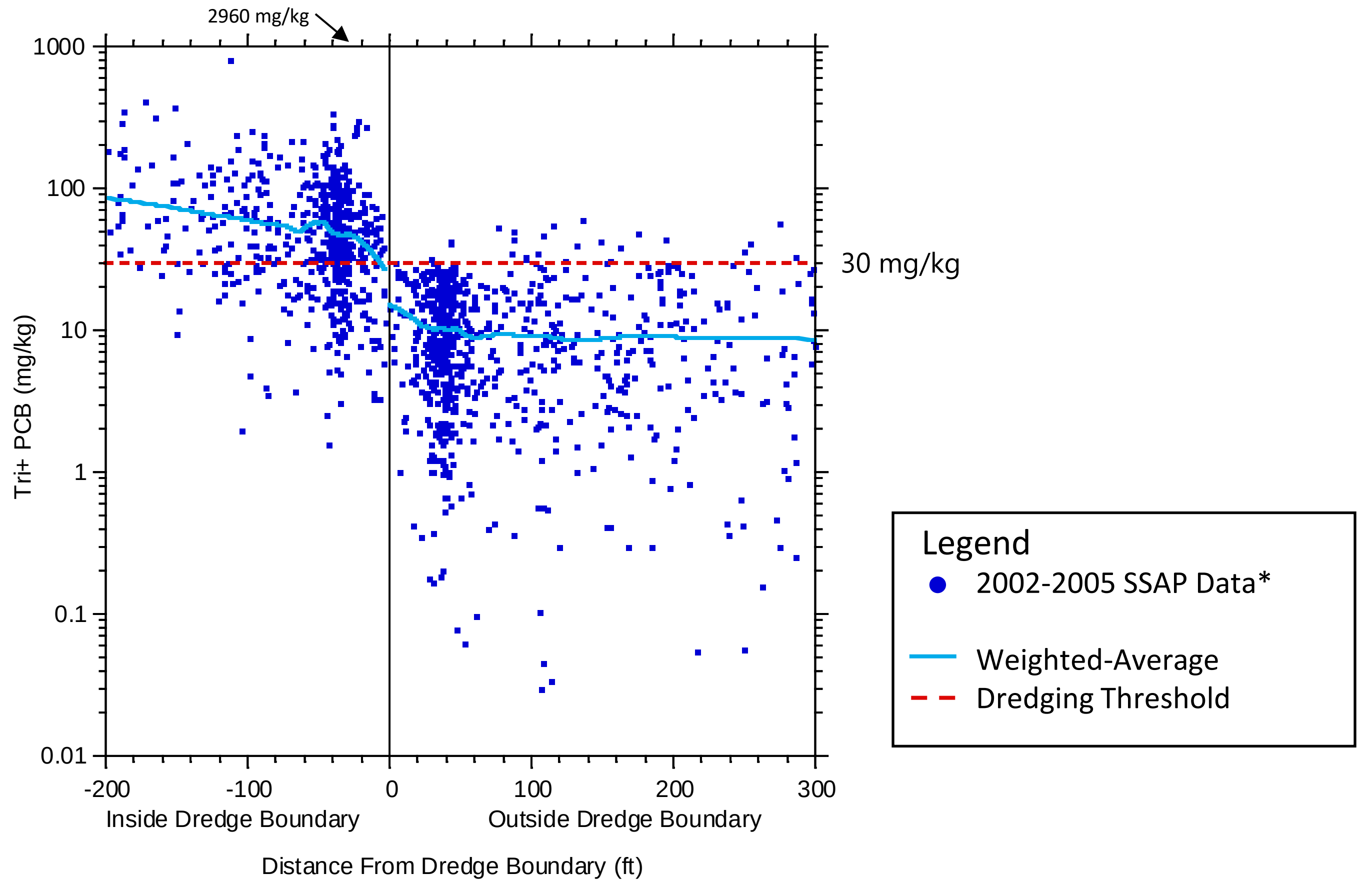
The weighted curves on these figures (blue lines) indicate that there is little variation in the PCB inventory from the dredging boundary out to the maximum distance values on the plot (150 ft in RS 1 and 300 ft in RS 2 and RS 3), indicating little gradient. These plots indicate that sediments close to the dredging boundaries are not particularly more contaminated than those located further away. Thus, these graphs indicate that finer-grained sediments close to the dredging boundaries are similar in average concentration to finer-grained sediments elsewhere in the river section, and a "donut" feature of high concentrations immediately proximate to the dredging boundaries as argued by the commenter(s) is not apparent. Fine-grained sediments have similar Tri+ PCB MPA value and maximum top 12-inch interval Tri+ PCB concentrations throughout each river section.

In conclusion, based on various studies previously done in the Upper Hudson River, the 0-2-inch sediment sampling is the appropriate metric to track the recovery of the sediment in the river as it is most directly linked to fish PCB exposure. In addition, the concern that high levels of contamination are found in the immediate vicinity of dredged areas is not borne out by the SSAP surface sediment (0-12 in) data. In addition to the considerations previously indicated, the value of better reproducibility and representativeness of taking samples of the top 2 inches using a box core (which grabs a larger area) than a 12 in deep core remains an important consideration for recent and future sampling.



*Majority of points from the SSAP data set were from 2002 to 2005, a small portion of the points were obtained in 2007 as a part of the SEDC sampling program.

	SSAP Maximum Sediment Tri+ PCB Concentration *vs.* Distance from Dredging Boundary River Section 1 2002-2005 (Maximum value in 0-12 in. interval)	Figure 9-1 January 2025

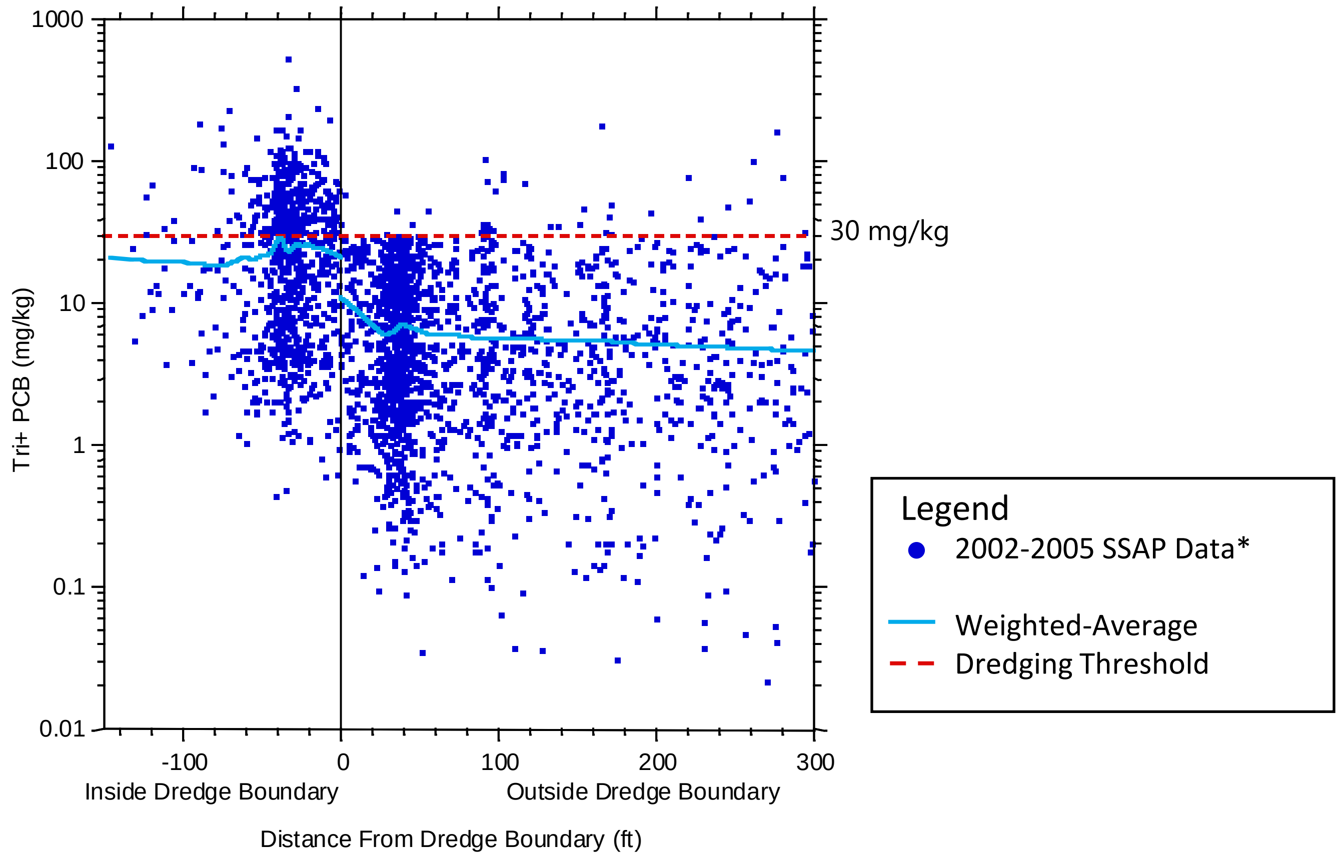


*Majority of points from the SSAP data set were from 2002 to 2005, a small portion of the points were obtained in 2007 as a part of the SEDC sampling program.

