General Electric Company
Pittsfield, Massachusetts

Housatonic River – Rest of River

Evaluation of Remedial Alternatives Using Sound Ecological Assumptions

October 2010

Tables

Attachments

1. Introduction

The General Electric Company (GE) has submitted to the United States Environmental Protection Agency (EPA) a Revised Corrective Measures Study (CMS) Report, dated October 2010, presenting evaluations of numerous remedial alternatives to address polychlorinated biphenyls (PCBs) in the Rest of River portion of the Housatonic River. That report was submitted pursuant to a permit issued to GE by EPA under the corrective action provisions of the federal Resource Conservation and Recovery Act (RCRA) on July 18, 2000, and reissued on December 5, 2007, to extend its expiration date (the Permit). As required by the Permit, the evaluations presented in that report took into account EPA's Human Health Risk Assessment (HHRA) (EPA, 2005a, c) and Ecological Risk Assessment (ERA) (EPA, 2004, 2005b) for the Rest of River and used numerous assumptions, procedures, and other inputs that EPA directed GE to use, including Interim Media Protection Goals (IMPGs) based on EPA's HHRA and ERA.

As the Revised CMS Report makes clear, GE disagrees with many of the assumptions, input values, interpretations, and conclusions in EPA's HHRA and ERA, as well as with numerous directives that EPA issued to GE for revising the IMPGs and conducting the CMS. In particular, GE has a fundamental disagreement with EPA regarding whether exposure to PCBs at environmental levels causes adverse effects on human health and the environment. GE has also shown that the exposure assumptions, assumed PCB toxicity values, and other interpretations and conclusions in EPA's HHRA and ERA – and thus underlying the IMPGs – greatly overstate both PCB exposures and asserted PCB risks in the Rest of River area.[1] Since the resulting IMPGs and other inputs that GE was required to use directly affect many of the evaluations presented in the Revised CMS Report, that report should not be regarded as GE's endorsement of the conclusions set forth therein.[2]

The introduction of this document generally discusses the evidence on the human health effects of PCBs and the impact of a scientifically supportable interpretation of that evidence on the assessment of whether the remedial alternatives considered in the Revised CMS Report would provide protection of human health. However, the main focus of this document is to illustrate the impact of applying scientifically sound assumptions and interpretations of the ecological studies and data used in EPA's ERA to evaluate the extent to which the various remedial alternatives would provide protection of the environment. To do so, this document presents the results of using alternate ecological IMPGs and alternate averaging areas for application of those IMPGs, both of which are based on scientifically sound assumptions and data interpretations in contrast to those used in EPA's ERA.

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[1] GE's position on these issues was presented in various prior submittals to EPA, including: GE's comments on EPA's HHRA (AMEC and BBL, 2003, 2005; GE, 2003) and on EPA's ERA (BBL Sciences et al., 2003, 2005; GE, 2004); GE's original IMPG Proposal (GE, 2005), which presented alternate IMPGs, was disapproved by EPA, and was subsequently revised at EPA's direction (GE, 2006b); GE's *Statement of Position on Objections to EPA's Disapproval of Interim Media Protection Goals Proposal* (GE, 2006a); GE's CMS Proposal (ARCADIS BBL and QEA, 2007a); GE's *Statement of Position on Objections to Certain Conditions and Directives in EPA's Conditional Approval of GE's Corrective Measures Study Proposal* (GE, 2007a); and GE's *Statement of Position on Objections to Condition No. 4 in EPA's Conditional Approval Letter for GE's Corrective Measures Study Proposal Supplement* (GE, 2007b).

[2] GE has preserved its position on these issues, and has reserved its right under the Permit to raise any objections on these or other issues in a challenge to EPA's modification of the Permit to select a remedy for the Rest of River.

For purposes of this analysis, GE has focused on a limited set of the combined sediment (SED) and floodplain (FP) remedial alternatives identified and evaluated in the Revised CMS Report – namely: (a) the combination of SED 2 (monitored natural recovery [MNR] in all reaches of the Rest of River) and FP 1 (no action); (b) the combination of SED 3 and FP 3; and (c) the combination of SED 10 and FP 9 (the combination also known as the Ecologically Sensitive Alternative [ESA]).

Overview of Human Heath Data

The scientific evidence demonstrates that the PCB toxicity values that EPA used in the HHRA to represent potential cancer risks and non-cancer effects, which are based on studies of laboratory animals, substantially overstate both the carcinogenic potential and the non-cancer impacts of PCBs in humans. In fact, review of the human studies shows that: (a) there is no credible evidence that PCBs have caused cancer in humans, even in highly exposed PCB workers; and (b) there is no credible evidence that exposure to PCBs at environmental levels has caused adverse non-cancer effects. For example, detailed reviews by Golden et al. (2003) and Golden and Kimbrough (2009) of the human epidemiological studies on cancer have shown that there is no causal relationship between PCB exposure and any form of cancer.[3] Similarly, a comprehensive review of the non-cancer data by Bernier et al. (2001) demonstrates that, with the possible exception of dermal (skin) and ocular (eye) effects in highly exposed PCB workers, there is no reliable evidence of a causal relationship between PCB exposure and adverse non-cancer health effects in humans.

Moreover, studies have demonstrated clearly that human cells are many times less sensitive than the cells of the laboratory test animals used in the studies on which EPA's toxicity values are based (rats and monkeys) to the effects of PCBs, especially the most potent PCB congener (PCB 126), potentially by several orders of magnitude (Silkworth et al., 2005; Westerink et al., 2008; Carlson et al., 2009). Further, the National Research Council's report on EPA's Dioxin Reassessment concluded that the available data on dioxins, including the so-called dioxin-like PCB congeners, support a threshold below which those compounds would not have carcinogenic effects, rather than the EPA assumption that those compounds cause such effects directly proportional to exposure at any and all exposure levels (NRC, 2006, p. 135). These studies confirm that use of the animal-based PCB toxicity values in the HHRA to represent the supposed toxicity of PCBs to humans is not scientifically supportable.

