Appendix C
Human Health Risk Assessment

Comments on Behalf of the Lower Passaic River Study Area Site Cooperating Parties Group on the Proposed Plan and Feasibility Study for the Lower Eight Miles of the Lower Passaic River Study Area Portion of the Diamond Alkali Superfund Site

Overview of Comments

Region 2's human health risk assessment (HHRA) in the Focused Feasibility Study (FFS) uses exposure assumptions that have been directed by the Region for use in the 17-mile Lower Passaic River Study Area (LPRSA) baseline HHRA (AECOM in prep). These assumptions fail to acknowledge the characteristics of the LPR as well as account for site-specific exposures particularly with regard to fish and crab consumption. The exposure parameters have very little basis and are inappropriate for the LPR and result in over-estimated risks that do not reflect the LPRSA and serve no purpose in managing human health risks. As a consequence of failing to perform a credible risk assessment, the Region's grossly overestimated risk estimates have resulted in unrealistic preliminary remediation goals (PRGs) and the selection of an unnecessary and counterproductive bank-to-bank remedy.

The deficiencies discussed below highlight the inadequacy of the FFS HHRA for remedy selection. The discussion of issues related to the HHRA as presented in Region 2's revised FFS for the lower 8 miles of the LPR is organized into four main topic areas:

Summary Comment: Region 2's exposure assumptions used in the FFS HHRA are not realistic and do not reflect site-specific data, resulting in overstated estimates of current and future risk.

Discussion: The FFS HHRA used exposure assumptions that were directed by Region 2 for use in the 17-mile baseline HHRA, including overly conservative fish and crab consumption rates, the assumption that all consumed catch is from the LPRSA, the assumption that exposure continues unabated for 30 years, and no accounting for loss of lipophilic contaminants during cooking. When combined with other conservative aspects of the risk assessment process (e.g., upper-bound exposure point concentrations [EPCs] and toxicity values), the exposure assumptions used by Region 2 result in excessive and unrealistic projections of both current and future risk.

Summary Comment: Region 2's toxicity assessment approach has resulted in overestimates of PCB and dioxin risks, and key uncertainties in the dioxin toxicity equivalence scheme are not acknowledged.

Region 2's approach of summing non-dioxin-like PCB and dioxin-like PCB cancer and noncancer risks does not account for a variety of issues and uncertainties associated with this compound class, and results in an overestimation of PCB risks.

Region 2 evaluates dioxins and furans having mechanisms of toxicity similar to that of 2,3,7,8-tetrachloro-*p*-dioxin (TCDD) using a toxicity equivalence factor (TEF) scheme, where each dioxin/furan congener is assigned a TEF that equates the toxicity of the congener to that of TCDD. The TEFs are applied to the measured congener concentrations in environmental media and the results are summed to provide a toxic equivalency (TEQ) concentration. The cancer slope factor (CSF) for TCDD is then applied to the average daily dose of TEQ calculated in a risk assessment to estimate potential risk due to the exposure scenario(s) evaluated. The U.S. Environmental Protection Agency (EPA) has identified a subset of 12 PCB congeners as "dioxin-like," and has assigned a TEF to each of these congeners (USEPA 2010). However, evaluation of the dioxin-like toxicity of the presumed dioxin-like PCB congeners is not necessarily appropriate.

Summary Comment: Region 2's incomplete background evaluation underestimates the contribution of upriver sources and significantly overstates the risk reduction that can be achieved by the selected remedy. The FFS HHRA also fails to effectively quantify and compare regional background risks from above Dundee Dam. In addition, the significant risks posed by pathogens in the river were not addressed.

Discussion: The FFS underestimates the contribution of the Upper Passaic River (UPR) to current and future conditions in the FFS study area. In Appendix E of the FFS, the Upper Passaic River sediments are identified as representative of background for the FFS study area, based on proximity and the demonstrated geochemical connection between the UPR and the LPR. Section 3 of Appendix E identifies the background sediment data set as consisting of 8 surface sediment samples collected immediately above the dam (four cores and four grabs) and two dam sediment trap samples. Table 3-1 of Appendix E presents the background sediment concentrations selected by EPA. Not only is Region 2 selective in its use of available sediment data to estimate background, it fails to acknowledge the significant volume of background fish tissue data collected above Dundee Dam, electing to use its regression model to estimate tissue concentrations from its limited sediment data.

Summary Comment: Region 2's selection of preliminary remediation goals is flawed and inconsistent with Agency policy and result in remedial goals that are unattainable.

Discussion: Region 2 has presented tissue PRGs that are based on the same overly conservative reasonable maximum exposure (RME) and toxicity assumptions used in the FFS HHRA. PRGs have been derived for the three chemicals of concern with individual cancer risks above 1×10^{-4} (TCDD-TEQ and total non-dioxin-like polychlorinated biphenyls [PCBs][1]) or an individual non-cancer hazard index (HI) above 1 (TCDD-TEQ, PCBs, and methyl mercury).

Not only are the resulting tissue PRGs inappropriately low due to the overly conservative RME and toxicity assumptions that were used, they are not attainable, especially for PCBs and methyl mercury. Levels of PCBs and methyl mercury in fish collected from the background area above Dundee Dam exceed even the highest (least stringent) PRGs developed by Region 2. Region 2 has significantly underestimated the contribution of background to the lower 8 miles.

Region 2's presentation of risks and PRGs in the FFS incorporates only the RME results of the HHRA, and ignores the central tendency exposure (CTE) scenarios that were evaluated for current and future baseline risks. The intent of evaluating both RME and CTE scenarios is to provide risk managers with a range of risk results, and promote more informed remedial decision-making (USEPA 1992, 1995).

Region 2 has not provided a sound rationale for excluding tissue PRGs that are based on CTE consumption rates, as well as other CTE exposure assumptions (i.e., cooking loss, exposure duration). The CTE scenario should be considered in the development of interim PRGs, in addition to the interim PRGs corresponding to 12 meals per year. This would provide a more representative and realistic set of tissue levels for use in setting interim remediation goals and monitoring remedy performance, particularly given that some species (e.g., carp) may take longer to attain levels considered safe for consumption.

In summary, Region 2 has significantly overestimated human health exposures from fish and crab and compounded the overestimation of risk with a poor assessment of toxicity. As a consequence, Region's grossly overestimated risk estimates have generated unrealistic and inappropriate PRGs that have resulted in the selection of an unnecessary and counterproductive bank-to-bank remedy. Not only are the resulting tissue PRGs inappropriate, they are not attainable for PCBs and mercury given the fact that Region 2 has chosen to ignore the influence of background.

[1] Only the total non-dioxin like PCB congeners were included in the development of the PRG for PCBs. Region 2 based this approach on the similarity of the calculated risks in the FFS HHRA for total non-dioxin-like PCBs and PCB-TEQ, and the assumption that any remedial action based on PRGs for total non-dioxin-like PCBs would address the presumed dioxin-like congeners.

I. COMMENTS ON THE FFS HUMAN HEALTH RISK ASSESSMENT

The FFS HHRA uses exposure assumptions that have been directed by Region 2 for use in the 17-mile baseline HHRA. These assumptions fail to acknowledge the characteristics of the LPR as well as account for site-specific exposures particularly with regard to fish and crab consumption. The exposure parameters have very little basis and are inappropriate for the LPR and result in overestimated risks that do not reflect the LPRSA and serve no purpose in managing human health risks. As a consequence of failing to perform a credible risk assessment, Region 2's grossly overestimated risk estimates have resulted in unrealistic PRGs and the selection of an unnecessary and counterproductive bank-to-bank remedy.

The deficiencies discussed below highlight the inadequacy of the FFS HHRA for remedy selection. The discussion of issues related to the HHRA as presented in Region 2's revised FFS for the lower 8 miles of the LPR is organized into four main topic areas:

A. *Exposure assessment*—Region 2's exposure assumptions used in the FFS HHRA are not realistic and do not reflect site-specific data, resulting in overstated estimates of current and future risk.

B. *Toxicity assessment*—Region 2's toxicity assessment approach has resulted in overestimates of PCB and dioxin risks, and key uncertainties in the dioxin toxicity equivalence scheme are not acknowledged.

C. *Consideration of background*—Region 2's incomplete background evaluation underestimates the contribution of upriver sources and significantly overstates the risk reduction that can be achieved by the selected remedy. The FFS HHRA also fails to effectively quantify and compare regional background risks from above Dundee Dam. In addition, the significant risks posed by pathogens in the river were not addressed.

D. *Selection of Preliminary Remediation Goals*—Region 2's selection of preliminary remediation goals is flawed and inconsistent with Agency guidance, resulting in remedial goals that are unattainable.

Key comments related to each of these four topics are discussed below.

A. Region 2's exposure assumptions used in the FFS HHRA are unrealistic, scientifically unsound and do not reflect site-specific data, resulting in overstated estimates of current and future risk.

The FFS HHRA uses exposure assumptions that were directed by Region 2 for use in the 17-mile baseline HHRA, including overly conservative fish and crab consumption rates, the assumption that all consumed catch is from the LPRSA, the assumption that exposure continues unabated for 30 years, and no accounting for loss of lipophilic contaminants during cooking. When combined with other conservative aspects of the risk assessment process (e.g., upper-bound EPCs and toxicity values), the exposure assumptions used by Region 2result in excessive and unrealistic projections of both current and future risk. Specific issues related to the exposure assumptions used in the revised FFS HHRA for the lower 8 miles of the LPR are summarized in the following table and discussed in detail below.

Analysis of EPA's Reasonable Maximum Exposure (RME) Assumptions			
Key Parameters	**EPA's FFS HHRA**	**CPG's Site-Specific HHRA**	**Basis of Difference**
Fish Consumption			
Fish Ingestion Rate (g/day)	34.6	8.9	The FFS HHRA fish ingestion rate is based on Region 2's flawed weight-of-evidence analysis of two angler surveys, neither of which is specific to the LPRSA, and both of which are more than 10 years old (Burger 2002; Connelly et al. 1992). When combined with the FFS HHRA assumption that all of the angler's fish is from the LPRSA (fraction ingested of 1), the EPA's estimate of fish consumption is unrealistic. ***CPG's fish ingestion rate is based on a creel/angler survey (CAS) specifically conducted for the LPRSA in 2011-2012. It was conducted in accordance with a peer-reviewed work plan over a period of 12 months, included on-site interviews and angler counts, and collected data needed to develop long-term estimates of fish consumption.***
Crab Consumption			
Crab Ingestion Rate (g/day)	21	2.1	The FFS HHRA crab ingestion rate is based on Region 2's flawed analysis of a 1999 Newark Bay angler survey that is not specific to the LPRSA, and is more than 10 years old (Burger 2002). When combined with the FFS HHRA assumption that all of the angler's crab is from the LPRSA (fraction ingested of 1), the EPA's estimate of crab consumption is unrealistic. ***CPG found little evidence of crab consumption in the LPRSA during the 2011-2012 CAS, which is consistent with other survey data of the LPR. Only one of nearly 300 anglers interviewed during the CPG's CAS reported consuming LPRSA crab. An FI of 0.1 has therefore been applied to the Region 2's crab ingestion rate to account for the very limited crabbing in the LPRSA and the close proximity of other more desirable crabbing destinations.***

Analysis of EPA's Reasonable Maximum Exposure (RME) Assumptions			
General Parameters			
Body Weight (kg)	70	80	EPA's value is based on its 1991 Standard Default Exposure Assumptions, which is outdated. ***CPG's value is based on more recent data published in EPA's 2011 Exposure Factors Handbook and recommended in 2014 Standard Default Exposure Assumptions. CPG's value is supported by site-specific angler body weight data collected during the CAS.***
Lifetime (years)	70	78	EPA's value is based on its 1991 Standard Default Exposure Assumptions. ***CPG's value is based on the more recent data published in the 2011 Exposure Factors Handbook.***

Cooking Loss				
Chemical	**EPA Default Cooking Loss (Fish and Crab)**	**CPG Fish Cooking Loss**	**CPG Crab Cooking Loss**	**Basis of Difference**
Chlordane	0%	32%	30%	EPA has made the unrealistic assumption that there is no loss of chemicals from fish or crab from cooking, or that cooking juices are always consumed. ***Based on angler behavior data collected during the CAS, CPG has incorporated cooking loss into its estimate of consumption risk, using cooking loss factors based on an extensive literature review.***
Dieldrin	0%	32%	30%	
DDx isomers	0%	32%	30%	
Heptachlor epoxide	0%	32%	30%	
Total PCBs	0%	30%	30%	
TCDD-TEQ	0%	48%	30%	

1. <u>Region 2's fish and crab consumption rates are inappropriate for the LPRSA, and overestimate consumption in the lower 8 miles.</u>

The fish and crab consumption rates used in the FFS HHRA are based on a deficient analysis that does not adequately consider the uncertainties and limitations of the data used. The consumption rates are from Region 2's February 2, 2012 Technical Memorandum on Fish and Crab Consumption Rates for the LPRSA Human Health Risk Assessment (updated from July 25, 2011) (Tech Memo, USEPA 2012). The Technical Memorandum discusses several sources of angler consumption rates, including guidance, state and regional angler surveys, and HHRAs conducted within the region. Using a "weight-of-evidence" approach, Region 2 settles on two studies as the basis of consumption rates for the LPRSA, neither of which is site-specific. One study is a 1991 survey of licensed New York State (NYS) anglers (Connelly et al. 1992), and the other is a 1999 survey of Newark Bay anglers (Burger 2002). Based on their deficient analysis, Region 2 calculates an RME adult fish consumption rate of 34.6 g/day for use in the LPRSA. This rate is the average of the upper 90th percentile rates for consuming anglers from the two studies

(37.3 g/day for Burger [2002] and 31.9 g/day for Connelly et al. [1992]). The RME adult crab consumption rate of 21 g/day is the 90th percentile rate for consuming crabbers based on Region 2's analysis of Burger (2002).