SSAP Maximum Sediment Tri+ PCB Concentration *vs.* Distance from Dredging Boundary
River Section 2
2002-2005 (Maximum value in 0-12 in. interval)

Figure 9-2

January 2025

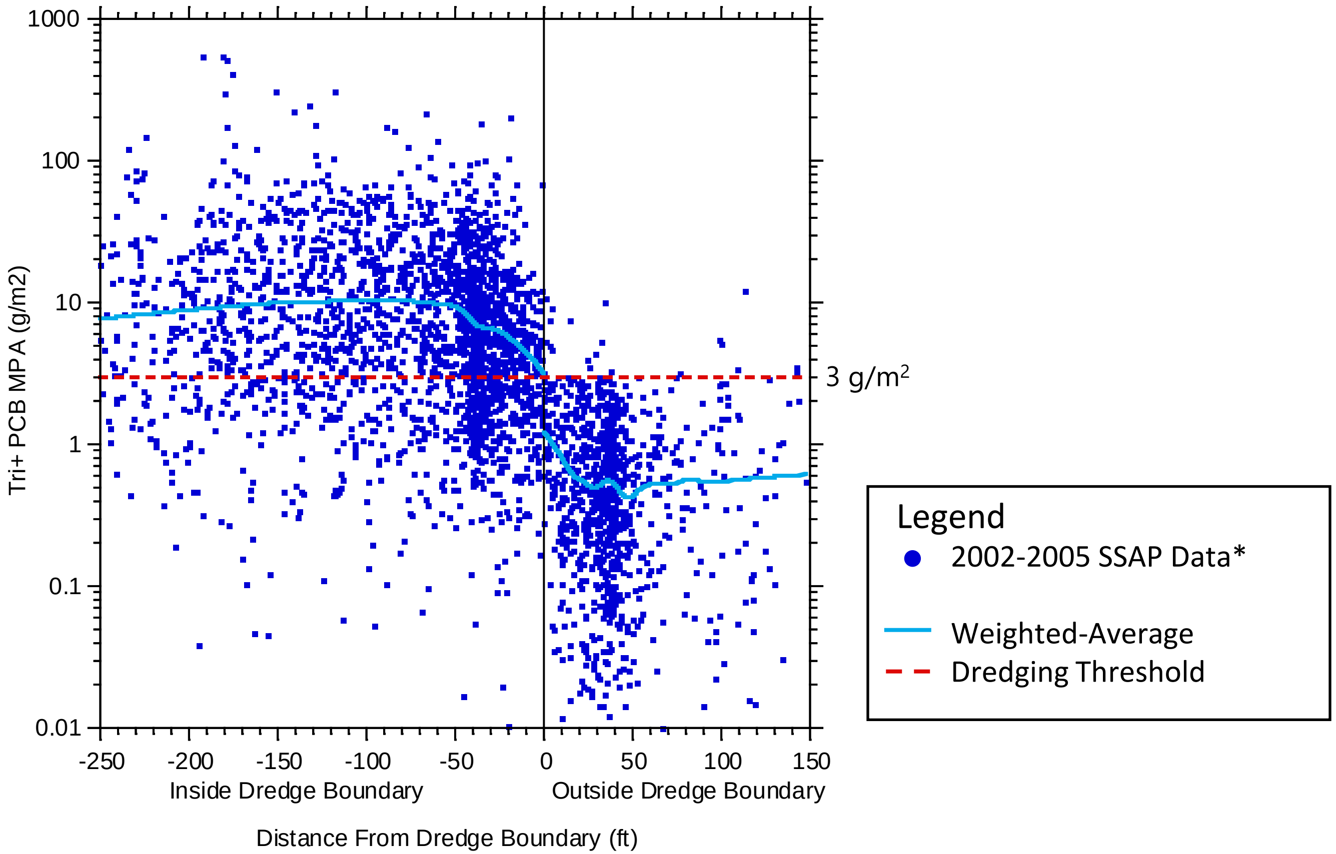


*Majority of points from the SSAP data set were from 2002 to 2005, a small portion of the points were obtained in 2007 as a part of the SEDC sampling program.

SSAP Maximum Sediment Tri+ PCB Concentration *vs.* Distance from Dredging Boundary
River Section 3
2002-2005 (Maximum value in 0-12 in. interval)

Figure 9-3

January 2025

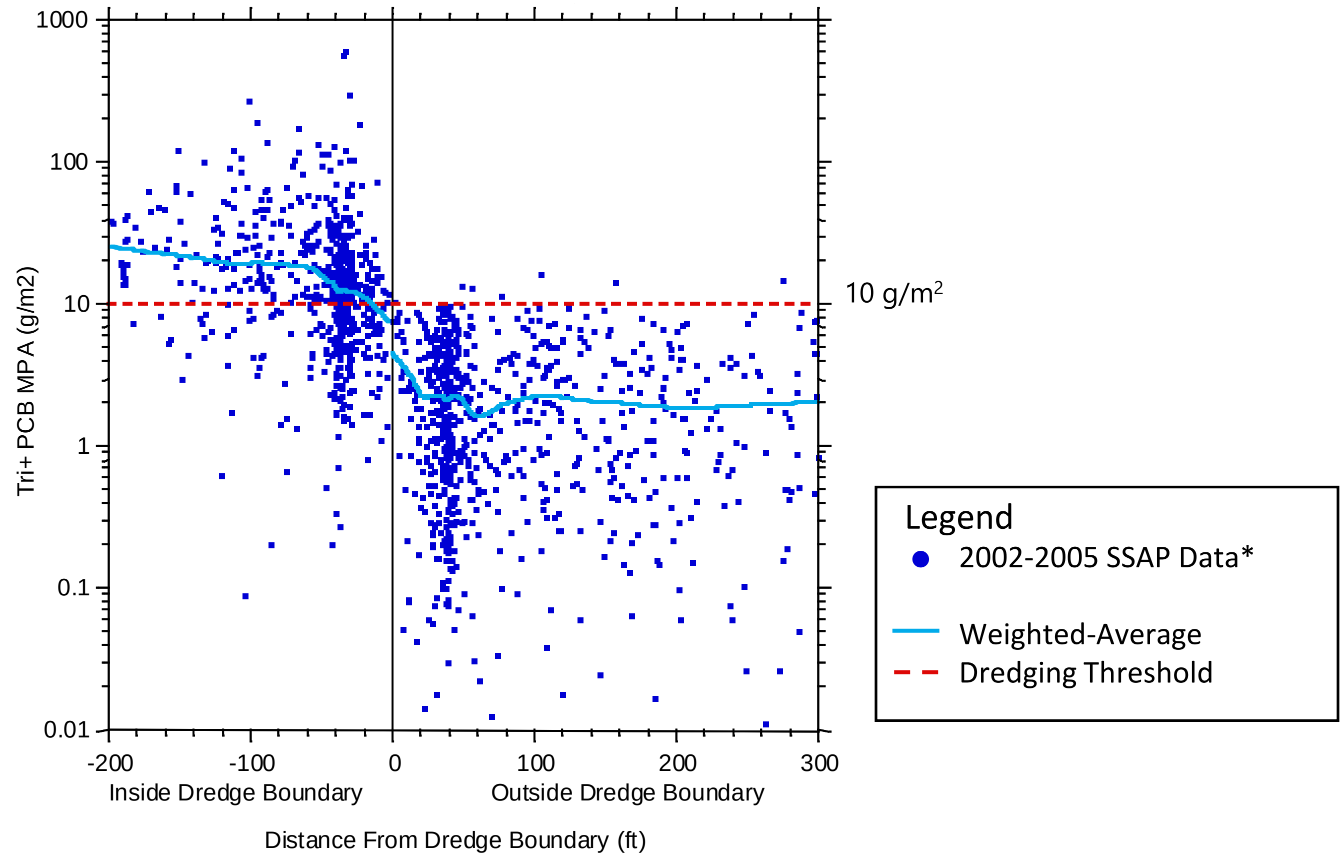


*Majority of points from the SSAP data set were from 2002 to 2005, a small portion of the points were obtained in 2007 as a part of the SEDC sampling program.