In addition, many of the exposure assumptions that EPA used in the HRRA overstate the exposures of individuals in the Rest of River to PCBs. For example, the HHRA assumed, for the high-use recreational scenario (which EPA applied to the majority of recreational areas in the floodplain), that an individual: (a) recreates in the same floodplain area 3 days/week, 7 months/year (90 days/year) for 65 years; (b) spends 100% of his or her time within the portion of the area containing PCBs over 1 mg/kg; (c) is exposed to PCB concentrations that are among the highest in the area in question (represented by the statistical upper bound of the PCB data) at all times; (d) ingests soil at double the rates shown in

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[3] For example, Kimbrough et al. (1999) and Kimbrough et al. (2003) studied a cohort of over 7,000 occupationally exposed workers in two GE capacitor plants and found no statistically significant increase in deaths due to cancer regardless of the degree of PCB exposure of the workers or the length of their employment in the plants.

more recent studies by the same investigators whose studies EPA's ERA relied on; (e) obtains 100% of his or her daily soil ingestion from the contaminated floodplain area; and (f) contacts soil with his or her hands, forearms, lower legs, and head during every exposure event for 5 months.

For these reasons, it is clear that application of the IMPGs based on EPA's HHRA, as presented in the Revised CMS Report, substantially overstates the risks that PCBs might cause cancer and adverse non-cancer effects in humans. In fact, the scientific evidence shows that exposure to PCBs at environmental levels will not cause such human health effects. Given that evidence, all of the combinations of remedial alternatives under evaluation, including SED 2/FP 1, would be protective of human health.

Overview of Assessment of Ecological Data Using Sound Inputs

As discussed above, the main purpose of this document is to illustrate the results of using scientifically sound IMPGs and averaging areas to assess potential impacts of the remedial alternatives on the groups of animals (which EPA calls ecological receptor groups) that were evaluated in EPA's ERA and for which ecological IMPGs were developed. Section 2 describes the alternate IMPGs and averaging areas used for this analysis and the bases for them. Section 3 discusses the extent to which, using these alternate inputs, the three combinations of remedial alternatives mentioned above (SED 2/FP 1, SED 3/FP 3, and SED 10/FP 9) would achieve the IMPGs. It also provides a conclusion regarding the impact of these revised IMPG evaluations on the assessment of whether these combinations would be protective of the environment. Section 4 presents an overall summary. As discussed in that section, this analysis shows that SED 2/FP 1 would be protective of the environment, as well as human health (as described above), and that therefore there is no justifiable basis for selecting a remedy involving removal of sediments and soils, which would unavoidably cause adverse impacts on the vegetation, wildlife, aesthetics, recreational use, and overall ecosystem of the Rest of River.

2. Description of Scientifically Sound Ecological IMPGs and Averaging Areas

This section describes alternate ecological IMPGs, as well as averaging areas for application of those IMPGs, based on scientifically sound assumptions and data interpretations, rather than those used in EPA's ERA.

2.1 Scientifically Sound IMPGs for Ecological Receptor Groups

GE's original IMPG Proposal (GE, 2005) presented alternate IMPGs for the ecological receptor groups to be evaluated. In doing so, GE took into account EPA's ERA by developing such IMPGs for the same receptor groups for which the ERA found significant risks, basing those IMPGs on the same underlying data sets used in the ERA, as well as a number of the same assumptions and procedures used in the ERA, and providing a rationale for any differences. On points on which EPA's data interpretations, analyses, assumptions, and/or toxicity values were not supported by the data and overestimate risks to ecological receptors, the alternate IMPGs were based on scientifically supportable data interpretations or input variables.

The alternate IMPGs that GE developed for ecological receptors and the bases for them, including the rationale for any differences from the data interpretations and inputs used in the ERA, were presented in Section 3.4 of the original IMPG Proposal, a copy of which is attached as Attachment A hereto.[4] Those alternate IMPGs for PCBs have been used, with certain modifications or adjustments, in the assessments presented in this document. The specific alternate IMPGs used here are described below.

Benthic Invertebrates: In assessing risks to benthic invertebrates (insects and other invertebrates that live on the bottom of waterbodies), the ERA relied on site-specific toxicity tests (both chronic and acute) and a site-specific benthic community study conducted by EPA. Based on those data, the ERA identified a variety of effect thresholds based on different test species and/or effects, including sediment concentrations associated with effects on 20% of the organisms tested (EC20s) and sediment concentrations associated with effects on 50% of the organisms tested (EC50s) in the various tests. EPA required GE to set the lower-bound IMPG for benthic invertebrates at 3 mg/kg, based on a combination of the lowest EC20 value from any of the chronic toxicity tests (i.e. the lowest level of PCBs in any test in which an effect was found in 20% of the invertebrates tested) and the five lowest EC20 values from the benthic invertebrate community study. The upper bound of 10 mg/kg was based on the mean of the EC20 values from the acute toxicity tests.