Region 2's Technical Memorandum states that a weight-of-evidence approach was followed to evaluate each source to determine its relevance and appropriateness for estimating consumption for the RME (USEPA 2012). However, the review performed by Region 2 has numerous flaws and inaccuracies that severely limit its usefulness, in particular as a scientific basis for developing one of the most important exposure parameters in the HHRA for the LPRSA. A true weight-of-evidence approach is a deliberate process by which individual lines of scientific evidence, some positive and some negative, are used in combination to make judgments about a particular conclusion or the selection of a particular assumption. However, several of the factors considered by Region 2, such as the number of consuming anglers identified in the study, whether the consumption rates are consistent across studies, and whether the consumption rates are consistent with those used in HHRAs for other sites in the region, are largely irrelevant to judging a particular study for its relevance or appropriateness to the task of deriving long-term consumption rates for use in a site-specific HHRA. In fact, application of such factors is inconsistent with the concept of a site-specific risk assessment. Region 2 did not directly evaluate the logic behind the study designs and their relevance for predicting long-term fish/crab consumption rates for the LPRSA. This is an important issue because fish consumption study results can be substantially impacted by the ways in which the studies are conducted and the purposes for which they are designed. As discussed below, these studies were not designed for the purpose of estimating long-term consumption rates for individuals who fish or crab in the LPRSA. Comments on Region 2's analysis and calculated consumption rates were prepared by the CPG during dispute resolution on the RI/FS risk assessment work plan (AECOM 2011a); these comments are part of the administrative record.

Region 2 states that the two selected studies (Burger (2002) and Connelly et al. (1992)) are the only studies that contained enough information to calculate statistical distributions for ingestion rates and included data from the New York/New Jersey Harbor Estuary (USEPA 2012). A site-specific creel/angler survey (CAS) of the lower 7 miles of the LPRSA performed by Tierra Solutions, Inc. in 2000 to 2001 (Desvousges et al. 2001; Ray et al. 2007) was disregarded by Region 2 for reasons that are unsound (AECOM 2011a). Region 2 also rejected the CPG's request to conduct a 2010 site-specific CAS that would have addressed many of these concerns. Because of these decisions, relevant site-specific information that would have improved the Region 2's analysis was not adequately considered. The CPG takes issue with Region 2's decisions for the LPRSA, as well as its choice of studies for several reasons, including:

- Had Region 2 implemented a more objective and technically defensible set of study selection criteria, the need for regional fish/crab consumption data would have been identified as critical, and the limitations of the selected studies would have been apparent.
- The 1999 angler survey of Newark Bay of Burger (2002) focused on investigating sociological reasons for angling and general patterns of fishing behavior and consumption. As such, key pieces of data needed for estimating consumption rate were not available and assumptions with a high degree of uncertainty had to be made.
- The 1991 statewide angler survey of Connelly et al. (1992) was a mail survey of licensed anglers that represents a very different demographic and geography than anglers that frequent the LPR, suffers from design issues (as identified by EPA in the 2011 edition of the Exposure Factors Handbook) that limit its usefulness for developing long-term consumption rates, and is now more than 20 years old.

- Finally, had Region 2 accepted the CPG's request to conduct a site-specific CAS of the entire LPRSA as part of the RI/FS,[2] there would be no need for the development of consumption rates based on surrogate data.

a) Summary of Burger (2002)

As noted above, Burger (2002) focused on investigating sociological reasons for angling and general patterns of fishing behavior and consumption, and was not designed to serve as a definitive study of fish and crab consumption rates, and Region 2's use of this study results in overestimates of fish and crab consumption in the lower 8 miles of the LPR. There are several critical issues associated with use of Burger (2002) for estimating long-term consumption in the FFS study area, including:

- The study did not collect data on the lower 8 miles of the LPR; therefore, the estimated fish and crab consumption rate represent Newark Bay.
- The study did not interview anglers for 8 months of the year, including months when fishing activity, as well as fish and crab availability, is lower.
- The study did not record data on the number, species, or sizes of fish or crab caught and kept by anglers.
- There is an implicit assumption that all of the meals are of Newark Bay fish and crab, although anglers may have included trips outside of the Newark Bay complex in their recall of monthly self-caught meals.
- The study based annual consumption on data obtained in one interview for each angler.

Burger's survey of the Newark Bay complex was selected by Region 2 as one of two surveys for developing the fish consumption rate and the sole basis of the crab consumption rate. The primary focus of Burger (2002) was to collect information about sociological reasons for angling and general patterns of fishing behavior and consumption. As such, key pieces of information needed for accurate risk assessment were not collected. For example, information regarding species, parts consumed, preparation or cooking practices, and sharing was not collected. Anglers were intercepted once between mid-May and mid-September at locations around Newark Bay and asked to recall the number of self-caught fish or crab meals per month they consume, portion size, and the months of the year they go fishing or crabbing (Burger 2002). Based on the responses obtained during the one intercept, the amount of fish or crab consumed over a year was calculated for the anglers who reported consuming their catch. Because of the limited data collected, Region 2 needed to make assumptions, which have led to overestimating consumption, which in turn, leads to overprediction of LPRSA risks.

For example, anglers likely based the number of monthly fish or crab meals consumed on their practice during the warm weather months when the survey was conducted. For anglers who reported also fishing or crabbing in colder weather months, the assumption that summer meal frequency and/or meal size is representative of cold weather practice is likely to overestimate annual consumption. For example, the highest fish consumption rate calculated by Region 2 in its reanalysis of Burger (2002) is 119 g/day. This rate is for a male angler who was intercepted in July and reported eating fish 8 times per month, fishing 12 months of the year, and eating a pound (16 ounces) of fish per meal (the highest fish meal size included in Region 2's reanalysis). Following Region 2's approach, this angler was assumed to eat a pound of fish (454 g) at each of his 96 meals per year. This translates to catching approximately 320 pounds per year of Newark Bay fish.[3] Irrespective of the fact that this rate of fish consumption requires a very high level of fishing activity and success, the assumption that the angler regularly eats more than double the average serving size of 7.3 ounces of other Newark Bay fish consumers at every meal of self-

[2] In a November 12, 2009 email message from Walter Mugdan to Geoffrey Grubbs, USEPA Region 2 declined the CPG's proposal to conduct a new CAS as part of the RI/FS for the LPRSA, as discussed at an October 29, 2009 meeting between USEPA Region 2 and CPG representatives.

[3] The ratio of edible fillet to whole fish is approximately 30% (EPA 1989).

caught fish and for 12 months of the year is at least highly unlikely and more likely ludicrous. In all likelihood, there is variation in the amounts of fish caught and consumed per fishing occasion (USEPA 2011); however, this variation could not be considered in the analysis due to limitations in the data collected. Based on literature on survey responses, discussed below, the angler's recall of fishing frequency and meal size is likely based on recent (July) behavior and is not representative of colder months of the year.

The accuracy and reliability of one-time recall data for estimating long-term consumption rates is known to be uncertain (USEPA 1997, 2011). In the 2011 Update to the Exposure Factors Handbook (USEPA 2011), EPA specifically identifies this issue as a limitation of Burger (2002). Further, recall survey methods tend to bias consumption rates high, especially for more avid anglers and longer recall periods (USEPA 1998; Connelly and Brown 1995; Chu et al. 1992; Fisher et al. 1991). This limitation and the associated impact on the data analysis and consumption rates are not acknowledged by Region 2.

There is also the implicit assumption that all of the meals are of Newark Bay fish and crab, although anglers may have included trips outside of the Newark Bay complex in their recall of monthly self-caught meals and the months of the year that they fish/crab. However, because fishing and consumption of fish/crab from locations within and outside of the Newark Bay complex was not distinguished in the survey, there is no way to make that distinction in the data analysis. Consequently, all fishing and consumption is assumed to represent Newark Bay fish and crab. This uncertainty, which is not acknowledged by Region 2, is likely to result in overestimates of Newark Bay consumption. Further, and most importantly no portions of the lower 8 miles of the LPRSA were included in the Burger (2002) study.[4] There are differences between the two water bodies in types and abundance of fish present and physical characteristics that are not accounted for, or even mentioned, in Region 2's analysis.

The description of the survey method and spatiotemporal sampling frame is not sufficient to assess its statistical rigor. Based on the limited description of the survey methodology provided, it appears that the sampling plan was not based on valid probability sampling, which attempts to survey an accurate representation of the larger population, but rather convenience sampling, which includes individuals who are most readily accessed to fill out the survey but cannot be generalized to the larger population. Therefore, while each individual who was encountered in Burger (2002) was reportedly interviewed only once, it is uncertain how representative the subset of anglers is of the larger population of Newark Bay anglers. If the data set is biased toward more avid anglers, the lack of any statistical weighting to adjust for the lower probability of encountering less avid anglers places more weight on the results of the avid anglers, and tends to bias consumption estimates high (USEPA 2011). Further, because the survey was conducted from May 15 to September 15, it did not capture the activities of individuals who may fish or crab from the area during the remaining eight months of the year. Because the behaviors of those individuals may differ from the behaviors of individuals who fish or crab in the summer, the results cannot be considered representative of the total angler population that uses the area. If the anglers who fish or crab in the non-summer months are less avid anglers than summer anglers, which is expected given seasonal fishing patterns, a part of the total angler population that is consuming at lower rates is missing from the distribution of consumption rates, further biasing high the upper 90th percentile rate of 37.3 g/day used by Region 2 in the calculation of LPRSA consumption rates.

Region 2 incorrectly states in the HHRA for the Revised FFS (Appendix D, p. 3-41) that the crab consumption rate is based on a 3-month period during which individuals reported catching crab and does not take into consideration crab meals eaten throughout the rest of the year, and that because of this, risks may be underestimated. Besides being incorrect, this statement is misleading. First, the survey was conducted over a 4-month period, not 3months as stated in Appendix D. Second, anglers were asked what months of the year they fish or crab, and as described above, all of the reported months were included in the estimate of annual consumption (as many as 6 months of the year for some interviewed crabbers).

[4] On August 20, 2010, Dr. Burger noted that her survey did not specifically sample the Passaic River area, as she was mainly interested in Newark Bay itself (Burger 2010).

b) Summary of Connelly et al. (1992)

Connelly et al. (1992) was the second of the two studies used by Region 2 as the basis of the fish consumption rates for the lower 8 miles of the LPR. This study was also used by Region 2 as the basis of the fish consumption rate for the Hudson River HHRA. There are several critical issues associated with use of Connelly et al. (1992) for estimating long-term consumption in the FFS study area, including:

- The study did not collect data on the lower 8 miles of the LPRSA,
- The target population was licensed NYS anglers with a different demographic profile than anglers in the FFS study area
- The study suffers from a low response rate even by mail survey standards, which limits the representativeness of the data
- The study represents fishing at water bodies that are hundreds of miles away from the LPRSA, and do not resemble the lower 8 miles of the LPR
- The study did not record data on the size of fish meals consumed by anglers, forcing the use of a default meal size
- The study is more than 20 years old and represents outdated information.

Connelly et al. (1992) was designed for the purpose of providing information about anglers' knowledge of fishing advisories in NYS and the impacts of advisories on their fishing and consumption behavior. In this mail survey of licensed NYS anglers, respondents were asked to record the numbers of fish caught and fish meals eaten by species and water body for the prior year. The response rate was approximately 52 percent, which is on the low end of accepted standards for mail surveys.[5] A lower response rate is likely to bias consumption estimates toward higher level consumers, leading to an overestimate of fish consumption rates. This is because individuals who do not respond to surveys of this type are likely to consume considerably less fish than individuals who do respond (Connelly et al. 1992; West et al. 1989a,b). Region 2 attempted to correct for this non-response bias by incorporating data from follow-up interviews with non-respondents; however, this adjustment was not made correctly. Had additional non-responding consumers that were left out of Region 2's analysis been properly included, the resulting fish consumption estimates would have been lower. In addition, data on meal size was not collected; therefore, Region 2 used an assumed meal size of a half pound of fish. In reality, some anglers may have eaten more or less than a half pound of fish per meal. This issue was identified in the 2011 Update to the Exposure Factors Handbook as a limitation of the study with respect to estimating consumption rates (USEPA 2011).

The fish consumption rates calculated by Region 2 from Connelly et al. (1992) are not supported by a more recent statewide study of New York anglers conducted by Connelly et al. (1996). This later study by the same Cornell University researchers was a diary study specifically designed to collect long-term fish consumption data and avoid the limitations associated with the 1992 study, including recall bias (Connelly et al. 1995, 1996). As shown below, the 90th percentile rate (13.2 grams/day) based on the more recent and better designed study is approximately two and a half times lower than the 90th percentile rate calculated by Region 2 (31.9 g/day).

Consumption Rate Percentile	Connelly et al. 1992 New York Multiple Rivers[a] (grams/day)	Connelly et al. 1996 New York All Waters[b] (grams/day)
50th	4.0	2.2

[5] Brown et al. (1989) reported a range of response rates from 41.7 percent to 89.8 percent for 38 recreational surveys conducted by their research unit at Cornell University, with a mean response rate overall of 71.8 percent.

90th	31.9	13.2
95th	63.4	17.9
Arithmetic Mean	17.3	4.9

[a] TAMS/Gradient (2000) analysis (Upper Hudson HHRA).
[b] USEPA (2011) analysis (Exposure Factors Handbook).

In addition, the statement in Region 2's Technical Memorandum (USEPA 2012) that Connelly et al. (1992) is representative of the New York-New Jersey Harbor anglers (and therefore LPRSA anglers) is misleading and wrong. Based on a comparison of race, the two target populations are quite different, as shown below. The impact of demographic differences on the consumption rates is an uncertainty not acknowledged by Region 2, and directly relates to the suitability of the NYS angler study as a surrogate for the FFS study area. For example, a major race group in the FFS study area, Hispanic anglers, is not represented in Connelly et al. (1992), and the White race group is overrepresented in the NYS angler study.