SSAP Tri+ PCB MPA *vs.* Distance from Dredging Boundary
River Section 1
2002-2005

Figure 9-4

January 2025

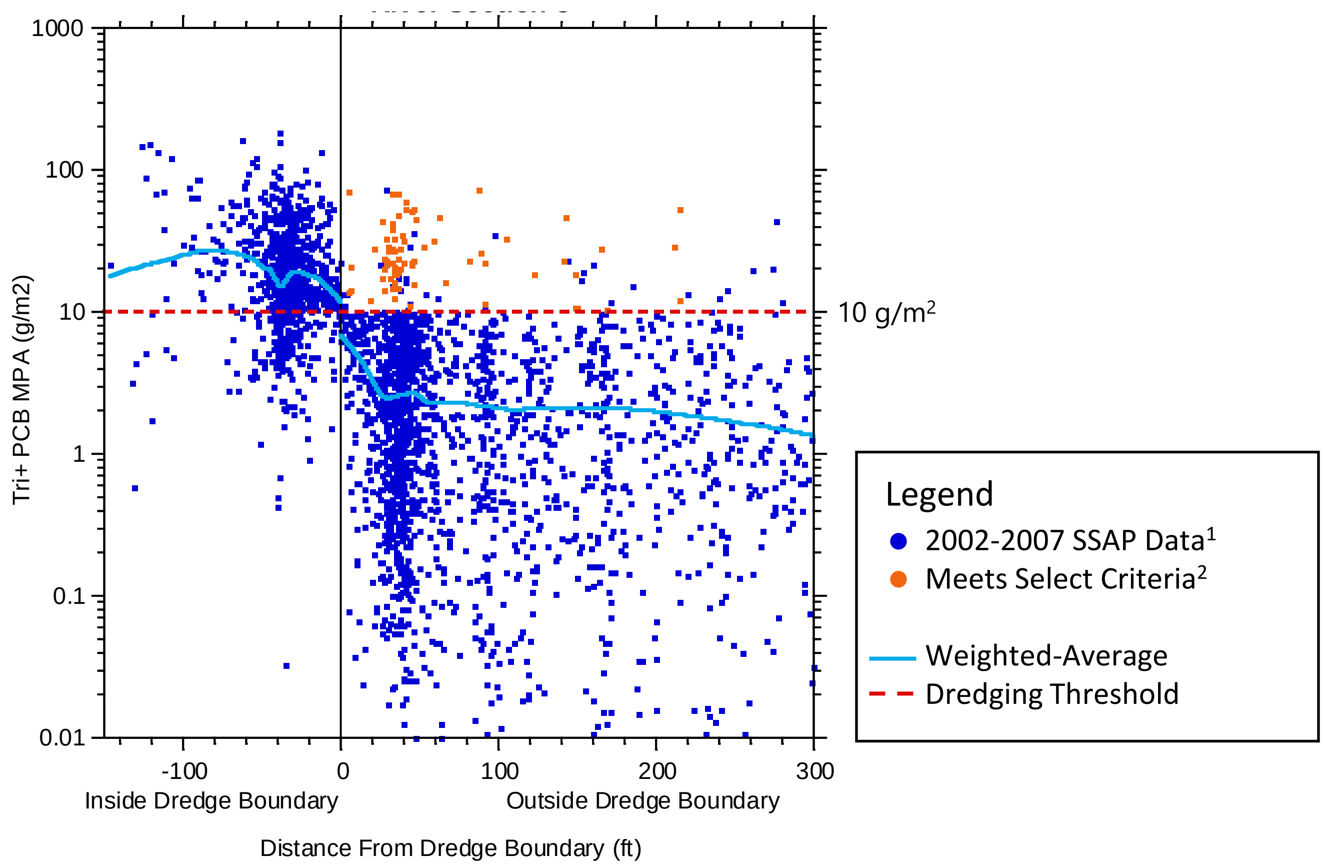


*Majority of points from the SSAP data set were from 2002 to 2005, a small portion of the points were obtained in 2007 as a part of the SEDC sampling program.

SSAP Tri+ PCB MPA *vs.* Distance from Dredging Boundary
River Section 2
2002-2005

Figure 9-5

January 2025



1. Majority of points from the SSAP data set were from 2002 to 2005, a small portion of the points were obtained in 2007 as a part of the SEDC sampling program.
2. The orange dots shown present spatially isolated locations that met the "Select" criterion of an inventory greater than 10 g/m^2 underlying a minimum of 12 inches of surface sediment less than 1 mg/kg Total PCB, which were permitted to remain according to the ROD criteria.

Hudson River PCBs Superfund Site; WSP	SSAP Tri+ PCB MPA *vs.* Distance from Dredging Boundary River Section 3 2002-2005	Figure 9-6 January 2025

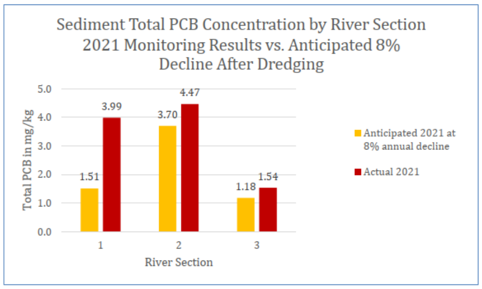
2.4.6 Comment 10: Sediment PCB concentrations remained high

Comment

One commenter noted that six years after dredging, the average PCB concentrations in the top two inches of surface sediment are two to three times higher than anticipated in the 2002 ROD, as reflected in their analysis reproduced below.

Figure 3

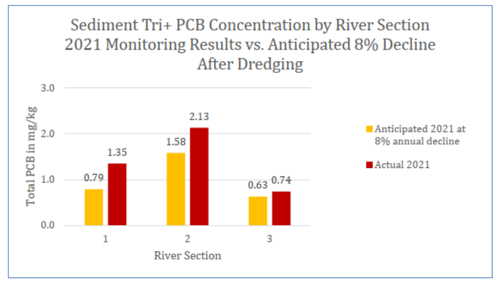
Total PCB Concentrations in Sediment by River Section: Sediment Sampling Results EPA Anticipated for 2021 Compared to the Actual Sediment Sampling Results Collected in 2021



Note: The 8% rate of decay is the rate[13] EPA anticipated in the 2002 ROD. The projected 8% rate of decay is based on data collected in 2016/2017 (the first year after dredging) as the baseline year.

Figure 4

Sediment Tri+ PCB Concentrations in Sediment by River Section: Sediment Sampling Results EPA Anticipated for 2021 Compared to the Actual Sediment Sampling Results Collected in 2021



Source: FOCH, 2023. The Friends Of A Clean Hudson: An independent Review of EPA's Upper Hudson River PCB Dredging Remedy. Hudson River PCBs Superfund Site, Operable Unit 2 (Upper Hudson), Prepared By: The Friends of a Clean Hudson, Hudson Fishermen's Association, Hudson River Sloop Clearwater, Hudson Riverkeeper, Scenic Hudson, Sierra Club-Atlantic Chapter. November.

Another commenter focused on the dredged area concentrations and stated that sediment Recovery-Sediment-Area (RSA) concentrations in dredged areas in 2021 (0.59 mg/kg, 1.7 mg/kg, and 0.72 mg/kg for RS 1, RS 2, and RS 3, respectively) exceeded the residual concentrations of 0.25 mg/kg Tri+ PCB for cohesive sediments and 0.5 mg/kg Tri+ PCB for non-cohesive sediments used in the 2000 FS model projections. They concluded that sediment concentrations in dredged areas remain significantly above the post-construction goals.

Commenters further stated that the remedy constructed in RS 2 and RS 3 left behind substantial PCB mass in the vicinity of dredged areas, creating a "donut" of PCB inventory around dredged areas. As an example, provided by the commenter, in RS 2, over 200 samples collected during Remedial Design (2002-2005) within 100 feet of dredge certification units had surface Tri+ PCB concentrations greater than 10 ppm, 80% of which were collected from the top 2 inches. Commenters asserted that sediments in non-dredged areas re-contaminated the sediments in dredged areas subsequent to construction of the remedy.

Additionally, commenters expressed concerns about the OM&M sediment sampling design, stating that it de-emphasizes fine-grained, cohesive sediment areas in RS 2 and RS 3, which have been shown to exhibit the highest surface PCB concentrations.

Overall, commenters indicate that the magnitude of remaining surface PCB concentrations and the lack of recovery contradict EPA's anticipated remedy performance and are expected to hinder progress toward achieving the target PCB levels in fish.

Response

The commenter's conclusion that PCB concentrations in the top two inches of surface sediment in 2021 are two to three times greater than anticipated is not correct. The commenter's memo (FOCH memo) compares the 2021 averages to the time-adjusted 2016/2017 averages, assuming an 8 percent annual decline. This approach is problematic for several reasons.

First, the commenter's calculation of simple arithmetic averages across river sections is technically inadvisable given the stratified sampling design, which incorporates variations by reach and area (dredged vs. non-dredged) with differing sampling densities (sample count per area). By design, dredged vs. non-dredged areas have different sample densities to account for the different variabilities in PCB concentrations. By calculating a simple arithmetic average, each sample value contributes equally to the derived average. This method of equal weighting leads to an overrepresentation of samples from the high-density stratum (*i.e., non-dredged area in RS 1 and RS2, and dredged area in RS 3*). The arithmetic average is also highly sensitive to outliers. Second, the commenter does not include confidence intervals for the average values, which are critical for understanding the uncertainty in the estimates, especially given the high variability in PCB sediment concentrations. With consideration of uncertainty bounds, which is the best practice in any statistical evaluation of this type, the average concentrations in 2021 are not statistically different from 2016/2017. This was demonstrated in the Appendix 2 to this FYR (Figures A2-6c). Within the uncertainty bounds, there are potential indications of declining concentrations; however, drawing definitive conclusions would be premature without 8-10 years of data. Finally, the assumption of an 8 percent annual decline is inappropriate for post-dredging conditions as discussed in response to Comment 1b.