However, use of EC20 values, especially the lowest ones in the various tests, is not appropriate for benthic invertebrates, which have evolved reproductive strategies based on the production of many more offspring than will ultimately survive and thus can well tolerate a 20% or greater reduction in survival or other effects. Section 3.4.1 of the original IMPG Proposal presented several alternate IMPG

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[4] In that proposal, the IMPGs were referred to as "Risk-based Media Concentrations" or RMCs.

values for PCBs in sediment based on the different types of benthic invertebrate studies conducted by EPA. These included a range of 7 to 18.5 mg/kg based on EPA's toxicity test data and values of > 42 mg/kg for coarse-gained sediment sites and > 16 mg/kg for fine-grained sites based on EPA's benthic community field study, which was more relevant to the goal of maintaining diverse and abundant communities of benthic invertebrates. For purposes of the evaluations in the present document, GE has used a single, more simplified range. The lower end of that range is 7 mg/kg, which represents the geometric mean (a type of average representing the typical value) of all the EC20 values from the various chronic toxicity tests conducted by EPA. The upper end of the range is 27.8 mg/kg, which corresponds to the geometric mean of the EC50s at coarse-grained sites for the various effects evaluated in EPA's benthic community field study. It is also applicable to fine-grained sites, because adverse effects were seen at lower concentrations at the coarse-grained sites than at the fine-grained sites. Thus, the alternate IMPGs used to assess benthic invertebrates consist of a range of sediment PCB concentrations of 7 to 27.8 mg/kg.

Amphibians: The IMPGs for amphibians were based on a site-specific wood frog study conducted by EPA. That study showed that PCBs had no effects on survival, hatching success, or metamorphosis of frogs, which are directly relevant to the health of the local frog population. The only effects reported in the study were a calculated increase in malformations in wood frog metamorphs (those which have just emerged from the tadpole stage) and a supposed skewing in sex ratio (more females than males), neither of which has a direct relationship to the sustainability of the local wood frog population. EPA required that the lower-bound IMPG, 3.27 mg/kg, be based on the calculated EC20 for metamorph malformations (i.e. the PCB concentration at which malformations were observed in 20% of the metamorphs studied). The upper-bound IMPG, 5.6 mg/kg, was based on the mean of the EC20 for metamorph malformations and the EC50 for sex ratio effects (more females than males).

Use of an EC20 value for metamorph malformations from this study to set an effects threshold for amphibians is not appropriate because, like benthic invertebrates, these frogs have a reproductive strategy in which they produce many more offspring than will ultimately survive and thus can well tolerate a 20% or greater effect, even if the malformations led to mortality. (EPA itself recognized that the EC20 for sex ratio was not biologically relevant.) Thus, use of EC50 values is more scientifically supportable. Section 3.4.2 of the original IMPG Proposal proposed an alternate IMPG range for the protection of amphibians. The lower bound of that range consisted of the EC50 for metamorph malformations (based on spatially weighted mean PCB concentrations in the pools studied in the metamorph portion of EPA's wood frog study), which was 38.6 mg/kg.[5] That value has been used here as an alternate IMPG for the protection of amphibians, and has been applied to PCB concentrations in vernal pool and backwater sediments.

Fish Protection: In developing effects thresholds for PCBs in fish for protection of the fish themselves, the ERA relied on EPA's two-phase site-specific study of reproductive effects of PCBs on fish, which evaluated such effects in adult largemouth bass from the Housatonic and their offspring (Phase I) and in

[5] This value is conservative given that the study showed no effects of PCBs on wood frog survival, growth, or metamorphosis.

eggs of non-native fish of various species injected with extracts of Housatonic fish (Phase II). The IMPG required by EPA for warmwater fish, 55 mg/kg, was based on a combination of the reported PCB effect threshold from Phase I and an average of the egg-based effect levels from Phase II for warmwater fish (divided by 2 to convert egg concentrations to adult fish concentrations). For coldwater fish – which are found only in reaches downstream of the Primary Study Area (PSA) (which extends from the Confluence to Woods Pond Dam) – EPA required that the IMPG be set at 14 mg/kg, based on dividing the warmwater fish IMPG by a factor of 4, which was arbitrarily selected to reflect the supposed greater sensitivity of coldwater fish such as trout (even though trout eggs were studied in Phase II and showed an effects threshold of 86 mg/kg).

As discussed in Section 3.4.4 of the original IMPG Proposal, Phase I of EPA's study did not show consistent evidence of PCB effects in fish. Therefore, GE proposed alternate IMPG ranges for PCBs based on the effects thresholds (EC50s) from Phase II of the study, but without dividing the egg concentrations by 2 to yield adult tissue concentrations (which has no basis). Further, for coldwater fish, the alternate IMPG was based on data from the trout eggs themselves, instead of applying an arbitrary factor of 4. The proposed IMPG ranges were 86 to 185 mg/kg for warmwater fish in the PSA, 144 to 185 mg/kg for warmwater fish downstream of the PSA, and 86 mg/kg for coldwater fish downstream of the PSA. For simplicity in the evaluations herein, GE has used alternate IMPGs of 86 to 185 mg/kg for all warmwater fish and 86 mg/kg for coldwater fish – both of which have been applied to PCB concentrations in whole-body fish tissue.

Insectivorous Birds: For insectivorous birds, represented by the wood duck, EPA required that the IMPG be based on a calculated effect level (set forth in the ERA) of less than 20% from a 1974 literature study of chickens, a species that has consistently been shown to be many times more sensitive to PCBs than wild bird species, such as wood duck. That IMPG is 4.4 mg/kg of PCBs in insect prey consumed by these birds.