Race	Percent Respondents	
	NYS Angler Survey[a]	**2011-2012 CAS of LPRSA[b]**
Caucasian	95%	57%
African American	3%	12%
Hispanic	--	23%
Asian-Pacific Islander	--	2%
American Indian	--	1%
Other	2%	3%

[a] Connelly et al. (1992).
[b] AECOM (2014a).

In addition to the uncertainty associated with the differing demographics, there is uncertainty associated with using consumption rates based on NYS water bodies for the LPRSA. Many of the NYS freshwater fisheries are quite different from the estuarine fishery of the LPRSA, and particularly the lower 8 miles. The sport fish targeted by NYS anglers include species, such as walleye and trout, which are rare or not present in the LPRSA[6]. It is highly uncertain whether consumption rates based on NYS freshwater fisheries are representative of a water body with a higher proportion of estuarine and pollution tolerant species, such as white perch. Despite the availability of site-specific data, as part of its analysis of the NYS and Newark Bay studies, Region 2 did not compare the fisheries and species abundance in the LPRSA with that of NYS water bodies or Newark Bay. Had such an analysis been performed, Region 2 may have come to a different conclusion about the suitability of these studies for estimating LPRSA consumption rates.

Finally, there would be no need for angler survey data from surrogate water bodies had Region 2 accepted the CPG's request to conduct a site-specific CAS of the LPRSA as part of the RI/FS. On October 29, 2009, CPG representatives met with Region 2 to discuss CPG's proposal to conduct a new CAS of the 17.4-mile LPRSA as part of the RI/FS. As discussed at that meeting, site-specific fish

[6] As part of the RI/FS for the 17 mile study area, the CPG has conducted several fish community surveys to characterize the distribution and relative abundance of species throughout the LPRSA (Windward 2010, 2011).

consumption exposure parameters are fundamental data needs for conducting a baseline risk assessment at a large and complex sediment site with bioaccumulative contaminants. The results of both the FFS and RI/FS HHRA's have shown the dominance of the fish/crab ingestion pathway to overall human health risk.

In the CPG's view, the CAS is an essential piece of the overall RI/FS data collection process needed to characterize the LPRSA, accurately assess site risks, and provide the foundation for sound risk-based decision-making. Region 2's stated reasons for declining to approve the study (resource constraints for the review of the CAS and the anticipated challenges of gaining Partner Agency concurrence) were weak justification for not supporting and working with the CPG in this endeavor. This decision was also inconsistent with the level of detailed, site-specific investigation and assessment required by the Region in other aspects of the project, including sediment, surface water, and tissue chemistry, hydrodynamic sampling and analyses, numerical modeling, and biological and benthic studies, to name a few.

In summary, Region 2's willingness to accept default or surrogate values to characterize some of the most important aspects of the RI/FS (i.e., the variables used to estimate risk for the risk-driving human exposure pathway—fish consumption), coupled with its decisions to ignore data from an existing, well-conducted CAS that includes a portion of the study area and to decline the CPG's proposal to conduct a new CAS of the entire LPRSA, and yet require comprehensive, detailed characterizations of other aspects of the RI/FS, is unbalanced and not justifiable.

Because of the importance of site-specific consumption data, the CPG independently conducted a CAS of the LPRSA (AECOM 2011b). The CPG's CAS has provided extensive valuable data on fishing and consuming behaviors of LPRSA anglers (AECOM 2014a, b), and is used in an alternative, site-specific analysis of fish consumption risk that is discussed in Attachment B of these comments. The following table summarizes key aspects of the studies selected by Region 2 and the CPG's 2011-2012 CAS.

Survey Characteristics	**Newark Bay Complex**[a]	**NYS Angler Survey**[b]	**LPRSA Creel/Angler Survey**[c]
Date	5/15/99 – 9/15/99	Recall of fishing & consumption from 1/1/91 - 12/31/91	9/16/11 – 9/15/12
Survey Type	On-site access	Mail	On-site access with boat/land counts
Target Population	Newark Bay anglers	NYS licensed anglers	LPRSA anglers
Survey Duration	4 months	Mailed January 1992; 3 reminders to non-respondents the following month	1 year
Number of Sample Days	Not specified	Not applicable	136 (intercepts) 164 (counts)
Response Rate (eligible anglers)	97%	53%	70% (all) 86% (first time)
Number of Respondents	267	1030 of 2000 questionnaires	391 interviews 294 anglers

[a] Burger (2002).
[b] Connelly et al. (1992).
[c] AECOM (2014a).

As discussed, Region 2's approach to estimating fish and crab ingestion rates used in the FFS HHRA were based on inappropriate sampling data from locations outside the LPR and a scientifically flawed analysis that did not adequately consider the uncertainties and limitations of the data. Region 2 also rejected the CPG's request to conduct a site-specific creel/angler survey that would have addressed many of these concerns. For the reasons discussed above and in the CPG's prior comments on Region 2's Tech Memo (AECOM 2011a), the consumption rates calculated by Region 2 and used in the FFS HHRA overestimate rather than underestimate fish and crab consumption in the lower 8 miles of the LPR. Given the significance of fish/crab ingestion rates to estimating human health risks, the estimates provided in the FFS HHRA are grossly overestimated and serve no purpose in managing human health risks. As a consequence, Region 2 has generated unrealistic and inappropriate PRGs and resulted in the selection of an unnecessary and counterproductive bank-to-bank remedy.

(1) Fraction Ingested

For both the RME and CTE scenarios, Region 2 has used a fraction ingested (FI) of 1, which means that all of the fish and crab eaten is assumed to come from the lower 8 miles of the LPR. Region 2 cites the following as the basis for an FI of 1: the availability of fish and crab in the LPRSA; the high population density coupled with numerous access sites providing anglers with opportunities to return to successful fishing spots; the assumption that municipal plans for park improvements, if implemented, will increase fishing and crabbing; and the possibility that anglers who move remain within the study area (USEPA 2012). This logic is not supported by site-specific data. Much of the lower 8 miles of the LPR is bordered by private property, bounded by rail, bridge, and highway infrastructure, or fenced off from the river. The primary points of public access are limited to the Kearny boat ramp and park on the east bank between RM 6.8 and RM 7.7, Pathmark Pier on the east bank at RM 6.4, Riverbank Park in Newark between RM 4 and RM 5, and the eastern shoreline near Kearny Point. The assumption that park improvements will result in increased fishing and crabbing is speculative. The possibility of moving and staying within the study area is not a factor for FI; rather, this factor is accounted for in exposure duration.

Region 2 has not considered a key factor in anglers' decisions about where to fish, which is the abundance of more desirable and easily accessible water bodies nearby, such as the Hackensack River, Newark Bay, and the upper Passaic River above Dundee Dam. The CPG's CAS found that limited angling takes place in the lower 8 miles. Figure 1 presents the number of angler trips that were observed during the 164 sample days of the CPG's 2011–2012 CAS of the entire LPRSA (AECOM 2014a). As shown in Figure 1, the number of angler trips counted in the lower 8 miles is much less than in the upper 9 miles of the study area (<u>less than ~5% of total counted trips are to sites in the lower 8 miles</u>).

Based on the low number of fishing trips observed in the lower 8 miles of the LPR, Region 2's RME fish consumption rate of 34.6 g/day is not credible. The RME adult rate equals approximately 56 LPRSA fish meals per year assuming a half pound (8 ounce) serving size, or 74 LPRSA fish meals per year assuming a 6 ounce serving size (Stern et al. 1996). Including the young child of the adult angler, who is assumed to consume LPRSA fish and crab at one-third of the adult's consumption rate, this equates to a total of 74 to 100 self-caught LPRSA fish meals per year for the RME adult angler. This number of annual self-caught fish meals represents a high level of fishing activity and success, which then needs to be sustained each year for the full 30 years of the combined young child and adult's exposure duration.

As an additional point of comparison, EPA's 95th percentile per capita consumption rate for freshwater and estuarine finfish is 14.1 g/day (USEPA 2011). This rate is based on the U.S. Department of Agriculture's Continuing Survey of Food Intakes by Individuals (CSFII), which gathers data on intake of various foodstuffs by thousands of individuals throughout the United States for a non-consecutive two-day period. The CSFII was designed and conducted to support unbiased estimation of food consumption across the U.S. population (USEPA 2011). For estimating per capita fish intake, all sources of fish are included, including store-bought, restaurant, as well as self-caught fish. <u>The LPRSA RME consumption rate of 34.6 g/day is two and a half times higher than the EPA's upper-bound consumption rate of freshwater and estuarine fish from all sources for the general U.S. population</u>.

Using similar logic to that used for fish, the RME adult crab consumption rate equates to harvesting 170 crabs per year from the lower 8 miles. Including the young child of the adult crabber, this equates to a total annual harvest of approximately 226 LPRSA crabs. This number of annual self-caught crab meals represents a high level of crabbing activity and success, or approximately 28 successful LPRSA crabbing trips per year,[7] which needs to be sustained each year for the assumed 30-year exposure duration. Based on the very limited crabbing activity measured in two separate surveys of the LPR (discussed below), there is considerable doubt as to the representativeness of the RME crab consumption rate for the lower 8 miles under current baseline or future conditions.

During the 2000–2001 CAS of the lower 7 miles, only five anglers were intercepted who reported catching crabs (Desvousges et al. 2001; Ray et al. 2007). Of those five, four reported not keeping them. The fifth reported not keeping crabs on one trip, using them as bait on another trip, and did not specify their disposition for the third trip. These findings are consistent with the CPG's 2011–2012 CAS. Of the estimated 294 anglers who were intercepted during the CPG's CAS, only three reported crabbing in the LPRSA, and of those three, only one reported that he consumes the crab he catches in the LPRSA (AECOM 2014a). These site-specific results contrast with Burger's 1999 survey of Newark Bay Complex (which included the Arthur Kill), where 110 crab consumers were reportedly intercepted over a 4-month period. Given that both water bodies have the same crab advisory (Do Not Catch, Do Not Eat), it appears that the disparity between the two water bodies in the level of crabbing activity is due to differences in site setting, access, and water body characteristics that make the LPRSA a less desirable crabbing destination. The following table summarizes crabbing data from the three surveys.

	Newark Bay Complex Angler Survey[a]	**CAS of the Lower 6 Miles[b]**	**LPRSA CAS[c]**
Survey Date	5/15/99 – 9/15/99	8/2000 – 8/2001	9/16/11 – 9/15/12
Survey Type	On-site access	On-site access with boat counts	On-site access with boat & land counts
Target Population	Newark Bay anglers	LPR anglers (RM 1-7)	LPRSA anglers
No. Crabbers Intercepted	111	5	3

[a] Burger (2002).

[b] Desvousges et al. (2001), Ray et al. (2007).

[c] AECOM (2014a).

Based on the data of Burger (2002), as well as more recent unpublished New Jersey Department of Environmental Protection (NJDEP) angler survey data, Newark Bay and the Arthur Kill are frequented by crabbers. NJDEP's 1995 survey of the Newark Bay Complex found more than 20 marinas and public access sites for fishing, plus others that are not official public access sites but used regularly by anglers (including crabbers) during the fishing season (Kirk-Pflugh et al. 1999). Based on the available information, Region 2's assumption that crabbing in the lower 8 miles of the LPR is comparable to Newark Bay is not supported, and use of a 100% of the crab consumed comes from the lower 8 miles overestimates risk from crab consumption. The effect of using more realistic values for FI on the FFS crab consumption risk estimates is shown below. As shown, estimated risks from consumption of crab muscle and hepatopancreas drop as much as 10-fold when more realistic assumptions about the fraction of the diet comprised of crab from the lower 8 miles of the LPR are used. RME cancer and noncancer risks approach EPA's acceptable risk targets, CTE cancer risks are within the target risk range of 10^{-6} to

[7] A successful crabbing trip is assumed to yield sufficient harvest for the adult crabber to consume 6 crabs per meal and the young child to consume 2 crabs per meal (1/3 of adult rate per EPA (2012)), assuming an average edible tissue weight of 45 grams. The assumption of 6 crabs per meal for an adult is consistent with Burger 2002.

10^{-4}, and CTE noncancer risks are acceptable when 10% of the crab consumed is assumed to come from the LPR.

Fraction of Crab Diet from Lower 8 Miles	Cancer Risk from Crab Consumption for Child/Adult (Muscle and Hepatopancreas)[a]		Noncancer Risk from Crab Consumption for Young Child (Muscle and Hepatopancreas)[b]	
	RME	CTE	RME	CTE
1 (100%)[c]	2.E-03	1.E-04	67	9
0.5 (50%)	1.E-03	5.E-05	34	5
0.3 (33%)	7.E-04	3.E-05	22	3
0.1 (10%)	2.E-04	1.E-05	7	1

[a] Total cancer risks from HHRA for Revised FFS (April 2014).

[b] Total noncancer screening hazard index (without target endpoints) from HHRA for Revised FFS (April 2014).

[c] Default FI value used for RME and CTE crab consumption scenarios.

In summary, by using an FI of 1 for both the RME and CTE scenarios, Region 2 has significantly overestimated fish and crab consumption in the lower 8 miles. The assumption that the entire annual catch could be supported by the lower 8 miles of the LPR is baseless, especially as there are more desirable locations close by. There are significant access issues within this reach and the recent CAS has shown that only ~5% of the total trips observed were in the lower 8 miles. Based on the limited number of trips observed in the lower 8 miles, the consumption rate is not supportable and would need to be supplemented by other sources (FI < 1). Consequently, the human health risks from fish and crab consumption are grossly overestimated and this contributes to the compounding effect of inappropriate PRGs and the misleading protectiveness of a bank-to-bank remedy.

(2) Cooking Loss

For both the RME fish and crab consumption scenarios, Region 2 unrealistically assumed that there is never any loss of chemical mass due to cooking or that the cooking juices are always consumed. This has resulted in an overestimate of RME risk for fish and crab consumption. As discussed in guidance (USEPA 2000, 2011) and the scientific literature, loss of hydrophobic chemicals upon cooking is a recognized phenomenon that can have a significant effect on the chemical exposure dose from tissue consumption. Losses vary with cooking method (e.g., broil, bake, pan fry), preparation method (e.g., trimmed/untrimmed, skin-on/skin-off), and species, as documented in numerous studies, including those of Zabik et al. (1979, 1982, 1995a,b,c 1996), Stachiw et al. (1988), Sherer and Price (1993), Moya et al. (1998), Wilson et al. (1998), and Wang and Harrad (2000), and Hori et al. (2005).