Regarding the dredged area concentrations, EPA acknowledges that the RSA levels in 2021 for all three sections exceed the residual concentrations used in the 2000 FS model (0.25 mg/kg Tri+ PCB for cohesive sediments and 0.5 mg/kg Tri+ PCB for non-cohesive sediments). It is important to note that the 0.25 mg/kg and 0.5 mg/kg values were selected to conservatively represent bed conditions immediately following backfill placement for modeling purposes. Post-dredging confirmation sampling showed that these criteria were achieved assuming the mixing of clean backfill with sediments having average Tri+ PCB concentrations below 1 mg/kg. As detailed in

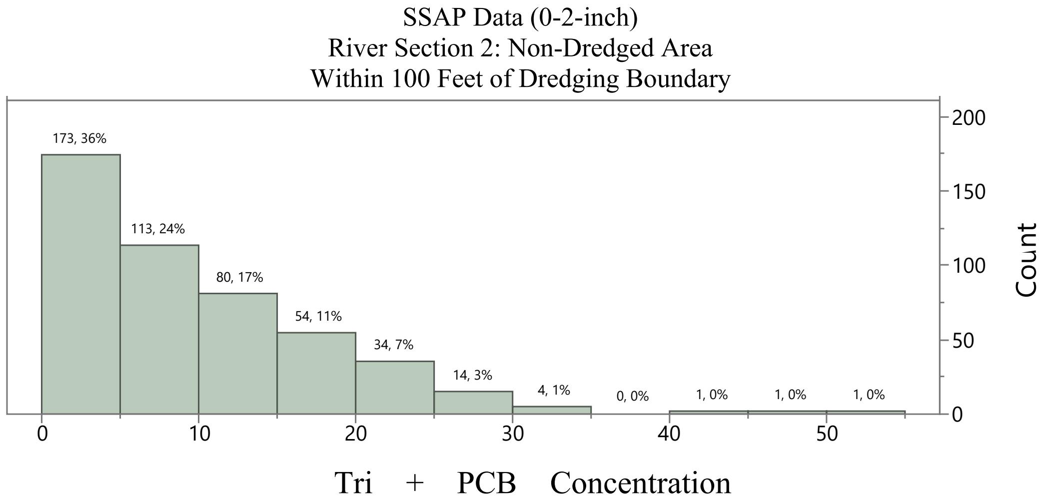
EPA's response to Comment 3a, these values were never intended to accurately predict post-dredging conditions, and they are not sediment RAOs. Increases in sediment concentrations in dredged areas compared to levels immediately post-dredging is expected as processes such as redistribution of PCBs from non-dredged to dredged areas could potentially impact surface sediment concentrations in dredged areas. The fact that the RSA levels in 2021 exceed modeling criteria used to conservatively represent the concentrations of backfill immediately after placement into a dredged area is not indicative of a remedy performance concern. It is also important to note that dredge areas in non-habitat areas (after the completion of backfilling) were deeper (as approved by EPA and agreed upon with NYSDEC) than the original depth making them (as expected) more likely to accumulate impacted sediment over time that moves along the river bottom. Therefore, a slight increase in surface concentrations in dredged areas after dredging is to be expected until these areas reach equilibrium with the other nearby surfaces.

EPA disagrees with the commenter's claim that areas near the dredging boundaries are under-sampled. The OM&M sediment sampling program is based on a probability-based sample selection procedure that supports unbiased estimation of mean PCB concentrations for each river section. This spatially balanced approach includes samples from the edges of certification units in proportion to the size of these areas. The table below demonstrates that the number of sediment sampling locations near dredging boundaries (i.e., within 50 feet) is proportional to the size of these areas. This alignment confirms that areas surrounding dredged regions are adequately represented and appropriately monitored under the OM&M program.

Table 10-1 Proportion of Non-Dredged Area Within 50 feet of Dredging Boundary

River Section	Proportion of Non-Dredged Area Within 50 feet of Dredging Boundary	
	Area-Based (% of Area)	Location-Based (% of Samples)
1	65%	67%
2	21%	24%
3	6.4%	7.6%

Finally, concerns about high levels of contamination in the immediate vicinity of dredged areas are not supported by the SSAP data or by the surface sediment data collected during the 2016 OM&M, 2017 NYSDEC, and 2021 OM&M monitoring efforts. Regarding the commenter's example for RS 2, the commenter does not account for the samples with low concentrations within the 100 foot dredging boundary. Based on the distribution of Tri+ PCB concentrations in 0-2-inch samples within this boundary, as illustrated in Figure 10-1 below, 36% of samples had concentrations below 5 mg/kg, with 24% between 5 and 10 mg/kg, and progressively smaller percentages at higher concentration ranges. On average, sediment concentrations near the dredging boundaries were comparable to those observed elsewhere in the river. The "donut" pattern of high concentrations immediately surrounding dredged areas described by the commenter is not supported by the SSAP data. This issue was also addressed in EPA's response to Comment 47 of the Second FYR (EPA, 2019b).



Note: Numbers above each bar represent sample count and percentage within each concentration range.

Figure 10-1 Distribution of Tri+ PCB concentrations in surface sediment samples (0-2-inch) collected within 100 feet of the dredging boundary in the non-dredged areas of River Section 2, based on SSAP program data.

Post-dredging data shown in Figure 10-2 below also illustrate that sediment concentrations near dredging boundaries in RS 2 and RS 3 are consistent with those observed in other areas within each river section.

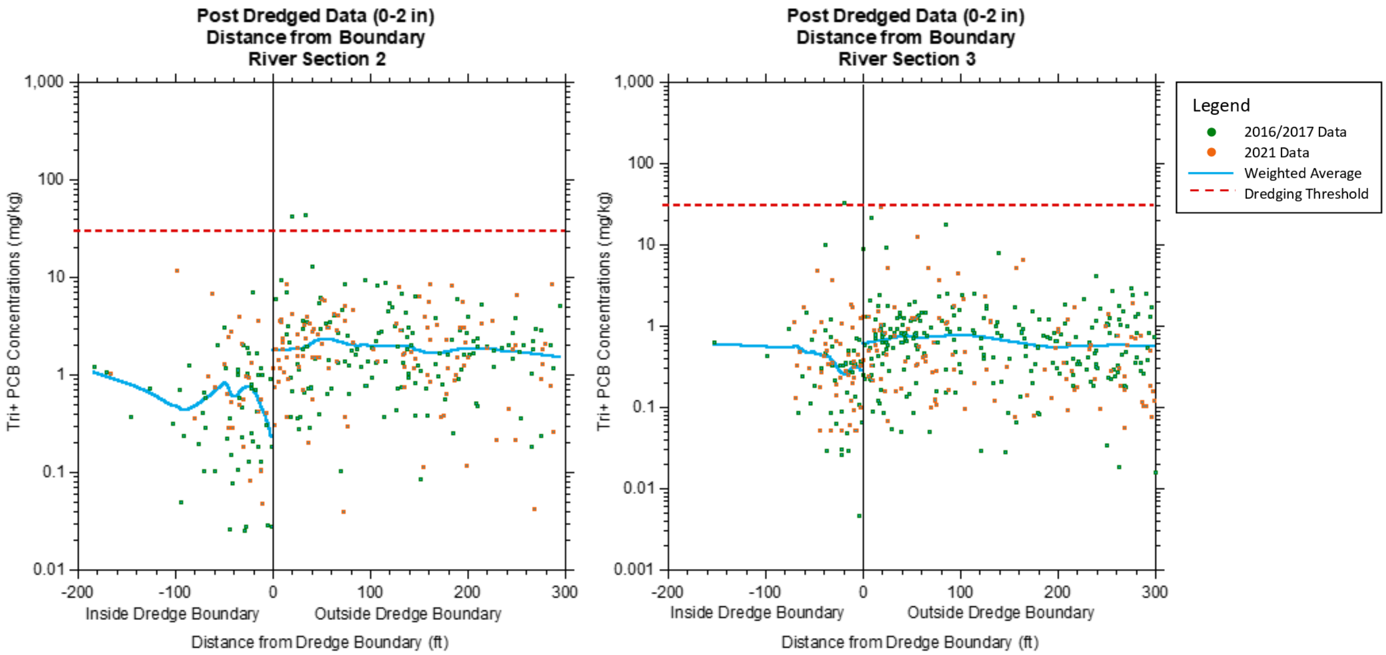


Figure 10-2 Post-dredging surface sediment Tri+ PCB concentrations versus distance from dredging boundary.