To provide more realistic values for wild insectivorous birds, Section 3.4.8 of the original IMPG Proposal proposed an alternate PCB IMPG range using a similar approach and assumptions to those used to develop the EPA-directed IMPG (as set out in the ERA) except for the toxicity values. That alternate range of IMPGs was developed using three different PCB toxicity values: (1) a low-end value (or lower bound) representing the no observed adverse effect level (NOAEL) in a study of the most sensitive wild avian species, the mallard; (2) a high-end value (or upper bound) reflecting a dose-based effect metric from a site-specific study of a more tolerant species, the tree swallow, conducted at the Housatonic River by EPA; and (3) the midpoint of those two values. The resulting range of alternate IMPGs, which apply to PCB concentrations in the prey of insectivorous birds, was 6.1 mg/kg to 68 mg/kg, with a midpoint of 37 mg/kg.

Because these IMPGs apply to PCB concentrations in the prey of insectivorous birds, they need to be translated into corresponding concentrations of PCBs in sediment and floodplain soil in order to assess whether they would be attained by the remedial alternatives. As discussed in the Revised CMS Report (Section 2.2.2.3), this translation is complicated by the fact that the wood duck's diet consists of both aquatic invertebrates, in which PCB concentrations are derived from sediments, and terrestrial invertebrates, in which PCB concentrations are derived from floodplain soil; and it is not possible to derive a value corresponding to the IMPGs in one medium without knowing the value in the other. In this situation, in evaluating the attainment of these alternate IMPGs for the combinations of sediment and floodplain alternatives, GE has used a procedure similar to that used in the Revised CMS Report for evaluating attainment of the insectivorous bird IMPG for such combinations of alternatives. As described in Section 4.2.3.5 of the Revised CMS Report, since each combined alternative involves a specific sediment component and a specific floodplain component, an assessment of IMPG attainment can be made through the following procedure: (1) determination of the sediment PCB concentration predicted by EPA's model at the end of the projection period in each relevant averaging area; (2) for each such area and sediment concentration, calculation of an associated target floodplain level that would allow attainment of the IMPG (using the method described in Appendix D to the Revised CMS Report); and (3) comparison of the post-remediation floodplain soil concentration in the averaging area to the target floodplain soil concentration calculated for that area.

For purposes of the present analysis, this procedure has been modified so that the above calculations have been made for the entire PSA as a single averaging area (rather than various smaller areas within the PSA), using average input values for the overall PSA. The reason for this approach is that, as discussed in Section 2.2 below, the local wood duck population extends well beyond the individual subreaches and areas of the PSA, and thus the entire PSA represents the most appropriate averaging area for the local wood duck population. This calculation procedure is described in more detail in Attachment B, which also presents the model-predicted sediment levels and the calculated associated target floodplain soil levels for insectivorous birds under each of the combinations of alternatives evaluated herein (SED 2/FP 1, SED 3/FP 3, and SED 10/FP 9). These levels have been used in the present evaluation to assess whether each of these combinations of alternatives would attain the alternate insectivorous bird IMPGs.

Piscivorous Birds: For piscivorous (fish-eating) birds, represented by osprey, EPA required that the IMPG be based the following inputs from its ERA: (1) a PCB toxicity value based on the same literature study of chickens discussed above, even though chickens are substantially more sensitive to PCBs than wild birds; and (2) a modeled food intake rate based on a group of bird species that does not include osprey or any piscivorous birds.[6] The resulting IMPG is 3.2 mg/kg, applicable to PCBs in the fish consumed by these birds.

Section 3.4.6 of the original IMPG Proposal proposed an alternate range of IMPGs for piscivorous birds using a similar approach and assumptions to those used in developing the EPA-directed IMPG (as set out in the ERA), but with different values for the two inputs mentioned above, which do not accurately represent risks to these birds. That alternate range of IMPGs was developed using the same three PCB toxicity values used to develop the alternate IMPG range for insectivorous birds (as described

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[6] It should also be noted that EPA's selection of breeding osprey to represent this category of birds was itself unsupported, since there is no evidence of breeding osprey in the Rest of River area. Most osprey that breed in Massachusetts nest along the coast. The only osprey observed in the Rest of River area during the EPA studies were migratory transients.

above), together with the measured food intake rate in a study of free-living ospreys. The resulting range of alternate IMPGs, which applies to PCB concentrations in the fish consumed by these piscivorous birds, was 6.7 mg/kg to 75 mg/kg, with a midpoint of 41 mg/kg. This range has been used in the evaluations presented in this document.

Piscivorous Mammals: In assessing risks to piscivorous mammals, represented by mink, EPA's ERA relied on its interpretation of a study conducted by EPA, in which farm-raised mink were fed a diet containing fish from the Housatonic River with various PCB concentrations. That study found no effects of PCBs on most of the outcomes studied (e.g., adult survival, breeding and whelping success, litter size, etc.). However, it reported that, at the highest PCB dose level in the study (3.7 mg/kg), there was a significant decrease in kit survival at 6 weeks of age. Based on a statistical analysis of these data, EPA established a 20% effects level for kit survival of 0.984 mg/kg, which is lower than the second highest dose in the study (1.6 mg/kg), at which no effects on survival were found. EPA then required GE to set the lower-bound IMPG for piscivorous mammals at that calculated 20% effects level, 0.984 mg/kg. The upper-bound IMPG was set at 2.43 mg/kg, which is the geometric mean (average representing typical value) of the reported NOAEL (1.6 mg/kg) and the reported lowest observed adverse effect level (LOAEL) (3.7 mg/kg) in the study.