A detailed review of relevant studies on mass contaminant loss in fish from cooking is summarized in AECOM (2012). The studies addressed a variety of fish species, including striped bass, carp, bass, catfish, perch, trout, flounder, salmon, walleye, and bluefish. Several of these species are relevant to the LPRSA. A variety of cooking methods was represented, including baking/roasting, broiling, grilling, boiling, poaching, pan frying, deep frying, microwaving, and smoking. The amount of chemical mass loss was variable within and between studies, which is likely due to a variety of factors, such as cooking time, temperature, tissue preparation (skinning and trimming) and fillet geometry, lipid content, initial chemical concentration, analytical methodology, and extraction efficiency, which are not consistently controlled for across the various studies. Despite the variability, the data are sufficiently consistent and robust to support inclusion of a quantitative cooking loss factor in the assessment of exposure dose from consumption of fish. The following table summarizes the results for three compound classes for which sufficient data are available (PCBs, DDx, and dioxins) (AECOM 2012).

Statistic	Range of Mass Loss by Multiple Cooking Methods		
	PCBs	Dioxin Compounds[a]	DDx Compounds
Median	0.30	0.48	0.32
Mean	0.32	0.48	0.34
Standard Deviation	0.17	0.12	0.18
Count of Values	79	11	70
Minimum	-0.17	0.28	0.03
10th Percentile	0.13	0.29	0.10
25th Percentile	0.20	0.46	0.21
50th Percentile	0.30	0.48	0.32
75th Percentile	0.42	0.55	0.41
90th Percentile	0.53	0.62	0.57
Maximum	0.74	0.63	0.80

Cooking method includes the following: deep frying, pan frying, baking/roasting, broiling/grilling, boiling/poaching, microwaving, and smoking.

[a]Excludes outlier of 100% loss.

Based on the observation that the cooking loss results for each of the three categories of contaminants of potential concern (COPCs) all fall into the same wide range, the case could be made for combining all studies into a single category of lipophilic organochlorine compounds and assigning one cooking loss factor to the entire set of compounds. However, in keeping with EPA's approach, the estimates of cooking loss from fish for the three compound classes are summarized as follows (AECOM 2012):

> **For total PCB mixtures**, cooking loss ranged from no loss to 74% loss across the 14 studies with relevant data. Median losses by cooking method ranged from 25% (bake/roast) to 39% (smoke), with a median of 30% when all PCB data are combined regardless of cooking method.
>
> **For dioxins, furans, and coplanar PCBs**, cooking loss ranged from 28% to 63% across the four studies with relevant data. Median losses by cooking method ranged from 29% (boil/poach) to 57% (bake/roast), with a median of 48% when all dioxin and furan data (except the extreme value of 100% loss) are combined regardless of cooking method. Combining all dioxin, furan, and dioxin-like PCB congener data also results in a median of 48%.
>
> **For DDx**, cooking loss ranged from 3% to 80% across the 10 studies with relevant data. Median losses by cooking method ranged from 22% (boil/poach) to 45% (smoke), with a median of 32% when all DDx data are combined regardless of cooking method.

In summary, by assuming there is no contaminant loss or that cooking juices are always consumed, Region 2 has overestimated RME fish consumption risks.

Region 2 chose to ignore EPA guidance and a significant body of peer-reviewed scientific literature that recognized the loss of hydrophobic chemicals from cooking. Cooking loss is a recognized phenomenon that has a significant effect on the calculated chemical exposure dose from tissue consumption by humans. In addition, Region 2's use of the cooking loss factor of 30% (based on total PCB mixtures) for PCB-TEQ overestimates fish consumption risks for this compound class. Cooking loss of dioxin-like PCBs is more like dioxins and furans, which has a higher cooking loss factor, than total PCB mixtures (Hori et al. 2005; Schecter et al. 1998). Consequently, the human health risks from dioxins/ furans, PCBs, and pesticides from fish and crab consumption are grossly overestimated. This is especially problematic as the human health-based PRGs are primarily based on these contaminants of concern (COCs).

2. The fish tissue exposure point concentrations do not reflect species abundance in the lower 8 miles.

In developing the fish tissue EPC used in the FFS HHRA, Region 2 pooled all samples of specimens that were caught in RM 0–8 and analyzed for fillet tissue chemistry during the 2009 RI/FS biota sampling event. This fish fillet data set consists of 16 American eel, 11 white perch, 6 white catfish, 4 common carp, 1 white sucker, and 1 smallmouth bass (n=39). The FFS HHRA states that the analytical data from these six species "were used to derive an equal-weighted concentration to represent the exposure point concentration (EPC) for fish" [p.3-12]. However, this is not an accurate characterization of the mixed species EPC nor does it consider consumption preferences. As shown below (Figure 2), the contribution of each species to the total mixed fish EPC is not based on equal weighting; rather it is based on the number of samples of each species in the total pool of samples. As shown, the species weighting based on sample number ranges from 3% for smallmouth bass and white sucker to 41% for American eel.

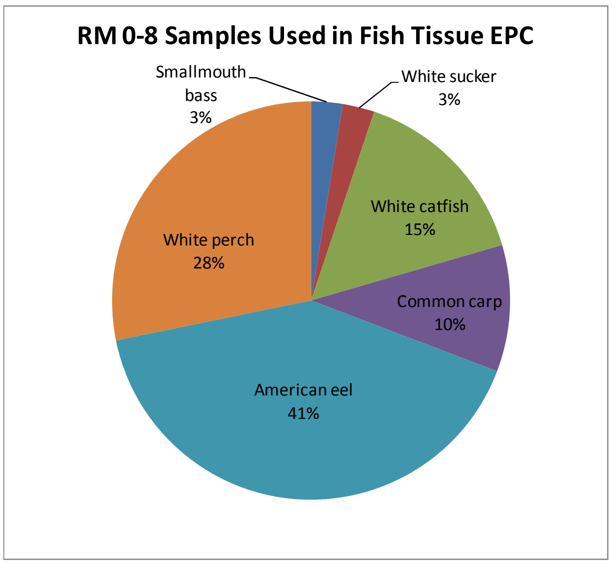

Figure 2. Species Composition in FFS HHRA Mixed Fish EPC (percent of total number of samples)

The number of samples per species used in the mixed species EPC is an artifact of the number of specimens of each species that was caught in the lower 8 miles of the LPR during the late summer/early fall 2009 fish community sampling and the number of samples of each species that was subsequently analyzed for tissue chemistry.[8] With the exception of species for which only a few specimens were caught (e.g., smallmouth bass, white sucker), the number of samples analyzed per species does not represent the total number caught or relative abundance, and does not reflect the distribution of fish species consumed by LPR anglers. Using Region 2's approach, the estimated EPC represents fish that were analyzed for chemistry, not those available for consumption. Region 2 selected the fish to be analyzed based on size and weight. Preference was given to fish that were at the upper end of the range of sizes caught (an example of this bias is shown in Figure 3 for common carp). As this approach preferentially selected many of the largest samples for analysis, it does not accurately reflect the fishery

[8] The approved Fish/Decapod QAPP (Windward 2009) identified white perch and American eel as target species in the estuarine zone, and channel catfish or brown bullhead and largemouth bass as target species in the freshwater zone. Additional species caught during the field program were retained for chemical analysis at the request of Region 2, including white catfish, white sucker, and common carp.

or consuming angler behavior. The resultant EPC used in the FFS HHRA is a gross overestimation of the actual RME EPC.

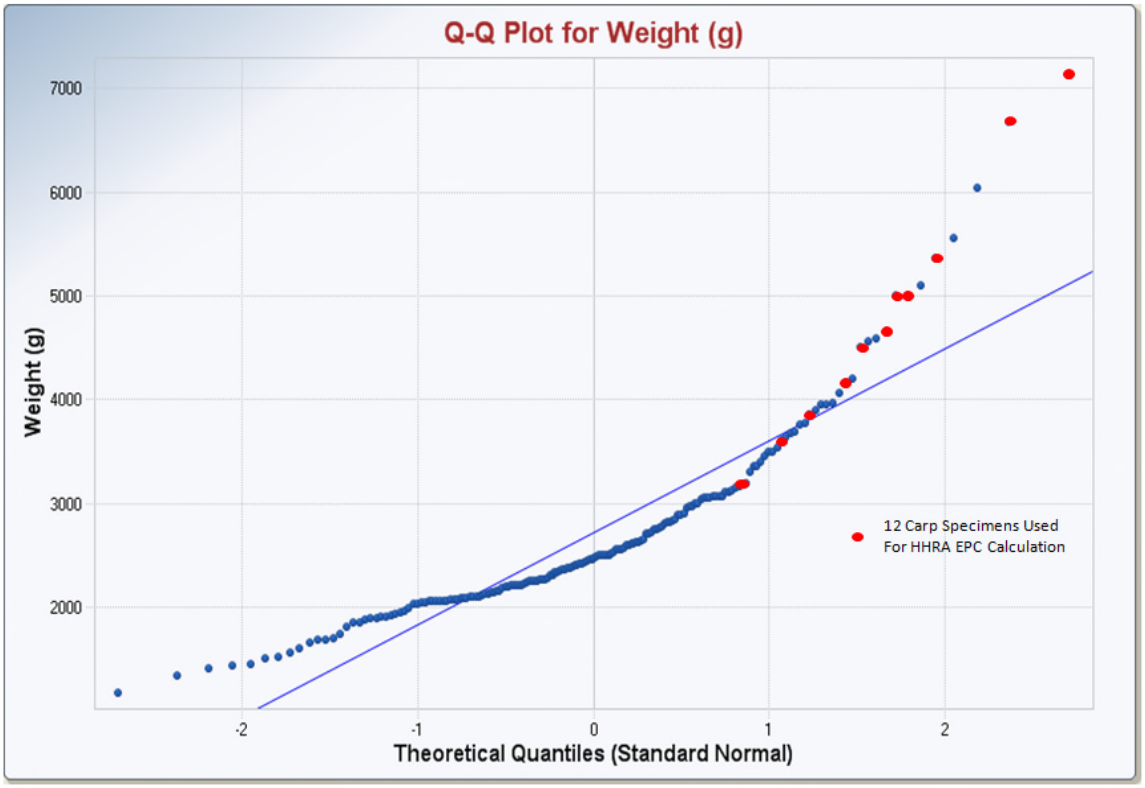

Figure 3. Size Distribution for All Carp Specimens from 2009 Sampling and Carp Specimens Selected for Tissue Analysis for the Baseline HHRA

To estimate relative abundance in the lower 8 miles, Region 2 has used relative abundance for all species that were caught throughout the LPRSA in the late summer/early fall 2009 fish community sampling (see Figure 3-2 of the FFS HHRA which is taken from the CPG's Fish and Decapod Field Report for the Late Summer/Early Fall 2009 Field Effort [Windward 2010]). However, use of relative abundance data for the entire 17 miles is misleading in that freshwater species not typically present in the estuarine lower 8 miles are included. In addition, Figure 3-2 of the FFS HHRA includes species that are not typically of interest to recreational anglers, such as mummichog, menhaden, and Atlantic silverside. Had Region 2 considered relative abundance of species of potential HHRA interest in the lower 8 miles in the development of the mixed fish EPC, a different composition would be apparent.

Figure 4 presents the relative abundance of fish species of potential HHRA interest for the lower 8 miles of the LPR caught by all methods for the late summer/early fall 2009 and the late spring/early summer 2010 fish sampling events. As shown, approximately 70% or more of the catch was white perch for each sampling event, followed by striped bass (average of 10%), and American eel (average of 9%). Bluefish and common carp (a species that is more abundant in freshwater than estuarine water) each made up about 4% of 2009 and 2010 catch, with small fractions of other species (white catfish, largemouth bass, smallmouth bass, white sucker, and brown bullhead). These data suggest a weighting scheme that places greater weight on white perch, and less weight on American eel, is supported.