EPA will continue to monitor surface sediment and fish tissue PCB concentrations and evaluate the effectiveness of the remedy through the OM&M program. EPA will consider additional studies if necessary to support the evaluation of remedy performance.

2.4.7 Comment 11: CSM - relationship of sediment, water, fish

Comment

Commenters indicated that EPA should update its understanding of the relationship between sediment and fish tissue PCB concentrations to determine how much further active remediation is required to meet risk reduction targets in the time frames needed to achieve the objectives of the ROD. Commenters also indicated that EPA should explain in this FYR how there would be declines in fish tissue PCB concentrations if there has been little recovery in surface sediment PCB concentrations. Commenters expressed a need to understand how the remaining PCBs in Upper Hudson River sediment are impacting fish tissue PCB concentrations over time.

Response

As discussed in this FYR, EPA has evaluated the data collected as part of the monitoring of the recovery of the Upper Hudson River and has determined that rates of decline in fish, water and sediment cannot be established until more data has been collected. Therefore, EPA cannot yet determine if the timeframes to reach the ROD targets and goals are reasonably consistent with the ROD expectations.

As noted in Comment 7 for this Third FYR, EPA will collect additional sediment and fish tissue data and will continue to evaluate data until a sufficient amount is available to determine statistically reliable rates of decline in fish and sediment. EPA has identified that special studies will be conducted to better understand the potential variability in recovery rates. The results of the special studies are anticipated to inform EPAs understanding of the fish water and sediment relationships.

2.5 Fishing advisories and restrictions

2.5.1 Comment 15: Concerns regarding fish consumption advisories

Comment

Commenters expressed concern that the use of fish consumption advisories as part of the OU2 remedy places the burden on the public to minimize exposure and that reliance on the advisories does not fully protect people from harm. They also stated that the advisories do not reduce risk to ecological receptors. Commenters further noted that communities along the river, particularly low-income communities, are particularly affected by the PCBs in fish, as these communities are more likely to consume fish from the river. Finally, commenters expressed a concern regarding the status of the program for advising communities about safe fish consumption once the NYSDOH runs out of funding for the program.

Response

Institutional controls (ICs) are an integral part of Superfund site management, investigation, remediation, and post-remediation monitoring. Institutional Controls are routinely employed at remedial sites and are routinely used by EPA and other government agencies at Superfund sites to reduce potential for human exposure to contamination. As discussed in the remedy selected as described in the 2002 ROD, ICs, including continuation of fish consumption advisories and fishing restrictions, were included as long-term control measures, along with active remediation and a long-term monitoring program. These controls are designed to prevent or limit exposure to PCBs through consumption of contaminated fish. EPA continues to support New York State with its implementation of the fish advisories, fish restrictions, and associated informational outreach. EPA understands that while the fish ICs rely on voluntary compliance and, therefore, are not by themselves fully protective, the OU2 remedy is significantly more protective with the legal fishing restrictions, consumption advisories and associated outreach efforts.

The RAO established in the ROD for protection of ecological receptors is to "*reduce the risks to ecological receptors by reducing the concentration of PCBs in fish*," because consumption of fish contaminated with PCBs remains the primary route of exposure for most upper trophic level wildlife species. The results of the Baseline Ecological Risk Assessment (BERA) supported EPA's decision that remedial action was necessary to reduce unacceptable risks to ecological receptors. The dredging remedy has reduced PCB inventory in the sediment, thereby reducing exposures to wildlife. EPA continues to monitor the fish tissue concentrations to compare to the risk levels calculated in the ROD and is also considering adjustments to the monitoring programs to better understand impacts to ecological receptors.

Based on public input received when the remedy decision was made in 2002, EPA committed to developing a comprehensive public involvement program to be implemented throughout the Hudson River cleanup project. Historically, EPA's community involvement efforts have largely focused on the upper river communities. This is the area where dredging took place and where the impacts and effects of the dredging were most directly felt by the local communities. Environmental justice considerations recognize the burden of industrial pollution from historical practices, as well as the potential impacts of cleanups themselves. Consideration of communities that may be fishing in the Hudson River for subsistence has been included in calculations for ingestion in risk models used to develop the remedy in the ROD. Populations of highly exposed or less exposed anglers have not been explicitly characterized but are anticipated to be represented in the fish ingestion rate distribution. For example, the 99th percentile fish ingestion rate from the 1991 New York Angler survey is 393 meals per year, or more than one fish meal per day. The Reasonable Maximum Exposure scenario used in the Human Health Risk Assessment is based on the 90^{th} percentile of consumption rates as reported in a 1991 New York State angler survey (Connelly et al. 1992) which corresponds to approximately 1 half-pound fish meal per week of fish caught from the Hudson River. The remediation goal in the ROD is designed to be protective of the RME scenario (e.g., one half-pound fish meal per week).

As a condition of the 2005 Consent Decree between EPA and the General Electric Company (GE), GE contributed $4 million to support the implementation of fish consumption advisories. In 2008, NYSDOH established the Hudson River Fish Advisory Outreach Project. The goal of the 20-year initiative is for all people who consume Hudson River fish and crab to be aware of and follow the Hudson River fish advisories. As discussed in issue 5 of the FYR, EPA supports these education and outreach efforts, including the need for continued funding of the outreach program. The additional funding will need to be in place in advance so that a smooth transition can occur and to avoid disruptions to the program. EPA will continue to coordinate with NYSDOH and engage in discussions with GE regarding continued funding.

The advisory outreach program focus includes newcomers to the Hudson Valley region, including hard-to-reach communities due to cultural and language differences. Outreach program activities include; identifying and supporting partners who can develop and administer fish advisory outreach programs; working with property owners to post signage at major fishing access sites; evaluating outreach efforts to determine what barriers exist, incorporating emerging health education methods into outreach efforts, and implementing culturally appropriate strategies to encourage people to follow the advisories.

In summary, fish consumption advisories and restrictions for PCBs will continue to be necessary for the foreseeable future to protect people's health and PCB exposure and will need to remain in place until PCB levels in fish are reduced to acceptable limits, and New York State determines that changes can be made. Please note that advisories would likely continue to be needed even if additional cleanup work is done due to the presence of other contaminants in the river in addition to PCBs, such as mercury. Unfortunately, advisories and restrictions are not fully effective for several reasons that are a focus of the outreach program. However, the fish advisories and restrictions are the best tool EPA and NYS have available to limit fish consumption while the river recovers because there is no feasible technical approach to fast track the recovery in the fish. While the river recovers, EPA will continue to work with New York State to ensure the ongoing maximum effectiveness of the advisories and restrictions.

2.6 Data collection and analysis

2.6.1 Comment 5: Fish data analysis method

Comment

Commenters expressed concern regarding multiple aspects of the fish data evaluations, including the use of percentages of fish meeting specific criteria, the need to account for lipid content when comparing wet weight values to ROD target levels, the calculation of reach-specific area-weighted averages and EPA's approach to demonstrating "progress toward" ROD goals.

Commenters contend that the percentage of fish that meet or do not meet specific criteria is not a meaningful metric for evaluating progress toward ROD goals. Instead, risk assessments should focus on average fish PCB concentrations, which are used to estimate exposure, rather than the distribution of concentrations within the population.

They also emphasized that using wet weight values without considering species-specific lipid distributions was misleading, as the ROD wet weight values were derived from bioaccumulation models that tied to species-specific lipid distributions. Comparisons to ROD targets and estimates of post-dredging PCB decline rates must consider lipid content.

The commenters further assessed that lipid-normalized results showed the rate of decline post-dredging was about half of the rate calculated using wet weight values only. Additionally, species-weighted averages should also be calculated on a river Reach-specific basis to better reflect the exposure risk for anglers, who may catch fish from multiple Reaches.

Finally, commenters indicated EPA's reliance on simple year-to-year comparisons of average fish PCB concentrations to demonstrate "progress toward" ROD goals lacked the statistical power cited by EPA as necessary for a protectiveness determination.

Response

1. Percentages of Fish Meeting Specific Criteria

Both average fish PCB concentrations and percentages of fish meeting specific criteria are discussed in the FYR. Percentages of fish meeting specific criteria is another line of evidence to assess recovery. While average fish PCB concentrations are fundamental to exposure assessments, examining percentages offers a complementary perspective in demonstrating progress towards recovery. A higher percentage of fish meeting specific criteria indicates the system is moving towards recovery.

2. Using Wet-Weight Concentrations and Lipid-Normalization

Because ROD target levels and remedial goals are human consumption limits that are independent of lipid distributions, it is relevant to directly compare measured wet-weight values to ROD target levels and remedial goals. It is important to note that exposure due to consumption of fish is most relevant in terms of wet weight. Lipid normalized data is relevant mostly in terms of trend analysis.