Section 3.4.5 of the original IMPG Proposal explained that EPA's mink feeding study did not provide conclusive evidence of any adverse effects on mink, even at the highest dose in that study (3.7 mg/kg). The reasons include that: (1) EPA's statistical analysis did not adequately take into account the variability in the mink survival data and the lack of a dose-response relationship (i.e., a proportional relationship between PCB exposure and effects); and (2) in any event, kit mortality prior to 6 weeks cannot be attributed to PCB exposure since no necropsies were conducted on the kits that died before 6 weeks, and necropsies on kits that died later confirmed that death was due to infections common in captive mink, not PCBs. GE proposed an alternate IMPG value of greater than 3.7 mg/kg for PCBs in the total diet of mink obtained from the Rest of River area. For the analyses presented herein, that assumed NOAEL (i.e., 3.7 mg/kg in prey items) was used as the dietary IMPG.

As with insectivorous birds, this dietary IMPG needs to be translated into corresponding concentrations in sediment and floodplain soil in order to assess attainment. Again, this translation is complicated by the fact that mink prey consist of both aquatic animals (in which PCB concentrations are derived from sediments) and terrestrial animals (in which PCB concentrations are derived from floodplain soil); and it is thus not possible to derive a target level corresponding to the IMPG in one medium without knowing the value in the other. In this situation, in the Revised CMS Report, GE has used the same procedure described above for insectivorous birds to evaluate attainment of the piscivorous mammal IMPG for the combinations of sediment and floodplain alternatives discussed therein. That procedure involves the following steps: (1) determination of the sediment PCB concentration predicted by the EPA model at the end of the projection period in the relevant averaging area; (2) for each such area and sediment concentration, calculation of an associated target floodplain level that would allow attainment of the IMPG (using the method described in Appendix E to the Revised CMS Report); and (3) comparison of the post-remediation floodplain soil concentration in the averaging area to the target floodplain soil concentration calculated for that area.

For purposes of this present analysis, this procedure has been modified in certain respects. First, as with insectivorous birds, these calculations have been performed for the entire PSA as a single averaging area (rather than dividing that area into two averaging areas, as EPA directed GE to do for the CMS). As discussed in Section 2.2 below, that approach is still highly conservative, because the objective of ecologically based remediation is to protect local populations and communities of biota rather than individual organisms (see EPA, 1999), and the local mink population extends throughout and beyond the PSA. Second, given that mink would forage both within and outside the defined floodplain in the PSA (represented by the 1 mg/kg PCB isopleth), the calculation of target floodplain soil levels has taken into account the proportion of the mink's foraging range that lies outside of that defined floodplain. Mink home ranges extend laterally about 200 meters from shorelines and would encompass tributaries as well as the main stem of the River.[7] Hence, the calculations presented herein included an adjustment to reflect foraging by mink within a corridor that extends 200 meters laterally from all waterbodies within the length of the PSA, including the main stem of the River, backwaters and impoundments, and tributaries to a distance of approximately 0.75 kilometer from the main stem. This foraging area goes beyond the 1 mg/kg isopleth.

This calculation procedure is described in more detail in Attachment B. That attachment also presents, for each of the combination of sediment and floodplain alternatives evaluated here, the model-predicted sediment levels and calculated associated target floodplain soil levels that would allow achievement of the alternate IMPG for piscivorous mammals (i.e., 3.7 mg/kg in prey items). These levels have been used to evaluate attainment of the alternate IMPG for each of these combinations of alternatives.

Omnivorous/Carnivorous Mammals: For omnivorous/carnivorous mammals, represented by the Northern short-tailed shrew, the ERA included an effect level based on EPA's interpretation of a site-specific field study on short-tailed shrews, conducted for GE in the Housatonic River floodplain. The authors of that study (Boonstra and Bowman, 2003) reported no effects of PCBs on any endpoint measured (i.e., density, survival, sex ratio, reproduction rates, growth, and body weight) at floodplain soil PCB concentrations up to a spatially weighted average of 43.5 mg/kg. However, based on its own statistical analysis of the data, EPA concluded in the ERA that there was a statistically significant effect of PCBs on shrew survival and established a statistical threshold level of 21.1 mg/kg of PCBs in soil. EPA then required GE to set the lower-bound IMPG for omnivorous/carnivorous mammals at that level. The upper-bound IMPG, 34.3 mg/kg, was based on the arithmetic average PCB concentration in one of the study grids that, under EPA's analysis, represented a LOAEL.

Section 3.4.3 of the original IMPG Proposal pointed out a number of problems with EPA's statistical analysis and proposed an alternate IMPG for PCBs of greater than 43.5 mg/kg in floodplain soil. This was based on: (a) GE's conclusion that the Boonstra and Bowman (2003) study showed no evidence of significant adverse effects of PCBs on shrew populations in the Housatonic River floodplain; and (b)

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[7] The basis for this home range was discussed in GE's *Statement of Position on Objections to Condition No. 4 in EPA's Conditional Approval Letter for GE's Corrective Measures Study Proposal Supplement* (GE, 2007b).

the consequent conclusion that the highest soil PCB concentration involved in that study (a spatially weighted average PCB concentration of 43.5 mg/kg) represents a NOAEL. As also noted in that section, this conclusion is further supported by EPA's own finding that shrews are the most abundant small mammals in the floodplain (EPA, 2004, Vol.6, p. J-58) and by Boonstra and Bowman's (2003) finding that the short-tailed shrew densities observed in their study are the highest ever reported, which establishes the absence of an adverse effect on the local shrew population from the PCBs present in the ecosystem. For the analyses herein, GE has used this value of 43.5 mg/kg in floodplain soil as the alternate IMPG for the protection of omnivorous/carnivorous mammals.

Threatened and Endangered Species: For threatened and endangered species, represented by the bald eagle, EPA developed a PCB effects threshold in the ERA using an egg-based toxicity value for PCBs from a field study of bald eagles at another site and applying a food intake rate based on a mathematical model for birds in general. That threshold was 30.41 mg/kg for PCBs in the tissue of fish consumed by bald eagles, and EPA required GE to set the IMPG at that level.