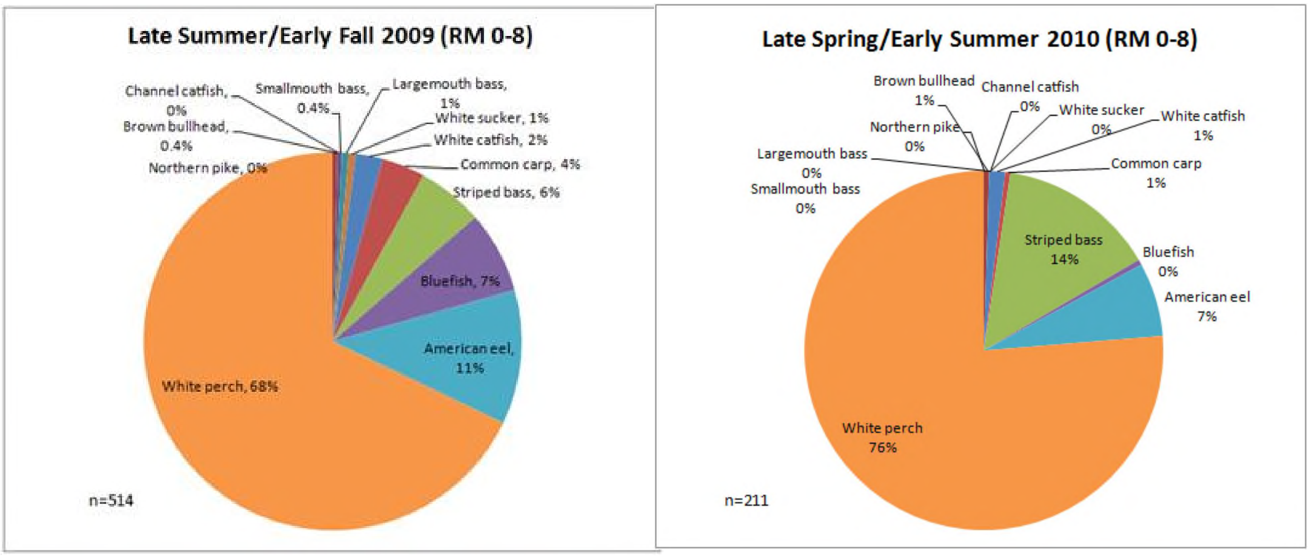

Figure 4. Relative Abundance of Fish Species of Potential HHRA Interest in Lower 8 Miles

3. Crab tissue EPCs are overestimated, resulting in overestimates of risk from crab consumption.

Region 2 has assumed that the crab consumer always eats or is exposed to the contaminants present in the hepatopancreas, as well as the muscle tissue, of the crab[9]. The FFS HHRA, which cites NJDEP (2002), states that "consumers who do not deliberately eat the hepatopancreas are likely to be exposed to all or part of its content due to its fluid nature and its dispersion in the cooking liquid" (p. 3-14). The FFS HHRA also states that because crabs are cooked whole, even eating only the muscle tissue still results in exposure to contaminants present in the hepatopancreas. However, this contention is not supported by a crab tissue study. Zabik et al. (1992) found the percent loss of PCBs from crab muscle tissue boiled with and without the hepatopancreas was similar (approximately 25% to 35%), indicating that chemicals present in the hepatopancreas do not end up in the muscle when the crab is cooked whole. While Zabik et al. (1992) evaluated PCBs, this finding likely applies to other lipophilic compounds. In addition, and as reported in the FFS HHRA, crab surveys conducted by NJDEP in 2005, 2006, and 2007 within coastal counties of New Jersey (ORC Macro 2006; Macro 2007, 2008), found that the majority of crab consumers remove the hepatopancreas either before cooking or after cooking, but before eating the crab. Of those responding, only 2% reported consuming the hepatopancreas separately. This latter finding is consistent with other Newark Bay surveys cited by Region 2, including May and Burger (1996), which found that most crabbers ate only cleaned crabs with the hepatopancreas discarded, and fewer than 3% ate the whole crab. A second study (NJDEP 2002, Kirk-Pflugh et al. 1999) reported that 15% of the population surveyed in the Newark Bay complex ate the hepatopancreas. Burger et al. (1998) reported that less than 10% of anglers that fish or crab in Barnegat Bay, NJ ate the whole crab. In addition, in their 2008 comments on Region 2's draft FFS, CSTAG recommended that consumption of crab muscle tissue be included in the development of PRGs for the LPRSA, because it is the tissue type typically consumed. Despite this recommendation, Region 2 did not include an evaluation of risks or PRGs from consuming crab muscle only in the revised FFS HHRA.

In summary, based on several surveys in Newark Bay and the New Jersey coast, the majority of crab consumers eat only the muscle tissue. For those consumers who may not remove the hepatopancreas before boiling or steaming the crab, contaminants that may disperse into the cooking water are not subsequently taken up by the muscle tissue (Zabik et al. 1992). While the percentage of crab consumers

[9] The hepatopancreas has been shown to have higher concentrations of many bioaccumulative contaminants than the muscle tissue, and NJDEP crab advisories warn consumers against eating the hepatopancreas or "green gland" or using the cooking liquids for soups and sauces (NJDEP and NJDHSS 2013).

who use the crab cooking liquid for soups and sauces is not known, it is unlikely to be the majority. For these reasons, the assumption that the crab consumer is always exposed to the contaminants present in both the muscle and the hepatopancreas overestimates risks for the vast majority of consumers, as shown below in Figure 5.

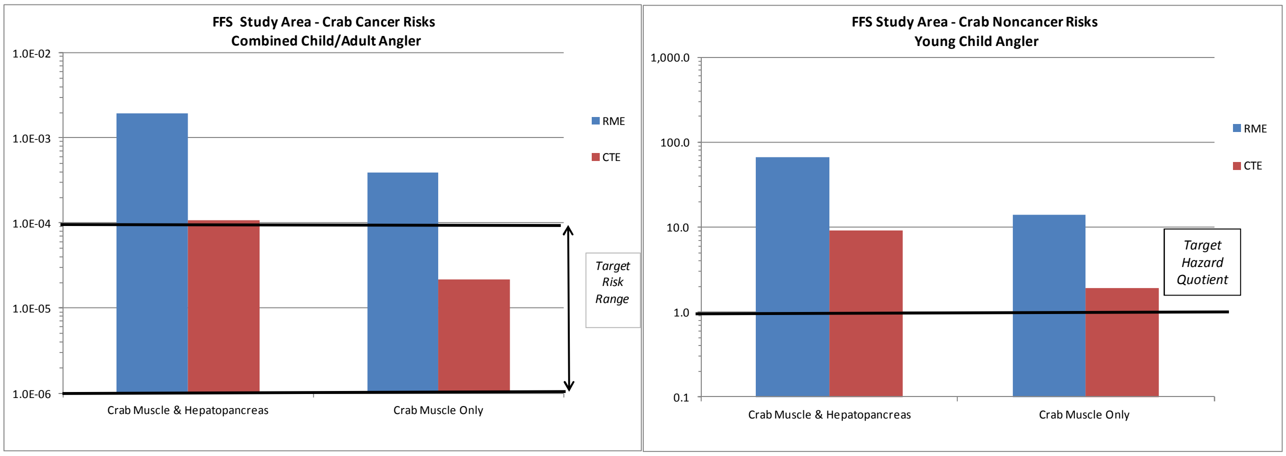

Figure 5. Comparison of Crab Risk by Tissue Type Consumed

<u>Calculation of Site-Specific Risks Using More Realistic Assumptions</u>

To address the need for a more scientifically sound and defensible risk assessment of the LPRSA, the CPG has conducted a separate site-specific human health risk assessment (SSHHRA) to provide a more reasonable estimate of upper-bound risks. This has been accomplished by developing a "more reasonable" RME scenario using more realistic exposure parameters and more realistic set of exposure scenarios.

The use of site-specific data is a critical part of the risk assessment and risk management processes, and is consistent with guidance concerning risk management decisions at contaminated sediment sites articulated by the National Academy of Sciences (NRC 2001) and USEPA (2002b, 2005). A site-specific approach is especially relevant for evaluating water-related recreational activities (e.g., fishing, swimming, boating) that depend on the characteristics of the water body and are often not well described by default exposure parameters. Site-specific risk evaluation requires knowledge of local receptor populations and their behaviors, as well as the characteristics of the site and surrounding area.

As stated in EPA's Guidance for Exposure Assessment (USEPA 1992), the intent of the RME is to estimate a conservative exposure that is above the average case but still within the range of possible exposures (defined as above the 90th percentile for the population of interest). EPA's guidance also advises that not all RME exposure factor inputs should be set to upper percentile (or maximum) values, so that resulting exposure estimates do not exceed the RME (USEPA 1989, 2004). With this in mind, the SSHHRA identifies values that are appropriate for evaluating a single alternative RME scenario. For exposure parameters that are best characterized by site-specific conditions, such as fish consumption or the frequency of a particular recreational activity, the SSHHRA uses values that are more realistic and technically supportable for the LPRSA than the assumptions directed by Region 2 and used in the FFS HHRA, but are still conservative and representative of an RME scenario.

Site-specific data for the LPRSA were gathered from a variety of sources including discussions with local organizations, observations of people using the river, interviews with anglers, and review of redevelopment and restoration plans. A year-long CAS of the LPRSA conducted by the CPG in 2011 and 2012 provides extensive information on angling in the study area that has been used in the SSHHRA.[10]

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[10] Based on the CAS findings, which are supported by extensive literature suggesting limited effectiveness of advisories in posted water bodies, such as the LPRSA, for anglers who still wish to consume their catch, the CAS data do not underestimate baseline

Studies published in the peer reviewed literature also provide information that has been considered in the development of more realistic assumptions and exposure parameters. Applicable data on general exposure factors (e.g., body surface area, body weight) have also been obtained from EPA sources.

Attachment B presents the alternative HHRA conducted by the CPG using more realistic and site-specific assumptions. This analysis includes all potential exposure scenarios that may be potentially complete at the LPRSA, including:

- Current and future recreators, including swimmers, waders, and boaters:
  - Direct contact with accessible nearshore and mudflat surface sediment and surface water
- Current and future anglers:
  - Direct contact with accessible nearshore and mudflat surface sediment and surface water, and ingestion of LPRSA fish and crab
- Current and future residents:
  - Direct contact with river sediment that may have deposited in backyards adjacent to the river following flooding events, referred to as "floodplain soil"
- Current and future workers:
  - Direct contact with accessible nearshore and mudflat surface sediment

The following figures compare the results of the SSHHRA for fish consumption with the results of the FFS HHRA for the RME and CTE. As shown in Figure 6, using more realistic RME assumptions, the estimated cumulative lifetime risk for the angler receptor is 4×10^{-4}. This risk estimate includes all potential exposure pathways for the angler, including occasional contact with river sediment and surface water while fishing (these risks are at or below the low end of EPA's target risk range of 10^{-6} to 10^{-4}), as well as fish consumption. This site-specific risk estimate is over 10-fold lower than the RME risk predicted by EPA in the FFS HHRA, and only slightly higher than the FFS CTE risk estimate.

Figure 7 compares the results of the SSHHRA and FFS HHRA for cumulative noncancer risks, without regard to target endpoints. As shown in Figure 7, using more realistic RME assumptions, the estimated cumulative noncancer risk for the young child angler (most sensitive age group for noncancer effects) is 17. This site-specific estimate is more than 10-fold lower than the RME risk predicted in the FFS HHRA, and only slightly higher than the FFS CTE estimate. The results for crab consumption are similar. The estimated cumulative site-specific risks from consuming LPRSA crab are over ten-fold lower than the corresponding RME risks in the FFS HHRA. The estimated cumulative site-specific risks from consuming crab muscle only are below USEPA's target risk levels (see Attachment B).

The SSHHRA illustrates the extreme overconservatism in the Region 2 FFS HHRA, which in turn, has resulted in exaggerated risks and unrealistic PRGs, as discussed below in Comment D.

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consumption in the LPRSA (see Section 5.3.2 of Attachment B for a discussion on the impact of the advisory). For the purposes of estimating risk from consumption of LPRSA fish and crab, the CPG's site-specific CAS data are superior to data from studies of surrogate water bodies (which are also subject to consumption advisories), as was used by Region 2 to develop the fish and crab consumption rates for the FFS HHRA.

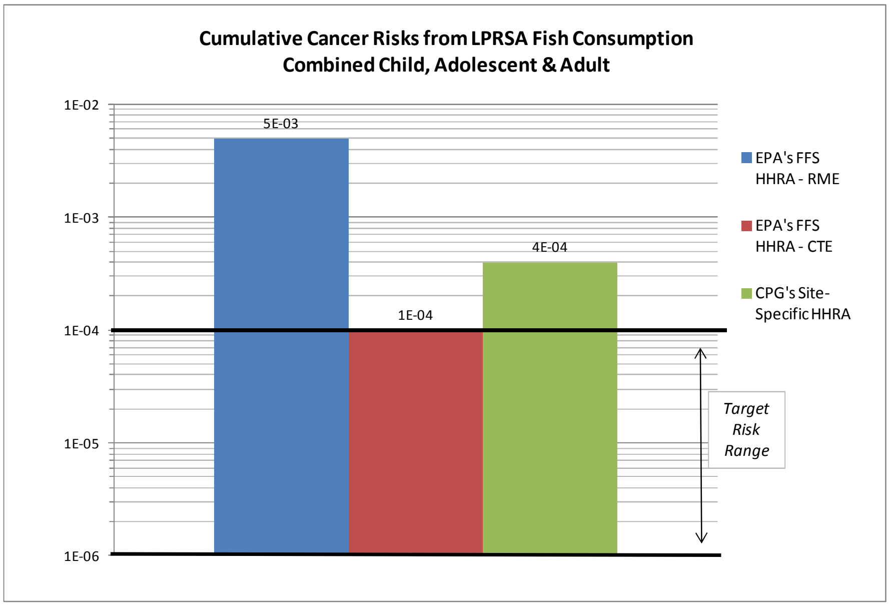

Figure 6. Comparison of FFS HHRA and Site-Specific Fish Consumption Cancer Risks

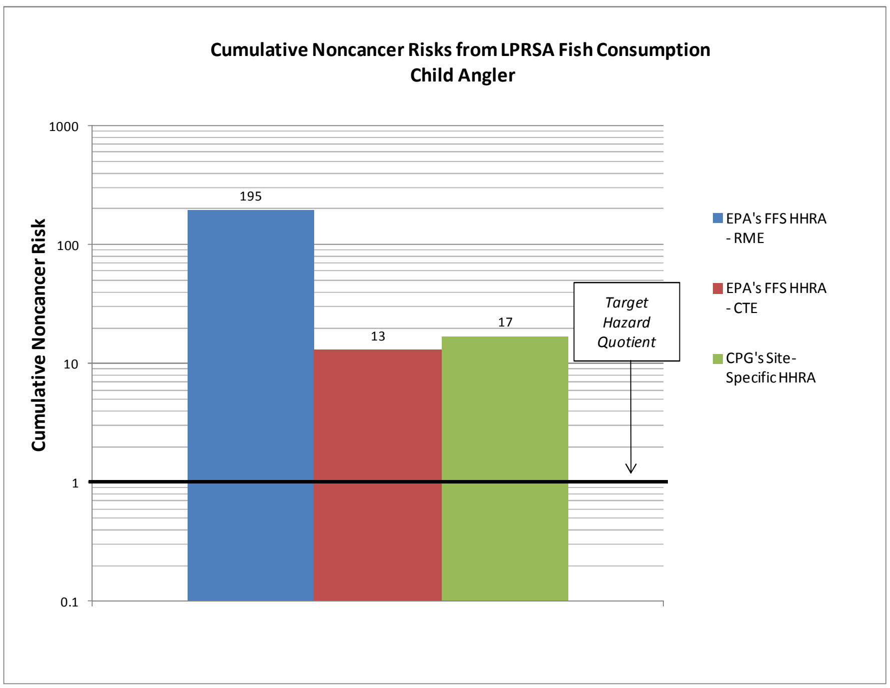

Figure 7. Comparison of FFS HHRA and Site-Specific Fish Consumption Noncancer Risks

B. The toxicity approach used in the FFS HHRA has resulted in overestimates of PCB and dioxin risks.

1. The FFS HHRA overstates the risks posed by PCBs.

Region 2's approach of summing non-dioxin-like PCB and dioxin-like PCB cancer and noncancer risks does not account for a variety of issues and uncertainties associated with this compound class, and results in an overestimation of PCB risks.