EPA agrees that lipid content needs to be considered in assessing the post-dredging PCB decline rates and presented the lipid-normalized data in the FYR. However, the lipid-normalization approach has limitations. The lipid-normalization approach assumes that:

- *PCB concentration is linearly correlated with lipid content and the correlation is very strong*. However, the relationship between the concentrations and the lipid content in the Hudson River may not be linear.
- *The intercept of PCB vs. lipid content regression line is zero, i.e., there is no partitioning of PCBs from the lipids into the non-lipid organic matter (NLOM) phase*. At low lipid levels, however, the role of NLOM becomes important.

Understanding that there are limitations on the validity of the assumptions described above, lipid-normalization under certain circumstances can introduce errors and lead to misinterpretation of data. As such, lipid-normalization may not be the best approach to distinguish changes due to exposure reduction (i.e., the positive impact of the dredging remedy) from those driven by lipid content fluctuations (ongoing variability in fish biology).

Literary studies also reported the limitations of lipid-normalization. Researchers have demonstrated that the correlation between PCB concentration and lipid content is not consistently strong and may vary across different species, time, and areas (Hebert and Keenleyside, 1995; Stow, Jackson, and Amrhein 1997). Applying lipid-normalization prior to carefully examining the relationship between PCB data and lipid content may introduce additional unexplained variability and result in incorrect conclusions (Hebert and Keenleyside 1995; Gewurtz et al., 2011). To address these issues, researchers recommend using regression-based approaches to account for lipid effects (Somers and Jackson, 1993; Hebert and Keenleyside 1995; Gewurtz et al., 2011). These methods are more reliable and flexible as they can handle measurement errors and better capture the true relationship between PCB and lipid content.

EPA is evaluating the best approach for incorporating lipids into statistical trend analyses, and may also consider other factors, such as age, sex, length and location of fish. EPA will include the findings from this evaluation in the next FYR addendum, which will be issued no later than 2027.

3. Reach-Specific Calculations

EPA recognizes the value in evaluating fish data at the river Reach level. EPA evaluates the data at various spatial scales including station by station; however, EPA's sampling program was designed at the River Section level to align with the ROD. Therefore, the River Section level is what is being reported in this FYR. Conducting Reach-specific analyses could introduce high uncertainties into EPA's data evaluations due to the smaller sample sizes associated with individual Reaches. It is important to note that only one Reach was sampled in RS 1 and RS 3; therefore, the results for RS 1 and RS 3 are already at the Reach level. Only results for RS 2 represent data from two Reaches (Reach 7 and Reach 6). EPA will continue to consider data at the River Section and Reach level.

4. Statistical Power and Temporal Trends

EPA agrees that year-to-year comparisons are insufficient and does not rely on them exclusively to evaluate progress. Instead, EPA emphasizes the need for at least eight years of post-dredging data to establish statistically robust trends and determine whether the system is on track to achieve long-term ROD goals. See EPA's responses on Comment 7 on the minimal number of years required for trend analysis.

2.6.2 Comment 13: Habitat related concerns

Comment

Commenters indicated that the integration of habitat reconstruction and recovery as an element of the remedy in this report is incomplete. Key assertions made by commenters included that full integration of the monitoring, sampling and data results is necessary to properly assess the progress toward these goals and provide a transparent reporting of continued response actions. In addition, commenters asserted that habitat should be added as a specifically measured endpoint for the regular monitoring and an appendix with the data toward meeting the ROD goals added for this summary.

Response

EPA agrees that habitat reconstruction is an important component of the ROD and is part of the remedy. However, EPA disagrees with the assertion that more information regarding the habitat reconstruction is necessary in this FYR report. The FYR assessment focuses on elements of the remedy that relate to the protection of human health and the environment from contaminants of concern or otherwise unacceptable risks. While the habitat restoration program is part of the remedy, the implementation of this program does not impact the exposure of site contaminants to human and/or ecological receptors. The cap and backfill components of habitat reconstruction serve chemical- and physical-protective roles; the ROD identifies and discusses species-specific receptors (i.e., fish, also identified in the ROD and evaluated in the BERA as measurement endpoints) to assess remedy effectiveness, not the various vegetation communities in which receptors reside and through which receptors move as they progress through their life cycles.

The reporting and progress of the habitat reconstitution program is detailed each year in the annual Monitoring, Maintenance and Adaptive Management (MM&AM) reports and addenda. A comprehensive summary of the program is also included in the FYR in Section 2.5.2.5. EPA continues to work closely with NYSDEC to evaluate the progress of the habitat recovery and make any necessary adjustments to the program.

2.6.3 Comment 16: Special studies

Comment

Several comments recommended the implementation of additional special studies to facilitate EPA's assessment of the remedy. These studies included the collection of additional fish species, the collection of sport fish during the summer months, the deployment of passive samplers, the collection of additional sediment samples, an update to the fish consumption survey, and the collection of more high-flow water column data.

a. Commenters suggested that EPA's FYR Report should provide detailed information about proposed additional fish collections and special studies. This includes specific data quality objectives, and the scope of work for each initiative. By providing this level of detail, the public can better understand how these studies will contribute to the ongoing assessment of PCB contamination in the Hudson River and the effectiveness of the remedial actions.

b. Commenters appreciated the EPA's efforts to evaluate specific fish metrics and species in particular locations. They supported the EPA's proposal for additional research to understand why certain fish species in specific areas are not recovering as expected. One commenter requested that the EPA include a comprehensive analysis of all four fish metrics in the proposed FYR addendum. Additionally, they urged the EPA to expand the number of recreational fish species to include brown bullhead, carp, channel/white catfish, largemouth/smallmouth bass, pumpkinseed, walleye, white perch, yellow bullhead, and yellow perch, as identified by the NYSDOH. This would provide a more accurate assessment of variability among fish species and a better representation of human health risks associated with consuming fish from the Upper Hudson remedial area.

c. Commenters raised concerns about the assumption that spring-collected fish accurately represent fish caught throughout the summer. Fish collected in the spring, especially black bass and bullhead, may have lower PCB concentrations due to lower lipid content. To address this, commenters suggested conducting a special study to collect these species in late summer when lipid content is higher. This would provide a more accurate representation of potential human exposure through fish consumption.

d. One commenter suggested that additional passive surface water samplers should be deployed in the Upper Hudson River to further refine the general areas where PCB concentrations are increasing. They also recommended further refining areas of elevated PCB concentrations in river sediments and floodplain soil in the Upper Hudson River that may present a continuing local source of contamination that could hinder fish recovery.

e. Commenters stated that the current sediment sampling strategy may be insufficient to accurately assess the recovery of the Upper Hudson River. "Areas of interest," identified during the 2016/2017 surface sediment sampling near dredged regions, may require increased sampling density and depth to capture the bioavailable surface zone. Additionally, the sampling approach used in RS 2 and RS 3 during remedial design may have underestimated the extent of remaining contamination. To address this issue, commenters suggest these areas be resampled.

f. The EPA's current fish consumption advisories for the Hudson River are based on an angler survey data from the 1990s. Commenters were concerned that the lack of updated information hinders accurate risk assessment and limits the effectiveness of institutional controls. To address this issue, some commenters recommended conducting an updated angler survey to determine current fishing practices, species consumption patterns, and specific locations of fish catch. This information would enable a more precise evaluation of human health risks, optimize fish consumption advisories, and ensure the effectiveness of ongoing monitoring and management efforts.

g. Commenters indicated that the EPA should implement a high flow event monitoring program that targets specific river sections to accurately identify the sources of PCB loading. This would involve sampling at multiple locations, including immediately downstream of each of the three defined river sections. By doing so, the EPA would be able to effectively evaluate the contribution of different river bottom portions to PCB release during high flow events. Commenters stated that prioritizing sampling at or near the Thompson Island Dam is crucial to understanding the sources of PCB loading from the remaining contaminated sediments in RSs 1 and RS 2.

Response

a. EPA is developing the scope of the special studies to be conducted over the next several years. As work plans for these special studies are developed, EPA will make them available as part of its regular engagement with the CAG.

b. Special studies will be conducted to provide insight into why different species and certain portions of the river appear to be recovering differently. Multiple special studies, including a fish aging study, are anticipated to help EPA better understand the different rates of recovery.

   The Upper Hudson River long-term monitoring program has provisions for collection and analysis of supplemental fish samples. The supplemental data collection program is intended to provide the necessary data for NYS to adjust fishing restrictions and advisories. EPA will continue to coordinate with NYSDOH and NYSDEC regarding the scope and timing of this data collection. EPA anticipates additional species of fish (not currently routinely collected) will need to be collected and tested for PCBs as part of this program.