Section 3.4.7 of the original IMPG Proposal proposed an alternate range of IMPGs for PCBs, using the same basic approach used in the ERA and to develop the EPA-approved IMPG, but with alternate PCB toxicity values and a more supportable food intake rate. The toxicity values used consisted of: (1) a low-end value that was the same as that used in the ERA; (2) a high-end value from another high-quality study on bald eagles; and (3) the midpoint of those two values. The food intake rate used was the rate presented in EPA's *Wildlife Exposure Factors Handbook* (EPA, 1993), based on the measured rates from field studies of free-flying bald eagles, rather than the modeled rate used in the ERA, which was based on birds in general. The resulting range of alternate IMPGs, which apply to PCB concentrations in the fish consumed by bald eagles, was 37 mg/kg to 93 mg/kg, with a midpoint of 65 mg/kg. This range has been used in the evaluations presented herein.

2.2 Scientifically Sound Averaging Areas for Ecological Receptor Groups

The IMPGs for ecological receptors are applied to designated averaging areas. In considering the appropriate size of these averaging areas, it is important to take into account the objective of ecologically based remediation. As stated in EPA guidance, that objective is to "reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota" – not to protect "organisms on an individual basis" (EPA, 1999, p. 3). Given this focus on local populations and communities, the averaging areas for the various animal groups to be evaluated should be established on a scale that is commensurate with the area utilized by the local populations or communities of those animals.

Based on this concept, GE proposed in the CMS Proposal (ARCADIS BBL and QEA, 2007a) and CMS Proposal Supplement (ARCADIS BBL and QEA, 2007b) to use, for certain animal groups, averaging areas that extend over the entire PSA. These groups included insectivorous birds (represented by wood ducks), piscivorous mammals (represented by mink), and omnivorous/carnivorous mammals (represented by short-tailed shrews). However, in its conditional approval letters for those documents, EPA directed GE to use smaller averaging areas for these animal groups, which ignore the extent of the local populations of these animals and overemphasize the potential effects of PCBs in small areas. In addition, for amphibians (represented by wood frogs), the CMS Proposal proposed to use EPA's wood frog population model (as described in the ERA), with certain modifications, to evaluate and compare the impacts of floodplain remedial alternatives on the local amphibian population in the PSA and to assess which of the vernal pools in the floodplain would require remediation based on potential population impacts. In its April 13, 2007 conditional approval letter, EPA directed GE not to use EPA's wood frog population model for this purpose in the CMS.

For several animal groups, use of the smaller averaging areas required by EPA is contrary to the objective of protecting local populations of biota. These groups include not only the four animal groups listed above, but also other groups, including piscivorous birds (represented by osprey) and threatened and endangered species (represented by bald eagles). For all of these groups, given the objective to protect local populations, use of the PSA as the averaging area is scientifically supportable and, in some cases, highly conservative (where the local population would extend beyond the PSA). A brief discussion of the averaging area(s) used for each of these groups is presented below. For the other ecological receptor groups, the same averaging areas used in the Revised CMS Report have been used.

Averaging Area for Wood Frogs: EPA's ERA defined the wood frog population in the PSA as those frogs breeding within the vernal pools in the floodplain of the PSA identified as suitable wood frog breeding habitat (EPA, 2004, Vol. 5, App. E. Attachment E.4). To evaluate the impacts of remedial alternatives on this local population, the CMS Proposal proposed to use EPA's wood frog population model with certain modifications; but EPA directed GE not to do so. GE disagrees with that directive, but, for simplicity, has not used that model in the illustrative analyses presented herein. At the same time, the use of every vernal pool and backwater area in the PSA as a separate averaging area (as required for the Revised CMS) is inconsistent with the objective of protecting the local population, which EPA itself defined as all the wood frogs breeding within the PSA vernal pools that have suitable breeding habitat. For the present analysis, GE has calculated a single spatial average PCB concentration across all vernal pools and another across all backwater areas, and applied the alternate amphibian IMPG to those two averaging areas.[8] However, as a sensitivity analysis, the alternate IMPG has also been applied to each vernal pool and each backwater area in the PSA.

Averaging Area for Wood Ducks: Wood ducks do not maintain stable home ranges and their preferred habitat lacks strong natural boundaries. As discussed in Section 4.2.3.3 of the Revised CMS Report, reported sizes of home ranges and foraging ranges for wood ducks are quite variable, with a wide range of reported values. Although a few limited segments of the PSA contain poor or marginal wood duck habitat, given the high mobility of birds, those limited segments do not create boundaries between distinct local populations. Rather, the local wood duck population in the PSA consists of a single, large, contiguous population that is part of an even larger regional population. In this situation, the overall PSA (excluding areas of unsuitable wood duck habitat, as shown on Figure 4-7 of the

[8] Since different averaging methods were used for vernal pools and for backwaters, a combined average concentration could not readily be calculated for both types of areas together

Revised CMS Report) has been used in this document as the averaging area for evaluating impacts on the local wood duck population.