Region 2 evaluates dioxins and furans having mechanisms of toxicity similar to that of 2,3,7,8-TCDD using a TEF scheme, where each dioxin/furan congener is assigned a TEF that equates the toxicity of the congener to that of TCDD. The TEFs are applied to the measured congener concentrations in environmental media and the results are summed to provide a TEQ concentration. The CSF for TCDD is then applied to the average daily dose of TEQ calculated in a risk assessment to estimate potential risk due to the exposure scenario(s) evaluated. EPA has identified a subset of 12 PCB congeners as "dioxin-like," and has assigned a TEF to each of these congeners (USEPA 2010). However, evaluation of the dioxin-like toxicity of the presumed dioxin-like PCB congeners is not necessarily appropriate.

Toxicity values for PCBs have been developed based on studies in animals using mixtures called Aroclors, specifically Aroclors 1016, 1242, 1254, and 1260. The CSFs developed by EPA for total PCBs and published on the Integrated Risk Information System (IRIS) are based primarily on the chronic rat feeding study of Brunner et al. (1996), and later published by Mayes et al. (1998), which evaluated Aroclors 1016, 1242, 1254, and 1260. This study is considered by EPA to provide the best information for distinguishing the cancer potential of different mixtures (USEPA 1996; Cogliano 1998). The highest upper-bound CSF from this study was 1.5 $(mg/kg\text{-}day)^{-1}$ for Aroclor 1254. Thus, EPA's range of CSFs for PCB mixtures is based primarily on the potencies observed in Brunner et al. (1996), in which Aroclor 1254 was the most potent. EPA used these Aroclor toxicity study results to develop a range of CSF for total PCBs, based on persistence of the congeners, chlorine content, and route of exposure.

The Aroclor mixtures have been demonstrated to contain dioxin-like PCB congeners, such that the toxicity study results for each Aroclor mixture (both cancer and noncancer toxicities) represent the summed toxicities of all of the congeners in each mixture, and thus include the sum total of dioxin-like and non-dioxin-like activities. Thus, the high risk and persistent CSFs of 1 and 2 $(mg/kg\text{-}day)^{-1}$ listed on IRIS are protective of exposures to the amount of TEQ from the 12 "dioxin-like" congeners present in the Aroclor 1254 bioassay test material. The level of TCDD-TEQ in the Aroclor 1254 test mixture has been shown to be 46.4 mg-TEQ/kg-PCBs (Cogliano 1998). Based on this analysis, calculating a risk for exposure to total PCBs using the PCB CSF, and a risk for dioxin-like PCB congeners using the TEFs and the CSF for TCDD is really a duplicative analysis of the potential toxicity of the dioxin-like PCB congeners.

Region 2's's approach in the FFS HHRA of summing non-dioxin-like PCB and dioxin-like PCB cancer and noncancer risks does not account for this overlap of the dioxin and PCB cancer potency and reference dose toxicity estimates, and overstates the contribution of PCBs to total risk. As noted above, the CSF for PCBs already includes the carcinogenic potential of the dioxin-like PCB congeners in the PCB (Aroclor) mixtures tested in the animal studies that form its basis.

In an effort to avoid double-counting, EPA has subtracted the concentrations of the 12 presumed dioxin-like congeners from the total PCB concentration and calculated risk for the remaining non-dioxin-like PCB total using the high risk and persistence PCB CSFs published on EPA's IRIS database (USEPA 2014a). However, this approach does not resolve the double-counting, because the CSF used to evaluate the non-dioxin-like PCBs is based on the toxicity of the total dioxin-like and non-dioxin-like congeners in the Aroclor mixture, and thus overestimates the potential toxicity of the non-dioxin-like congeners. Thus, by summing cancer (and noncancer) risks for non-dioxin-like PCBs and PCB-TEQ, the resulting risk estimates for total PCBs are overstated; however, the magnitude of this increase in risk cannot be determined.

One way to estimate this increased risk estimate is to compare the total TEQ in both the Aroclor 1254 mixture and in the samples of environmental media. As stated above, the amount of TEQ present in the Aroclor 1254 bioassay test material is 46.4 mg-TEQ/kg-PCBs (Cogliano 1998). If site and media-specific TEQ concentrations are below 46.4 mg-TEQ/kg-PCBs, then it can be concluded that the PCB TEQ content does not exceed the level of protectiveness afforded by the high risk and persistence CSFs for total PCBs. Conversely, if the site and media-specific PCB TEQ concentrations are above 46.4 mg-TEQ/kg-PCBs, then it can be concluded that the environmental medium is enriched in the dioxin-like congeners, and that a separate analysis of dioxin-like PCB congeners may be warranted.[11]

To specifically evaluate this for the LPRSA, the PCB TEQ content in six species of LPRSA fish and three crab tissue types are compared to the benchmark of 46.4 mg dioxin-like TEQ per kg PCBs in Figure 8.

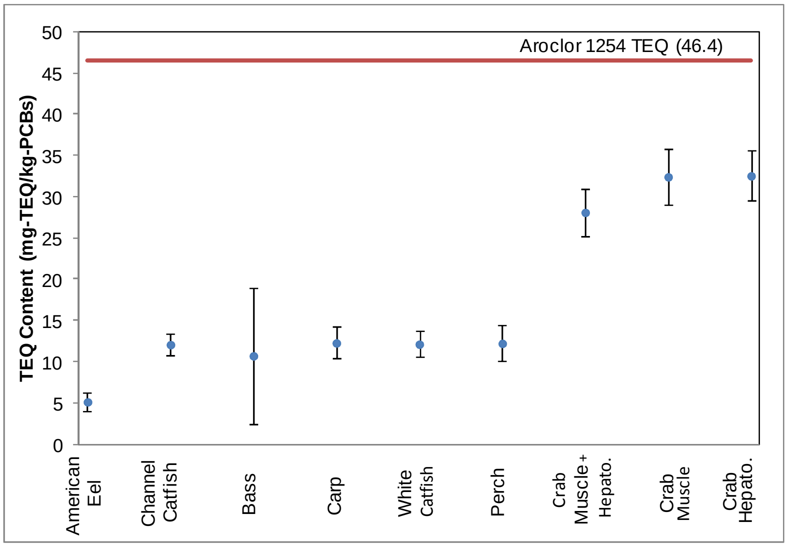

Figure 8. Mean and 95% Confidence Limits for PCB TEQ Content in LPRSA Fish and Crab

As shown, the mean and 95% confidence limits of PCB TEQ content for all species and tissue types fall below the benchmark of 46.4 mg dioxin-like TEQ per kg PCBs. These findings indicate that PCB TEQ levels in LPRSA fish and crab has not exceeded the TEQ level in the Aroclor 1254 bioassay. This suggests that the PCB CSF is adequately protective for evaluating potential cancer risks of PCBs in LPRSA fish and crab, and an additive analysis of PCB-TEQ risks is not only not necessary, but results in overstating PCB cancer risks. These findings are consistent with an expanded analysis of fish tissue from PCB-impacted waterways across the U.S., which found mean and 95% confidence limit TEQ levels lower than 46.4 mg-TEQ/kg-PCBs for all waterways and a range of PCB levels in fish tissue (Keenan and Samuelian 2005).

The issue of double-counting is recognized by Region 2 in its Responsiveness Summary for the Hudson River Proposed Plan (USEPA 2002a). In the revised baseline HHRA for the Hudson River, Region 2 evaluated cancer risks from exposure to dioxin-like PCBs using the latest scientific consensus on TEFs for dioxin-like PCBs "as an additional consideration for the risk manager." Risks from dioxin-like PCBs were not combined with non-dioxin-like PCBs, but were presented separately. Region 2 states that this approach was based on the Agency's "ongoing effort to develop a procedure for combining these cancer risks to avoid potential double counting" (USEPA 2002a). This approach has also been adopted at the Lower Duwamish Waterway in Region 10, where total PCB and PCB-TEQ risks are presented separately in the final baseline HHRA for this sediment site (Windward 2007). It is also the approach described in the Department of Defense's 2013 technical guidance titled, "Questions/Answers on Dioxin" (TSERAWG 2013). The Tri-Service Environmental Risk Assessment Working Group (TSERAWG) provides the following guidance for use at U.S. Army, Navy, and Air Force sites:

> "*How are dioxin-like PCBs addressed in the risk assessment?*

[11] Notwithstanding issues and concerns related to the application of the EPA's TEF scheme to PCBs, as discussed in Comment B-3 of the CPG's comments on the FFS HHRA.

If the mixture contains dioxin-like PCBs, then the risk of these compounds should be evaluated either as a dioxin TEQ or as PCBs, but not both for the same non-cancer Hazard Quotient or cumulative cancer risk. This avoids double-counting exposure risks." (TSERAWG 2013)

In summary, the current state-of-the-science supports the contention that PCB risks in the FFS HHRA are overstated, and the approach used by EPA is unnecessarily conservative. Despite Region 2's efforts to avoid double-counting, its approach overestimates the potential toxicity of the non-dioxin-like congeners. Thus, by summing cancer (and noncancer) risks for non-dioxin-like PCBs and PCB-TEQ, the resulting risk estimates for total PCBs are overstated.

2. <u>The 2,3,7,8-TCDD CSF used in the FFS HHRA is inconsistent with the CSF used by EPA to develop national risk-based screening levels for use at Superfund sites.</u>

Region 2 has used an outdated cancer potency estimate for dioxin that is inconsistent with practice in most other EPA regions and with the Agency's own national screening levels, and overstates risks for dioxin and dioxin-like compounds by approximately 15%. EPA's IRIS database does not currently provide a cancer classification for TCDD, and indicates that "the cancer assessment for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) is currently underway" (USEPA 2014). Due to the lack of a final peer-reviewed and consensus-based CSF for TCDD, it is necessary to use what is considered by EPA to be a "Tier 3" value (USEPA 2003). For the evaluation of dioxin and dioxin-like compounds in the FFS HHRA, Region 2 has selected an outdated value that is inconsistent with the hierarchy established and used by EPA's Regional Screening Level (RSL) workgroup for setting national harmonized screening levels for use in contaminated site screening (USEPA 2014b). The RSL workgroup is comprised of staff within the Office of Superfund Remediation and Technology Innovation, as well as the regions. As discussed in their white paper on the selection of Tier 3 toxicity values (USEPA 2013) and the User's Guide for the RSL table (USEPA 2014c), the RSL workgroup has selected Tier 3 toxicity values for use in deriving national chemical- and medium-specific screening levels based on the following hierarchy:

1. ATSDR minimal risk levels (MRLs),
2. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment's (OEHHA) Chronic Reference Exposure Levels (RELS) from October 2013 and the Cancer Potency Values from July 21, 2009 with updates in 2011 for dioxin/furans and dioxin-like PCBs,
3. EPA Provisional Peer Reviewed Toxicity Values (PPRTVs) appendix screening toxicity values, and
4. Health Effects Assessment Screening Table (HEAST) (last published by EPA in 1997).

Based on the above hierarchy, the RSL workgroup selected the California EPA (CalEPA) CSF of 130,000 $(mg/kg\text{-}day)^{-1}$ over the older HEAST value of 150,000 $(mg/kg\text{-}day)^{-1}$ for deriving RSLs for dioxin and dioxin-like compounds since the inception of the RSL table in September 2008.[12] It is EPA's intent that the RSL web site is the source of screening levels for all EPA regions. In fact, the EPA RSLs are the screening values that Region 2 required the CPG to use in the selection of COPCs for the LPRSA baseline HHRA.

The CPG recognizes that regions may choose to use different toxicity factors than those selected by the Agency's workgroup for RSL development. However, with respect to TCDD, several post-2008 baseline HHRAs conducted outside of Region 2 have used the CalEPA CSF for TCDD, including sites in Regions 1, 4, 5, 6, 9, and 10. Region 2's rationale for using the older HEAST value cites consistency with other HHRAs and because the older HEAST value is based on the incidence of all significant tumors combined, not just liver tumors, as is the case with the CalEPA CSF. However, the HHRAs cited by Region 2 (Hudson River, Housatonic River, and Centredale Manor/Woonasquatuckett River in Region 1)

[12] Prior to September 2008, the Region 3 Risk-Based Concentration (RBC) and Region 9 Preliminary Remediation Goal (PRG) tables used the older HEAST value.

were conducted prior to 2008 when the CalEPA CSF was selected for RSL development. In a recent baseline HHRA performed in Region 1, the CalEPA CSF for TCDD is used (e.g., *Baseline Human Health and Ecological Risk Assessment. Southwest Properties, Wells G&H Superfund Site, Operable Unit 2,* Woburn, Massachusetts, TRC for EPA Region 1, March 2014).

With respect to the issue of tumor incidence, the tumor classification for the rat bioassay of Kociba et al. (1978), which is the basis of the HEAST CSF of 150,000 (mg/kg-day)$^{-1}$, relied on pre-1986 methodology. It was reassessed in 1990 by seven pathologists including Kociba and Dr. Robert Squire, a pathologist consultant to the EPA Carcinogen Assessment Group. Using an updated National Toxicology Program (NTP) liver tumor classification scheme, the reevaluation indicated lower tumor incidence rates and a slope factor of 52,000 (mg/kg-day)$^{-1}$ based on liver tumors alone, and a slope factor of 75,000 (mg/kg-day)$^{-1}$ based on total significant tumors (Sauer 1990).