   EPA modified the forage fish collection program in 2021, to focus solely on spottail shiner. This will reduce uncertainty in time trends (e.g., avoids uncertainty introduced by combining different species) and allow for a direct comparison to the ROD RAO. Additionally, collection of whole-body largemouth bass that is representative of the size targeted by river otter will commence in an upcoming fish collection season. This data will provide information on the current risk exposure for river otter and allow an evaluation of time trends in PCB concentrations.

c. EPA recognizes that lipid content in fish may fluctuate during a year; however, EPA is currently focused on determining temporal trends in PCB concentrations in each medium. Consistency in data collection is very important, and altering the fish collection schedule could introduce additional variability, hindering the effectiveness of remedy assessment. EPA will continue coordinating with NYS regarding data necessary for adjustments to fish advisories and restrictions, including consideration of the time of year for collection.

d. Issue 3 in the FYR addresses areas of elevated PCBs that should be evaluated to assess their potential impacts to the recovery of the river. EPA is evaluating the results of the passive sampling study that was completed in 2023 and is continuing to develop the scope of these special studies, which may include additional deployments of passive samplers.

e. The 2021 sediment sampling program was the second round of sampling performed during the post-dredging period. The design objectives of the program were adjusted from the 2016 program to account for changes in EPA's understanding of the system. The total number of samples for each river section were allocated to reaches in dredged and non-dredged areas (i.e., strata) within that river section proportionally according to the area and variance in sampling data.

   The OM&M sampling program is based on a stratified, random probability-based, unbiased sampling approach called the Generalized Random Tessellation Sampling (GRTS) algorithm (Stevens and Olsen, 2004). The OM&M program monitors the areas surrounding the dredged areas in RS 2 and RS 3 and, based on the evaluation of the most recent 2021 data, areas surrounding dredged areas in RS 2 and RS 3 do not have elevated concentrations.

   In order to address concerns regarding sediment levels around areas of interest, EPA conducted an evaluation to compare 2021 Tri+ PCB data to the 2016/2017 Tri+ PCB data in and around these areas. The analysis included Tri+ PCB concentrations near the three areas of interest and the changes in the spatial extent of each of the areas of interest. The 2021 results verified the comparatively elevated Tri+ PCB concentrations in the three areas of interest, but their spatial extents did not appear to increase between 2016/2017 and 2021. None of the 2021 samples taken within these areas had Tri+ PCB concentrations exceeding the RS 2 and RS 3 dredging criterion of 30 mg/kg. The average Tri+ PCB concentrations in all three areas have decreased based on the 2021 data. A full discussion of this evaluation can be found in Appendix 2, Section 4.3.

EPA will determine if it is appropriate to include special studies that address the bioavailable surface zone in RS 2 and RS 3. Based on the current evaluation of the post-dredging sampling data, additional sediment sampling is not necessary at this time. The next sediment sampling event will be conducted in 2026 and will be discussed in the next five-year review.

f. EPA does not develop fish consumption advisories. As discussed in the Second FYR Responsiveness Summary, the 1991 New York Angler survey was used in the development of the exposure assessment and identification of species consumed for the human health risk assessment (EPA 2019b). While it is understood that consumption patterns will not remain the same over time, EPA assessed the need to update the risk calculations based on the information currently in hand. EPA has reviewed the current literature and believes the consumption rates, as well as the species mix, remain appropriate and representative.

g. EPA understands the importance of high flow events in transporting PCBs in the UHR. EPA is planning for a special study which will include water sampling at Rogers Island during high-flow conditions. EPA has previously considered high flow sampling near the Thompson Island Dam and determined that was not necessary. Sampling at Rogers Island requires careful consideration of logistical and safety challenges which are unique to this location.

2.6.4 Comment 17: Water column data analysis

Comment

Commenters suggested EPA should evaluate the changes in load as the river passes downstream over the remaining contaminated sediments in order to understand which reaches of river may be important sources of sediment PCB flux to the water column. Specifically, for Figure 3 of the Third FYR, commenters requested that EPA presents a graph in the report using PCB load as well as PCB concentration, in order to provide an estimate of the change in water column PCB load as the river passes over the remaining contaminated sediments in the Upper Hudson.

Response

One of the RAOs identified in the 2002 ROD was to "minimize the long-term downstream transport of PCBs in the river". The post-dredging OM&M program includes sampling at various stations under varied flow conditions. Under low flow conditions, the relationship between concentration and flow is negative, with increasing flow values resulting in decreasing concentrations; however, above a certain flow threshold, the relationship becomes positive, with increasing flow values resulting in increasing concentration. This non-linear relationship between concentration and flow is likely reflective of a dilution-dominated flow regime at relatively low flows when sediment-water exchange represents the dominant flux to the water column, and a resuspension-dominated flow regime at higher flows (see Figures A1-3 and A1-4 in Appendix A of the Third FYR).

Under the OM&M program, high-flow samples are taken at Schuylerville and Waterford monitoring stations, which allows EPA to conduct load estimation to the Lower Hudson River. Due to safety considerations, high-flow samples are not collected at all upstream stations in the UHR (i.e., Bakers Falls, Rogers Island, and Thompson Island Dam), making an assessment of the load passing these stations impractical without high-flow data. In the Third FYR, the estimated annual Tri+ PCB loads over time as well as the FTN loads at Waterford monitoring station are presented in Figure A1-19 of Appendix A. By removing variability in the water column Tri+ PCB loads introduced by flow and seasonality, the results indicate FTN Tri+ PCB loads to the Lower Hudson River are decreasing.

The objective of Figure 3 presented in the Third FYR was to spatially evaluate the pre-dredging and post-dredging difference in water column exposure concentrations during the routine flows from May to November and compare them to the corresponding pattern in fish tissue concentrations. Only routine water samples collected between May and November are presented in this figure due to differences in sample collection frequency during the pre- and post-dredging periods and recognizing that the high-flow sampling program was only implemented at the Schuylerville and Waterford stations. Figure 3 demonstrates that water column concentrations have decreased at all three long-term monitoring stations within the project area (Thompson Island Dam, Schuylerville, and Waterford) compared to the pre-dredging period.

The data from the OM&M program allows EPA to understand exposure concentrations and load gains between the stations under the various conditions and how the load changes over time. EPA has proposed a special study to collect water samples at Rogers Island during high-flow events to better understand the impact of high flows on upstream PCB load entering the OU2 area.

2.6.5 Comment 18: Pre- and post-dredging data comparison

Comment

Commenters suggested that comparison of pre-dredging and post-dredging data is not useful when evaluating the current phase of the remedy, monitored natural recovery. They suggested that the analysis should focus on post-dredging data and compare it to the expected post-dredging concentrations outlined in the ROD. Commenters emphasized the importance of distinguishing between the reductions associated with dredging and monitored natural recovery. By isolating the impact of monitored natural recovery, a more accurate assessment of its contribution to overall PCB reductions can be achieved.

Response

EPA's focus at this phase of the project (MNR) is on the post-dredging data and trends. However as discussed in the FYR, EPA does not yet have sufficient data to establish what the current rates of decline are in the fish, water or sediment. EPA needs eight or more years of post-dredging data before that trend can be established (see comment 7a). In the meantime, comparisons of the pre-dredging and post-dredging data are useful to understand how the system has recovered, and the impacts dredging has had on the system. In addition to these comparisons, EPA has conducted multiple evaluations on post-dredging data for water, sediment, and fish within the FYR. EPA will conduct trend analysis once sufficient data are available and will integrate other lines of evidence to assess the overall progress of the Upper Hudson River ecosystem's recovery.

2.6.6 Comment 19: EPA should use arithmetic mean rather than geometric mean

Comment

Commenters requested clarification from EPA on the rationale for using geometric means in the pre- and post-dredging comparisons of fish and surface water PCB data presented in Figure 3 of the FYR main document. They questioned whether the conclusions would be altered if arithmetic means were used instead. They reminded EPA that the arithmetic mean, not the geometric mean, was used to assess fish PCB concentrations during the current phase of the remedy. Commenters requested clarification on whether EPA used the arithmetic mean or geometric mean for species-weighted average calculations. While acknowledging that the geometric mean provides a potentially more accurate statistical representation of the data, they argued that arithmetic means are more relevant to risk assessment and should also be used in the pre-and post-dredging comparisons and surface sediment recovery assessments.

Response

The commenters expressed a preference for analyses based on arithmetic means unilaterally. This unconditional preference for arithmetic averages does not recognize the inherent difficulties in developing statistically valid inferences from right-skewed data (the probability distribution of the value of interest is not symmetrical around its mean). EPA has carefully selected appropriate, statistically valid methods for each of their data evaluations, which at times require statistical inferences based on arithmetic means and in other cases depend on geometric means, which generally have more stable statistical properties. Specifically, EPA uses the arithmetic mean when evaluating PCB concentrations for risk assessments and regulatory comparisons with fish tissue target levels and remedial goals. For example, fish tissue species-weighted average PCB concentrations are calculated as arithmetic means. Sediment area-weighted average PCB concentrations are also developed using arithmetic means, representing exposure conditions for fish.

For assessing changes in concentrations over time — such as pre-dredging versus post-dredging comparisons (Figure 3) or identifying trends during the monitored natural recovery period — EPA uses geometric means. PCB data at the Hudson River are right-skewed, which leads to difficulties estimating arithmetic means and their uncertainty bounds accurately. Right-skewedness in the data distribution necessitates larger sample sizes to develop precise estimates of the arithmetic mean and specialized statistical methods for estimating confidence limits. The USEPA software ProUCL was developed in part as a response to this difficulty. When comparing population means from right-skewed distributions, these difficulties are compounded, so EPA used normal theory statistics for log-transformed sample data. When data are log-transformed, the geometric mean is the natural estimator of central tendency. Geometric means are less variable and as a result statistical measures of uncertainties for geometric means are more accurate.