Averaging Area for Mink: For mink, the PSA represents a highly conservative averaging area for the local population. Since mink are wide-ranging predators, with home ranges for individuals in riverine habitats extending from around 2/3 of a mile to 3-5 miles along shorelines and laterally about 200 meters from the shorelines (see GE 2007b), the PSA (which is about 10 miles long) supports only a portion of the local mink population – i.e., the local mink population in Berkshire County extends well beyond the PSA. EPA's own ERA states that the PSA could contain foraging ranges for "one to several mink" or "more if tributary habitat is included" (EPA, 2004, p. I-7) and that "some individuals may forage part of the time outside the PSA" (*id*. p. I-111). These statements recognize that the mink using the PSA, as well as tributaries and other areas adjacent to the PSA, are simply individuals which make up part of the larger local population.[9] In light of the objective to protect local populations and communities of biota, the pertinent averaging area should be based on the habitat used by the local mink population. Since that habitat extends beyond the PSA, use of the PSA as the averaging area for application of the IMPG levels for mink is highly conservative. For the purposes of the present analysis, the entire PSA (excluding areas of unsuitable mink habitat, as shown on Figure 4-8 of the Revised CMS Report), was used as the averaging area to assess attainment of the piscivorous mammal IMPG. However, as discussed in Section 2.1 and Attachment B, the calculation of the target floodplain soil levels for mink took into account the portion of the mink foraging range between the Confluence and Woods Pond Dam that falls outside the defined floodplain (i.e., the 1 mg/kg PCB isopleth).

Averaging Area for Shrews: As shown in the Revised CMS Report (Section 4.2.3.2. and Figure 4-6a), based on habitat descriptions provided by EPA's consultants, approximately 80% of the floodplain within the PSA contains suitable habitat for shrews. Shrew habitat is contiguous throughout that area without identified natural boundaries. Shrews populate most of the floodplain, and the shrew population is not divided into distinct populations. Rather, it is one large, contiguous local population that is part of a larger population in the Appalachian Mountains (Brant and Orti, 2003). Given the objective of protecting local populations and communities of biota, the entire area of the PSA shown as shrew habitat on Figure 4-6a of the Revised CMS Report has been used in the present analysis as the averaging area for evaluating impacts on and protection of the local shrew population.

Averaging Areas for Osprey and Bald Eagle: Both osprey and bald eagles forage within waterbodies over large distances. For such wide-ranging species, the local populations clearly extend not only throughout the portion of the Housatonic River in the PSA, but also to other waterbodies in the general area. To be conservative, in the present evaluation, the alternate IMPGs for these receptors have been applied to two overall averaging areas – one consisting of Reaches 5 and 6 and the other consisting of Reaches 7 and 8. The average fish concentrations within these two larger areas were calculated as

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[9] This is supported by the May 8, 2009 comments of the Massachusetts Department of Fish and Game (MDFG) on GE's Response to EPA's Interim Comments on CMS Report (which comments were reiterated in EPA's January 15, 2009 conditional approval letter for GE's August 2009 Work Plan) that the local populations of many state-listed rare species go well beyond the PSA. This conclusion applies to mink.

weighted averages of the EPA model-predicted fish concentrations for each of the individual subreaches comprising these two larger averaging areas. The weighting factors used to calculate these averages consisted of two components – one to account for habitat quantity and the other to account for habitat quality – because bald eagles and osprey will forage preferentially where there is the most and the best habitat. Since these receptors prefer open areas for foraging, the first component in developing these weighting factors was the surface area of the River within each reach. The second component was used to account for the relative quality of the different habitat types, given that ospreys and bald eagles generally prefer large open water bodies rather than confined canopies (as in the riverine habitat) or visually occluded water (as in the backwaters) (see Peterson, 1986; Vana-Miller, 1987). Thus, the large impoundments offer the highest quality foraging habitat, followed by the smaller impoundments and backwaters, and then followed by riverine reaches. To reflect these differences, each habitat type was assigned a relative habitat quality weighting factor as follows:

- Riverine habitat: weighting factor = 1, applied to Reaches 5A, 5B, 5C, 7A, 7D, 7F, and 7H;
- Small impoundment and backwater habitat: weighting factor = 3, applied to Reaches 5D, 7B, 7C, 7E, and 7G;
- Large impoundment habitat: weighting factor = 5, applied to Woods Pond and Rising Pond.

The overall weighting factor for each subreach was assigned based on the surface area of the reach multiplied by the applicable habitat quality weighting factor for the reach, as listed above. The weighing calculations and resulting weighted-average fish concentrations for Reaches 5/6 and Reaches 7/8 used in the comparisons to the IMPGs for piscivorous birds and threatened and endangered species are shown for the relevant combinations of alternatives in Table 1.

3. Evaluation of Selected Combinations of Remedial Alternatives

This section provides an evaluation of the extent to which three selected combinations of sediment and floodplain remedial alternatives (SED 2/FP 1, SED 3/FP 3, and SED 10/FP 9) would achieve the IMPGs (which is one of the Selection Decision Factors under the Permit) using the alternate ecological IMPGs and averaging areas described in Section 2. Apart from those inputs, this evaluation followed the same approach and used the same procedures used and described in the Revised CMS Report, including use of EPA's PCB fate, transport, and bioaccumulation model to evaluate the sediment components of these combinations of alternatives. Although GE does not agree with all the EPA-required inputs to the EPA model, GE has used the base-case results of the EPA model runs, as presented in the Revised CMS Report, in the analyses of the sediment components to simplify the analyses and due to the lengthy run times for EPA's model.[10]

Section 3.1 presents comparisons of the modeled sediment or fish concentrations and estimated floodplain soil PCB concentrations resulting from implementation of the selected combinations of alternatives with the alternate ecological IMPGs, using (where applicable) the alternate averaging areas. Section 3.2 provides a discussion of the implications of these comparisons for the assessment of whether these combinations of alternatives would provide overall protection of the environment (one of the General Standards in the Permit).