In 1982, NTP released a new 2-year rat and mouse gavage study of TCDD (NTP 1982). The number of treatment groups and dose ranges were similar to that used by Kociba et al. (1978). Based on its review of NTP (1982), Kociba et al. (1978), and a 1980 reevaluation of the tumor incidence of the Kociba study, the California Department of Health Services (CDHS) concluded that the most sensitive species, sex, and site for the induction of cancer by TCDD is the male mouse with hepatocellular adenomas or carcinomas (CDHS 1986). Applying a linearized multistage model to the NTP (1982) male mouse hepatocellular adenoma/carcinoma tumor data and assuming route-to-route extrapolation, a unit risk factor of 38 (µg/m^3)$^{-1}$ was derived. This upper-bound potency estimate equals the oral CSF of 130,000 (mg/kg-day)$^{-1}$ used by CalEPA (2002).

In summary, Region 2's use of the HEAST CSF for 2,3,7,8-TCDD is inconsistent with guidance developed by EPA for establishing harmonized screening levels for use at sites across the country. Following the lead of the RSL Workgroup, which includes EPA national and regional staff, many EPA regions have also adopted the more recent CalEPA CSF for use in risk assessment of dioxin-like compounds. Consequently, risks for dioxin and dioxin-like compounds are overstated by about 15% in the FFS HHRA. Given that TCDD is the controlling COC, the use of an inappropriate CSF further compounds the unreliability of the resulting PRG and consequently, the selection of an inappropriate remedy.

3. <u>The discussion of uncertainty regarding the use of toxicity equivalency factors in general, and for dioxin-like PCBs in particular, is inadequate and incomplete.</u>

Region 2 has provided an incomplete and uninformative description of the uncertainties associated with the use of TEFs in calculating risks for dioxin and dioxin-like compounds (DLCs). Additional uncertainty in the application of the TEF methodology to PCBs is not acknowledged at all, potentially leaving risk managers and stakeholders with a greater impression of certainty in the PCB-TEQ risk estimates than is warranted. The numerous uncertainties associated with the application of the TEF approach to human health risk assessment of DLCs, including PCBs, have been discussed extensively in the literature and guidance (Haws et al. 2006; NRC 2006; USEPA 2003, 2010; van den Berg et al. 1998, 2006), and are summarized in USEPA (2010). However, the FFS HHRA identifies only the following from USEPA (2010):

> "TEQ uncertainty only pertains to the confidence associated with the estimation of TCDD equivalents in a mixture. There is also uncertainty associated with assessing exposures to environmental mixtures of TCDD and DLCs and with quantitatively linking health effects to the TCDD and DLC exposures." (p. 3-45)

This is an inadequate discussion of uncertainties associated with the TEF scheme. The draft 17-mile LPRSA baseline HHRA (AECOM [in prep]) provides a detailed discussion of the many uncertainties identified in USEPA (2010), including:

- "Dose additivity under the TEF method assumes a common mode of toxic action mediated through AhR [aryl hydrocarbon receptor] binding and downstream biochemical and toxic responses. There is some evidence suggesting that some toxicities associated with some DLCs may be mediated through other ligands and processes (i.e., not mediated through the AhR). Effects mediated by other mechanisms (AhR independent) are not accounted for by the TEF method.

- Dose additivity under the TEF method assumes parallel dose-response curves. This is supported by some empirical data, but, in practice, parallelism is difficult to show for all DLCs and exposure scenarios, particularly in the low response region of most interest in environmental risk assessment.
- Dose additivity under the TEF method assumes that toxicological interactions are not occurring at environmental levels of the DLCs. Some data suggest that combined exposures of some DLCs may have antagonistic, rather than additive, effects; these could be species-specific. It may also be noted that joint toxic action of dioxins with non dioxin-like compounds could result in additive or nonadditive responses.
- Under the TEF method, the TEF of a DLC is assumed to be equivalent for all exposure scenarios, for all end points of concern, and all are full agonists. The ranges of relative potencies (RePs) shown in the Haws et al. (2006) database demonstrate the uncertainty in this assumption as the ranges represent RePs from various study types and endpoints.
- Under the TEF method, it is assumed that RePs from animal studies are predictive of RePs in humans. However, the human AhR demonstrates some differences when compared to the AhR from experimental animal species.
- Expert scientific judgment, which depends on the knowledge and evaluations of the expert scientists involved, was used to select the DLCs included in the WHO TEF approach by evaluating experimental data against specific criteria (van den Berg et al. 2006). It may be noted that not all of the DLCs identified in releases from anthropogenic sources are included.
- Expert judgment and a consensus process were used to derive the WHO 2005 TEFs (van den Berg et al. 2006), including evaluation of information from the Haws et al. (2006) database.
- The kinds of information available for comparing the responses to individual DLCs to those of the index compound are highly variable across chemicals, including many types of and numbers of in vivo (including different test species) and in vitro studies. In addition, a number of different methods are employed to calculate ReP values (Haws et al. 2006).” (USEPA 2010)

While point estimate TEFs have been identified and were used to estimate risk for DLCs, they are known to be variable and uncertain, spanning a range of at least an order of magnitude. This significant uncertainty is not recognized by Region 2 in the abbreviated discussion included in the FFS HHRA.

The application of TEFs to the evaluation of PCB cancer risk is a particular area of uncertainty. The TEFs for PCB DLCs have been developed based on a database of laboratory studies in which the relative potency of a test compound was compared to a reference compound, usually 2,3,7,8-TCDD. The hierarchy for the TEF derivation prefers the use of *in vivo* studies (studies done in animals), but will include *in vitro* studies (studies done on enzymes, cells, tissues or body fluids, but outside the whole animal) if *in vivo* data are not available.[13] Uncertainty is introduced each time the assumption of similar mechanism is employed, specifically, in the assumptions that:

- 2,3,7,8-TCDD induces tumors in laboratory animals and, therefore, will also do the same in humans.

[13] The *in vivo* studies in the database are generally short-term studies of noncancer endpoints, the assumption being that the relative potency measured for a test compound and the reference compound for a short-term noncancer endpoint would also be the same relative potency that would be observed for a two-year cancer bioassay. This is also the basic assumption of the *in vitro* results, i.e., that the comparative potency measured in the *in vitro* study is also predictive of potency of tumor induction. As *in vitro* studies tend to measure only a single outcome or reaction (e.g., receptor binding), whole animal studies are preferred as the relative potency estimates are assumed to take into account the potential broad range of effects the compound may have on the living animal, and the effects that whole animal physiology can have on specific interactions of the chemical with various biological components.

- A compound that can elicit a similar toxicological response in laboratory animals as 2,3,7,8-TCDD based on the measurement of a single toxicological endpoint will also act by the same mechanism of action as 2,3,7,8-TCDD and will also induce tumors in animals and, therefore, humans.
- A compound that can elicit a similar toxicological response in an *in vitro* assay as 2,3,7,8-TCDD will act by the same mechanism of action as 2,3,7,8-TCDD *in vivo* and will also induce tumors in animals and, therefore, humans.

There is also uncertainty in the assumption that a subset of PCB congeners exerts toxicity in a manner similar to that of 2,3,7,8-TCDD. While the derivation of the TEFs has adhered to a logical set of assumptions and these assumptions have some biological plausibility, it is not necessarily true that they are biologically valid. Region 2 has failed to acknowledge any of this uncertainty.

Despite EPA's adoption of the 2005 World Health Organization (WHO) TEFs for certain coplanar PCBs, there are several reasons why application of the current dioxin TEF scheme introduces considerable uncertainty into risk assessment of PCBs. The first criterion of the current TEF scheme requires that the DLC be structurally similar to dioxins and furans. Dioxins and furans are rigidly planar molecules with centrally-located oxygen atom(s) while PCBs are never truly coplanar, and lack the central oxygen atoms. In addition, PCBs that are approximate stereoisomers of dioxin/furan Ah receptor agonists bind the receptor much more weakly than strong Ah receptor agonists such as dioxins and furans. Even with the most favorable chlorination pattern, the affinity of PCBs for the Ah receptor is not nearly that of potent dioxin/furans (Silkworth and Carlson 2011). Only a handful of Ah receptor agonists have been tested for human Ah receptor affinity even though marked species differences have been demonstrated. For example, TCDD's and other potent agonist's affinity for the human Ah receptor is 10-fold less than the receptor affinity in ultra-sensitive animal models (Ema et al. 1994; Fan et al. 2009; Flaveny et al. 2009; Zeiger et al. 2001; Westerink et al. 2008).

The National Research Council of the National Academy of Sciences (NRC 2006) has stated that depending on the system examined, "the estimated affinity of binding of TCDD (and related compounds) to the human AhR is about 10-fold lower than that observed to the AhR from "responsive" rodent species and is comparable to that observed to the AhR from "nonresponsive" mouse strains." More recent studies have indicated that the difference may be even greater. Westerink et al. (2008) compared CYP1A activity (a cytochrome P450 enzyme) in rat H4IIE cells and human HepG2 cells for an extensive array of chemicals including TCDD and most dioxin-like PCBs. The investigators found that for PCB 126 (regarded as the most potent of the PCBs assigned TEFs), the rat was three orders of magnitude more sensitive to induction of liver enzyme activity than humans. Carlson et al. (2009) investigated whether the difference in relative potency of PCB 126 between rats and humans, as measured by induction of CYP1A1, was also true for other AhR regulated genes that could be important to toxic effects subsequent to AhR binding. They found that 47 human genes responding in a dose-response manner consistent with the TEF concept were more than 100 times less sensitive than 79 similarly responding rat genes.

In summary, Region 2's discussion of uncertainty relating to the TEF scheme and its applicability to dioxin-like PCBs, in particular, is completely inadequate. A more thorough discussion of the issues and associated uncertainties and acknowledgement of the overestimation of dioxin-like PCB risks is warranted, so that risk managers and decision-makers are better informed.

C. The Region's background evaluation underestimates the contribution of upriver sources to the FFS study area and significantly overstates the risk reduction that can be achieved by the selected remedy.

1. The basis of the background sediment data set is unclear and ignores relevant data, resulting in an underestimate of the contribution of upstream background to the FFS study area.

The FFS underestimates the contribution of the UPR to current and future conditions in the FFS study area. In Appendix E of the FFS, the Upper Passaic River sediments are identified as representative of background for the FFS study area, based on proximity and the demonstrated geochemical connection between the UPR and the LPR. Section 3 of Appendix E identifies the background sediment data set as consisting of eight surface sediment samples collected immediately above the dam (four cores and four grabs) and two dam sediment trap samples. Table 3-1 of Appendix E presents the background sediment concentrations selected by Region 2. Not only is Region 2 selective in its use of available sediment data to estimate background, it fails to acknowledge the significant volume of background fish tissue data collected above Dundee Dam, electing to use its regression model to estimate tissue concentrations from its limited sediment data.

Region 2's basis for the selection of these data to represent background conditions for the LPRSA is not presented in Appendix E, other than to state they present "recently-deposited surficial sediments". This approach ignores the large background sediment data set collected as part of the RI/FS above Dundee Dam, in accordance with the approved Reference and Background QAPP. Region 2 has also not described the derivation or statistical basis of the background levels for COCs identified in Table 3-1 of Appendix E of the FFS. The following table compares background sediment concentrations identified in the FFS (Table 3-1 of Appendix E) with concentrations developed using the full background sediment data set and presented in the 17-mile LPRSA RI draft baseline HHRA and baseline ecological risk assessment recently submitted to Region 2. As shown, the data set and background concentrations differ between the two, with background levels in the FFS lower than the RI/FS risk assessments for several key constituents.

	FFS			**RI/FS Risk Assessments**		
Chemical	**No. of Samples**	**Concentration (mg/kg)**	**Statistic**	**No. of Samples**	**Concentration (mg/kg)**	**Statistic**
2,3,7,8-TCDD	10	2E-06	not provided	--	--	--
TCDD-TEQ	--	--	--	30	1.46E-04	Max
Total non-DLC PCBs	10	0.46	not provided	--	--	--
Total PCBs	--	--	--	30	0.8	Max after removing outlier
Total HPAHs	10	53	not provided	--	--	--
Benzo(a)pyrene	--	--	--	30	136	Max

HPAHs = high molecular weight polycyclic aromatic hydrocarbons

The background sediment concentrations presented in Table 3-1 of Appendix E do not match the "averages" presented in Table 3-3 of the Data Evaluation Report (DER) 2 of Appendix A. Further, Region 2's background sediment concentration of 460 µg/kg for PCBs cannot be duplicated from the data provided in Table 3-3 of DER 2. The lack of transparency in the Region's evaluation of the UPR sediment data and selection of background sediment concentrations is a significant issue that warrants further consideration. Region 2's background data and evaluation approach requires further justification and stakeholder review, particularly given the importance of background conditions to the FFS study area.

2. The contribution of background to consumption risks in the lower 8 miles is underestimated.

In the Region's FFS HHRA, background concentrations of a limited subset of COPCs in tissue were estimated from background sediment concentrations using the sediment-tissue regression models developed by Region 2. Concerns regarding the efficacy and reproducibility of the regression model are addressed in comment responses related to bioaccumulation modeling and PRG development. Site-specific background tissue data collected under the approved Reference and Background QAPP were not used to estimate background fish consumption risks. Region 2 does not explain the rationale for modeling background tissue concentrations in lieu of using the measured background tissue data that were collected with the objective of characterizing background levels. Use of modeled background tissue concentrations when empirical data are available introduces unnecessary uncertainty into the FFS HHRA, and results in underestimates of the contribution of background to site risk. This approach highlights the disparity between the FSS and the 17-mile RI/FS whereby data needs were identified by Region 2 for the RI and were collected by the CPG under the direction of Region 2 but were then ignored for the purposes of the FSS.