Commenters also asked whether the conclusions would be altered if arithmetic means were used in Figure 3. This request is essentially to compare the ratios of arithmetic means as opposed to the ratios of geometric means. When comparing two populations from right-skewed distributions typical in environmental data, the ratio of geometric means is more robust to difference in the variances between the two populations.

Letting X represent right-skewed sample measurements and $Y = LN(X)$ represent the natural log-transformed measurements with mean and variance $(\mu \; and \; \sigma^2)$. These parameters are often termed the log-mean and log variance.

When the data follow a log-normal distribution, the true population arithmetic mean is

$$Arithmetic\ Mean = e^{\mu + \frac{\sigma^2}{2}}$$

and the geometric mean, which is the true population median, is

$$Geometric\ Mean = e^{\mu}$$

With this parameterization, the ratio of geometric means (*GM*) for two different data populations is given by:

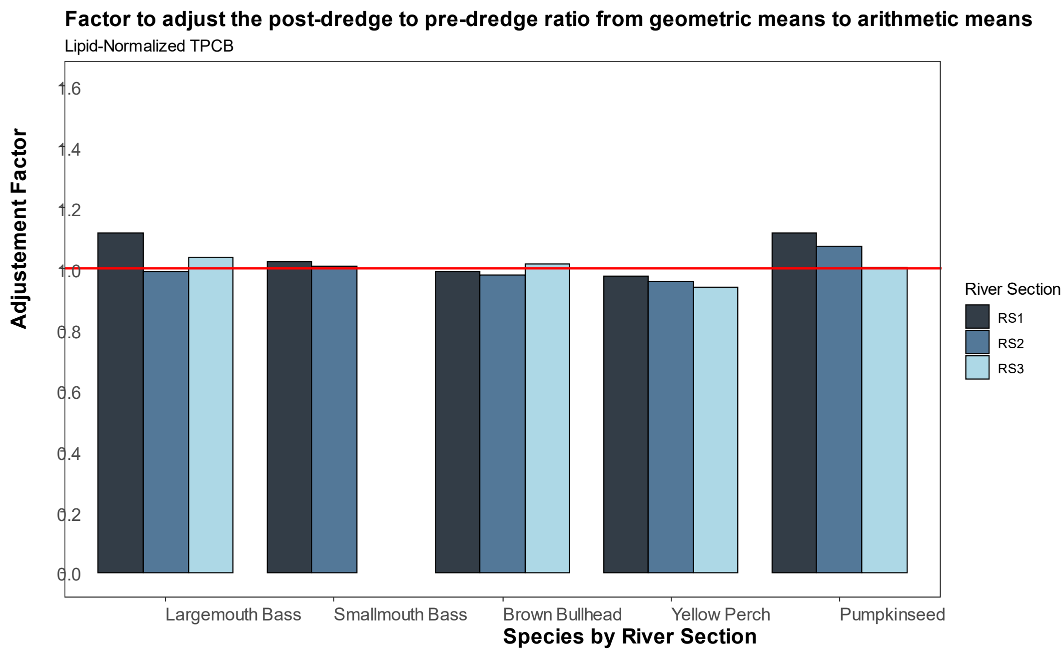
$$\frac{GM_1}{GM_2} = \frac{e^{\mu_1}}{e^{\mu_2}} = e^{\mu_1 - \mu_2}$$

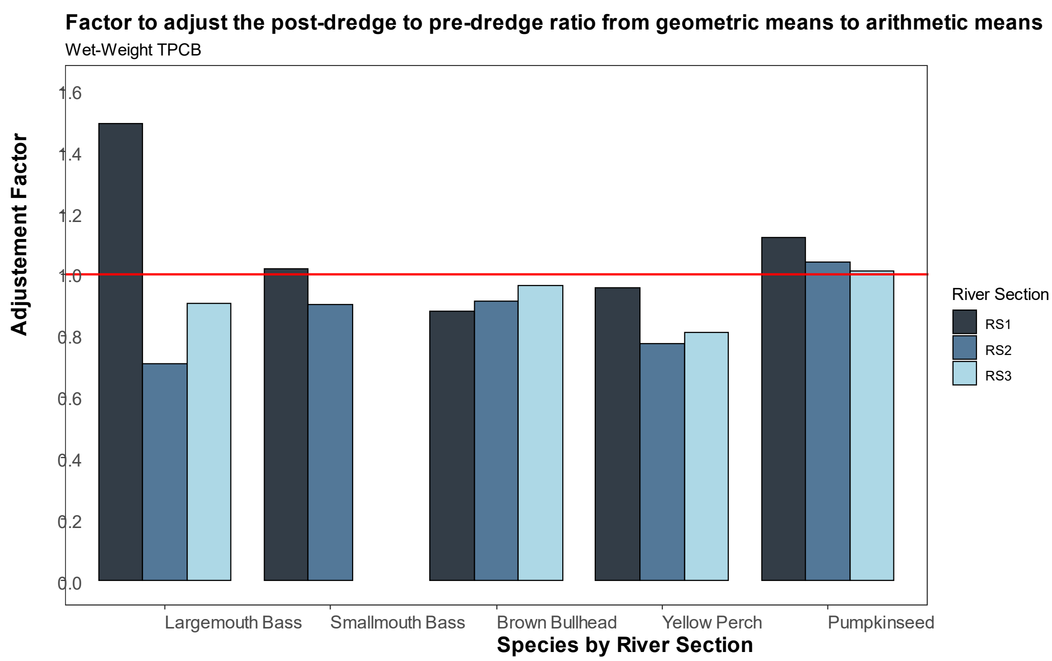
The ratio of arithmetic means for two different populations is given by:

$$\frac{Arithmetic\ Mean_1}{Arithmetic\ Mean_2} = \frac{e^{\mu_1 + \frac{\sigma_1^2}{2}}}{e^{\mu_2 + \frac{\sigma_2^2}{2}}} = e^{\mu_1 - \mu_2} \times e^{\left(\frac{\sigma_1^2}{2} - \frac{\sigma_2^2}{2}\right)} = \frac{GM_1}{GM_2} \times e^{\left(\frac{\sigma_1^2}{2} - \frac{\sigma_2^2}{2}\right)}$$

The above equation shows that for a lognormal distribution, the ratio of arithmetic means is proportional to the ratio of geometric means, scaled by the factor $e^{\left(\frac{\sigma_1^2}{2}-\frac{\sigma_2^2}{2}\right)}$. The two ratios will be equal when the two populations under comparison have equal variances.

For Hudson River data, assuming subscripts 1 and 2 represent post-dredging and pre-dredging period datasets, respectively, the factor $e^{\left(\frac{\sigma_1^2}{2}-\frac{\sigma_2^2}{2}\right)}$ mathematically represents the relationship between the post-dredging to pre-dredging ratio based on geometric means and the same ratio based on arithmetic means. Figure 19-1 shows the adjustment factor for wet-weight TPCB and lipid-normalized TPCB by species and river section. The adjustment factors are generally below 1, consistent with the expectation that post-dredging data generally exhibit lower variance compared to pre-dredging data. For the factors that are greater than 1, most are below 1.2, except for wet-weight TPCB data for largemouth bass at RS 1. An adjustment factor below 1 means that the ratio based on arithmetic means is less than those based on the geometric means, indicating a greater percentage reduction when using arithmetic means. Using the arithmetic means in Figure 3 would not alter the conclusions; however, the ratios derived from arithmetic means might lead to an erroneous conclusion of greater recovery in the post-dredging datasets.





Note: The factor is calculated using the variance of log-transformed TPCB data from pre-dredging (2004-2008) and post-dredging (2016-2021) fish samples. The pre-dredging and post-dredging variances represent the weighted-averages of yearly variances, calculated only for years with at least 10 samples.

Figure 19-1 Adjustment factor used to convert post-dredging to pre-dredging ratio from a geometric mean basis to an arithmetic mean basis.

2.6.7 Comment 20: Independent third-party review

Comment

The commenter suggests that an independent third party should be involved in the post-remedy evaluations.

Response

EPA is receptive to the concept of a third-party independent review. Such a third-party review would need to be focused to the appropriate technical subject matters which, in this case, would primarily be the recovery of the Upper Hudson River. There are several challenges associated with such a review, including finding an appropriate independent/qualified party and administrative/contractual arrangement. EPA will discuss and coordinate this further with NYSDEC (the author of this comment) regarding identifying potential third-party reviewer(s), the scope of a review, and the timing/schedule.

EPA continues to encourage independent review of its work and has brought national subject matter experts onto its team at various times during the project. Project data is available upon request (if not already posted on the web) and the project team is available to discuss its technical analysis upon request.

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