Only a limited subset of the COPCs that are present in the background tissue data set were included in Region 2's modeling of background tissue concentrations. The reliance on the regression relationships developed for the lower 8 miles limited Region 2's ability to evaluate a full list of potential background contaminants. (Issues related to the application of regression relationships based on the lower 8 miles to develop tissue concentrations in the upriver regime are addressed in the comments on the bioaccumulation modeling.) The need to rely on this limited set of regression relationships would have been eliminated had Region 2 used the empirical tissue data available in the RI/FS data set developed by the CPG in accordance with the QAPP approved by Region 2 for this express purpose.

The following table compares the fish consumption cancer risks calculated for the LPRSA and background (UPR) in the CPG's draft baseline HHRA and the FFS HHRA.

Baseline Cancer Risk from Fish Consumption

Adult/Child Angler

COC	2014 Draft BHHRA - LPRSA[a]				2014 EPA FFS - Lower 8 Miles[d]	2014 Draft BHHRA - Upper Passaic River[a]				2014 EPA FFS - Upper Passaic River[e]
	Mixed Diet with Carp[d]		Mixed Diet without Carp[d]			Mixed Diet with Carp[d]		Mixed Diet without Carp[d]		
	Mean	UCL	Mean	UCL	UCL	Mean	UCL	Mean	UCL	Modeled
TCDD-TEQ	2×10^{-3}	3×10^{-3}	7×10^{-4}	9×10^{-4}	4×10^{-3}	3×10^{-5}	5×10^{-5}	2×10^{-5}	4×10^{-5}	2×10^{-5}
PCB-TEQ	5×10^{-4}	7×10^{-4}	2×10^{-4}	3×10^{-4}	6×10^{-4}	2×10^{-4}	3×10^{-4}	2×10^{-4}	2×10^{-4}	Not modeled
PCBs, total[b]	7×10^{-4}	1×10^{-3}	3×10^{-4}	4×10^{-4}	8×10^{-4}	3×10^{-4}	3×10^{-4}	2×10^{-4}	3×10^{-4}	2×10^{-4}
Dieldrin	7×10^{-5}	9×10^{-5}	5×10^{-5}	6×10^{-5}	9×10^{-5}	9×10^{-5}	1×10^{-4}	9×10^{-5}	1×10^{-4}	Not modeled
Heptachlor epoxide	1×10^{-5}	2×10^{-5}	1×10^{-5}	1×10^{-5}	Not a COPC	2×10^{-5}	3×10^{-5}	2×10^{-5}	3×10^{-5}	Not a COPC
Total Cancer Risk[c]	**3×10^{-3}**	**4×10^{-3}**	**1×10^{-3}**	**1×10^{-3}**	**5×10^{-3}**	**4×10^{-4}**	**6×10^{-4}**	**4×10^{-4}**	**5×10^{-4}**	**2×10^{-4}**

Notes:

[a] All risks were calculated using RME exposure assumptions; only the tissue EPCs (mean and UCL) were varied in the 2014 draft BHHRA risk calculations.

[b] Total PCBs for 2014 FFS HHRA includes only non-dioxin-like congeners.

[c] Total cancer risk for 2014 Draft BHHRA is based on total PCBs (sum of all congeners); 2014 FFS HHRA sums total non-DLC PCB and PCB-TEQ.

[d] Species comprising mixed fish diets and sample locations differ:

Draft BHHRA Mixed Fish Diet with Carp = sitewide perch, carp, LM/SM bass, eel, and channel catfish;

Draft BHHRA Mixed Fish Diet without Carp = sitewide perch, LM/SM bass, eel, and channel catfish;

2014 FFS HHRA = RM 0-8 perch, carp, SM bass, eel, white catfish, and white sucker.

[e] Modeled tissue concentrations for white perch and American eel (50%/50%) using EPA's background sediment concentrations (Table 3-1 of Appendix E).

As shown, background fish consumption cancer risks presented in the FFS HHRA are only one-third to one-half of the background risks calculated in the draft BHHRA (AECOM [in prep]).

This discussion on background risk again highlights the disparity between the FSS and the 17-mile RI/FS whereby data needs were identified by EPA for the RI and were then ignored for the purposes of the FSS. Similarly, a bioaccumulation model was required as part of the remedial investigation; however, Region 2 chose to take a statistical approach that currently cannot be replicated. A comparison of background risks estimated by the FFS and the baseline HHRA shows the implication of Region 2's choices in failing to incorporate all the available facets of the remedial investigation. A credible evaluation of background would have provided a realistic counter-point to the efficacy of the PRGs for PCB and mercury.

3. The Region's FFS HHRA does not evaluate or acknowledge the significant non-chemical pathogen risks that will not be addressed by the sediment remedy

Based on an analysis of microbial risks to individuals who may visit the river for recreational purposes, as well as for transients that may live along the banks of the river, the presence of pathogens in river surface water pose significant acute and chronic public health risks. The probabilities of contracting gastrointestinal illness over the course of a year range from 0.1 to 1.0 (100%) for fecal bacteria and less than 0.01 to 1.0 (100%) for *Giardia*. Using the same exposure assumptions directed by Region 2 for the baseline assessment of chemical risks, a quantitative microbial risk assessment (QMRA) was performed using surface water data for several bacteria and protozoa (provided in Attachment I). Potential risks of gastrointestinal illness from acute (one time) and annual (repeated) exposures to surface water for the wader, angler, boater, and swimmer receptors were evaluated. All receptor populations evaluated for acute exposure to fecal bacteria in saltwater (below RM 8) are found to have risks that are at or above the acceptable risk guidelines established by EPA. Acute risks for the swimmer and homeless receptors exposed to fecal bacteria in freshwater (above RM 8) are at or above the acceptable risk guidelines. All of the annual average freshwater and saltwater scenarios for all fecal bacteria pose risks that are well above EPA's acceptable illness rate of 32 to 26 illness per 1,000 exposures. In addition to significant acute and annual risks of illness for the homeless receptor from exposure to fecal bacteria, the annual average risk estimate from exposure to *Giardia* ($p = 1.00$) suggests that every homeless person who is exposed has a very high probability of being infected with *Giardia*.

Based on the results of the QMRA, it is clear that the release of pathogens via combined sewer outfalls (CSOs) poses a significant public health threat to recreational users of the LPRSA. Activities that involve intensive direct contact exposures, such as swimming, pose both acute and chronic risks of gastrointestinal illness in excess of EPA's benchmarks. For transient individuals who may spend extended periods of time living along the banks of the river, the risks of infection from exposure to bacteria and protozoa are highly significant. Direct contact with sediment and fish/shellfish, as well as contaminated shellfish, pose additional pathogen risks not quantified in this analysis.

Consequently, any remediation and restoration activities directed at improving water quality and reducing public health risks need to take into account the CSOs that are a major ongoing source of microbial risks to receptors using the river for recreation and other purposes. Region 2's FFS does not address or even acknowledge this significant source of risk.

D. The Region's approach used to develop PRGs is flawed and inconsistent with guidance, resulting in remedial goals that are unattainable.

1. The development of tissue PRGs relies on the same overly conservative assumptions used in the FFS HHRA, which has led to unrealistically low PRGs.

In Appendix E, Region 2 has presented tissue PRGs that are based on the same overly conservative RME and toxicity assumptions used in the FFS HHRA. PRGs have been derived for the three chemicals of concern with individual cancer risks above 1 x 10^{-4} (TCDD-TEQ and total non-dioxin-like PCBs[14]) or an individual noncancer HI above 1 (TCDD-TEQ, PCBs, and methyl mercury). PRGs have been developed for the RME adult angler using the target cancer risk levels of 10^{-6}, 10^{-5}, and 10^{-4} for TCDD-TEQ and non-dioxin-like PCBs, and using the target noncancer hazard index of 1 for TCDD-TEQ, non-dioxin-like PCBs, and methyl mercury. Not only are the resulting tissue PRGs inappropriately low due to the overly conservative RME and toxicity assumptions that were used, they are not attainable, especially for PCBs and methyl mercury. Levels of PCBs and methyl mercury in fish collected from the background area above Dundee Dam exceed even the highest (least stringent) PRGs developed by Region 2. As discussed below, Region 2 has significantly underestimated the contribution of background to the lower 8 miles.

2. Region 2 has not included PRGs based on the "average" consumer of LPR fish or crab, resulting in an incomplete and overly stringent set of PRGs.

The presentation of risks and PRGs in the FFS incorporates only the RME results of the HHRA, and ignores the CTE scenarios that were evaluated for current and future baseline risks. The intent of evaluating both RME and CTE scenarios is to provide risk managers with a range of risk results, and promote more informed remedial decision-making (USEPA 1992, 1995). The CTE scenario uses average (or median) exposure parameters to estimate the average exposure of an individual. By not considering the CTE results, information useful to decision-makers and stakeholders is lost, and an incomplete picture of risks and preliminary remedial goals for consideration is presented in the FFS. Based on a simple comparison of RME and CTE risks, PRGs based on CTE assumptions would be 15-fold higher than the RME PRG presented in the FFS for fish consumption, and over 7-fold higher than the FFS RME PRG for crab consumption (noncancer).

The CTE fish consumption rate used in the FFS HHRA equates to approximately six half-pound fish meals per year. NJDEP's statewide advisory levels for the general population[15] that consumes marine and estuarine fish are set using consumption rates equivalent to or lower than the CTE consumption rate of six meals per year (six meals per year of bluefish and four meals per year for American eel) (NJDEP 2013). Thus, there is clear precedent for use of risk-based levels corresponding to consumption rates that fall in the range of the CTE scenario in public health protection. Region 2 has not provided a sound rationale for excluding tissue PRGs that are based on CTE consumption rates, as well as other CTE exposure assumptions (i.e., cooking loss, exposure duration). The CTE scenario should be considered in the development of interim PRGs, in addition to the interim PRGs corresponding to 12 meals per year. This would provide a more representative and realistic set of tissue levels for use in setting interim remediation goals and monitoring remedy performance, particularly given that some species (e.g., carp) may take longer to attain levels considered safe for consumption.

3. Region 2's selection of sediment PRGs is inconsistent with guidance and results in cleanup goals that are unattainable.

Region 2's has selected risk-based PRGs for sediment that are lower than the background levels they established for sediment. This is inconsistent with guidance which states that cleanup below background levels is not required under CERCLA (USEPA 2002b). Region 2's rationale for the selection of risk-based PRGs lower than background is based on the false premise that post-remediation, mixing of suspended sediments entering the FFS study area with cleaner sediment in the remediated river bed will result in surface sediment concentrations that are lower than the background concentrations above Dundee Dam. The flaws in the Region 2's logic regarding the contribution from above Dundee Dam to the FFS study area are discussed in the comments on the Remedial Investigation Conceptual Site Model (CSM) (See Appendix B, Comment III.D). A result of the flawed approach is Region 2's selection of a human health

[14] Only the total non-dioxin like PCB congeners were included in the development of the PRG for PCBs. Region 2 based this approach on the similarity of the calculated risks in the FFS HHRA for total non-dioxin-like PCBs and PCB-TEQ, and the assumption that any remedial action based on PRGs for total non-dioxin-like PCBs would address the dioxin-like congeners.

[15] Consumption of these species by high risk populations is advised against (NJDEP and NJDHSS 2013).

PRG for PCBs (44 µg/kg), for example, that is 5 to 10 times lower than the value background sediment concentration identified by EPA (460 µg/kg) (and 10 to 20 times lower than the value identified as background for PCBs by the CPG) (AECOM [in prep]). By failing to properly account for the contribution of background to the FFS study area, Region 2 has selected sediment PRGs that are unattainable.

In DER 2, Region 2 acknowledges the significance of the UPR on conditions below the dam for PCBs, as well as several other COPCs:

> "Moreover, Total PCB concentrations in the Upper Passaic River have been relatively constant since 1990, at approximately 500 µg/kg with Total PCB concentrations ranging from 280 to 710 µg/kg in post-1990 deposition (see Figure 3-5 and Table 3-3). The lack of contaminant concentration decline in the Upper Passaic River since 1990 suggests that the sediments transported over the Dundee Dam will continue to provide contaminated solids that will influence sediment PCB concentrations in the Lower Passaic River." (p. 3-8, DER 2, Appendix A of FFS)

Region 2, in fact, concludes that the UPR above Dundee Dam is (1) an important contributor to the annual sediment burden in the LPR for PCBs, cadmium, chromium, copper, lead, mercury, and some pesticides (e.g., DDx); (2) a significant contributor for some pesticides (e.g., dieldrin, aldrin); and (3) the dominant contributor for PAHs (Table 3-3 of DER 2). Thus, based on the Region's own analysis, the exclusion of background from consideration in the selection of PRGs is not supported, and any remedy designed to achieve cleanup levels below background will be unsuccessful.

4. <u>The species selected in the FFS for the development of tissue PRGs lead to lower sediment PRGs than calculated using the four species that Region 2 has directed the CPG to use in the RI/FS.</u>

Only two species (white perch and American eel), which are assumed by Region 2 to be consumed at equal diet fractions, were used to develop the human health tissue PRGs presented in the FFS. This approach does not include species, such as bass and catfish, which are preferred by anglers. Based on an analysis of the impact of including a broader list of species in the estimation of bioaccumulation-based PRGs and using a mechanistic model in lieu of simplistic sediment-tissue regression relationships, including bass and catfish would result in sediment PRGs at a 10^{-4} risk level approximately three-fold higher than when only perch and eel are used.

In summary, Region 2 has significantly overestimated human health exposures from fish and crab and compounded the over-estimation of risk with a poor assessment of toxicity. As a consequence, Region 2's grossly overestimated risk estimates have generated unrealistic and inappropriate PRGs that have resulted in the selection of an unnecessary and counterproductive bank-to-bank remedy. Not only are the resulting tissue PRGs inappropriate, they are not attainable for PCBs and mercury given the fact that Region 2 has chosen to ignore the influence of background.

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