3.1 Comparisons to Ecological IMPGs

For the ecological receptor groups for which IMPGs were developed, the modeled sediment or fish concentrations and estimated floodplain soil exposure point concentrations (EPCs) resulting from SED 2/FP 1, SED 3/FP 3, and SED 10/FP 9 have been compared to the alternate IMPGs (or range of IMPGs) using (where applicable) the alternate averaging areas described in Section 2. These comparisons are presented in a series of tables (using a similar tabular format to those used for the combinations of alternatives in the Revised CMS Report) as follows:[11]

- Table 2: Benthic invertebrates;
- Table 3: Amphibians (as represented by wood frog);
- Table 4: Protection of fish (warmwater and coldwater);
- Table 5: Insectivorous birds (as represented by wood duck);
- Table 6: Piscivorous birds (as represented by osprey) and threatened and endangered species (as represented by bald eagle);

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[10] GE continues to preserve its position on the issues relating to the model inputs and on all other issues on which it has previously presented its position to EPA; and it reserves the right under the Permit to raise any objections on these or other issues in a challenge to EPA's selection of a remedy for the Rest of River.

[11] As in the Revised CMS Report, in those tables that present model results for predicted sediment or fish concentrations, the numbers of years required to achieve the IMPGs are presented.

- Table 7: Piscivorous mammals (as represented by mink); and
- Table 8: Omnivorous/carnivorous mammals (as represented by short tailed shrew).

These comparisons show the following:

- For benthic invertebrates (Table 2), the model results indicate that SED 2/FP 1 would achieve average surface sediment PCB concentrations below the upper-bound IMPG in 29 of the 32 averaging areas (with most achieved at the present time) and below the lower-bound IMPG in more than half (17) of those areas. SED 10/FP 9 would achieve the upper-bound IMPG in 30 averaging areas and the lower-bound IMPG in 23 of those areas. SED 3/FP 3 would achieve the upper-bound IMPG in all averaging areas and would achieve the lower-bound IMPG in all but one of those areas.

- For amphibians (Table 3), all three combinations evaluated would achieve the IMPG in the overall averaging area comprising all vernal pools in the PSA and in the overall averaging area comprising all backwaters in the PSA. In addition, SED 2/FP 1 and SED 10/FP 9 would achieve the IMPG in 41 of the 66 individual vernal pools in the PSA and in all individual backwater areas. SED 3/FP 3 would achieve the IMPG in all individual vernal pools and backwater areas in the PSA.

- For protection of fish (Table 4), all three combinations would achieve the IMPGs for both warmwater and coldwater fish in all relevant averaging areas, with such levels already achieved at the present time in all areas except two (Reaches 7A and 7C), where it would be achieved within 3 to 7 years.

- For insectivorous birds (represented by wood duck) (Table 5), based on the average model-predicted sediment concentrations in the PSA at the end of the projection period and the associated target floodplain soil target levels that would allow attainment of the insectivorous bird IMPGs (see Attachment B), all three combinations would achieve the upper bound, midpoint, and lower bound of the IMPG range within the PSA.

- For piscivorous birds (represented by osprey) (Table 6), based on the model predictions of whole-body fish PCB concentrations for the relevant size ranges consumed by such birds, all three combinations would achieve the upper-bound and midpoint IMPGs in both averaging areas (with those levels attained at the present time or within the first few years of the simulation). For the lower-bound IMPG, SED 2/FP 1 would not achieve that IMPG in either of the two areas, SED 10/FP 9 would achieve that IMPG in one of the two averaging areas (Reaches 7/8 – in 37 years), and SED 3/FP 3 would achieve that IMPG in both areas (in 51 years for Reaches 5/6 and 11 years for Reaches 7/8).

- For piscivorous mammals (represented by mink) (Table 7), based on the average model-predicted sediment concentration in the PSA at the end of the projection period and the associated floodplain soil target level that would allow attainment of the IMPG (see Attachment B), SED 2/FP 1 would not achieve the IMPG, and both SED 10/FP 9 and SED 3/FP 3 would achieve the IMPG.

- For omnivorous/carnivorous mammals (represented by the short-tailed shrew) (Table 8), all three combinations of alternatives would achieve the IMPG in the PSA.

- For threatened and endangered species (represented by the bald eagle) (Table 6), based on the average model-predicted whole-body fish PCB concentrations for the relevant size ranges consumed by the bald eagle, all three combinations would achieve the upper bound, midpoint, and lower bound of the IMPG range within both averaging areas, with all those IMPGs achieved at the present time (except for the lower-bound IMPG in Reaches 5/6, which would be achieved very shortly after remediation).

3.2 Evaluation of Overall Protection of the Environment

As shown in the Revised CMS Report, achievement of IMPGs is one of several balancing factors under the Permit; it is not determinative of whether an alternative would provide overall protection of the environment. To begin with, as noted above, the overall goal for ecologically based remediation is to "reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota" (EPA, 1999, p. 3). Thus, in evaluating a particular alternative, it is important to consider the extent to which it would achieve that goal. Moreover, as EPA guidance makes clear, the standard of "overall protection" of the environment includes a balancing of the short-term and long-term adverse ecological impacts of the alternatives with the residual risks (EPA, 1990, 1997, 1999, 2005d). Thus, it is critical that any IMPG exceedances be weighed against the adverse impacts of further efforts to achieve the ecological IMPGs.

In this case, as shown in Section 3.1, using IMPGs and averaging areas that are scientifically sound, the combination of SED 2/FP 1 would achieve levels below or within the range of those IMPGs for all ecological receptors in all averaging areas, with the exception of benthic invertebrates in 3 of the 32 averaging areas and piscivorous mammals in the PSA. However, the exceedances of the IMPGs for benthic invertebrates in 3 averaging areas would not be expected to have an adverse impact on the local benthic invertebrate community, since the local community extends well beyond those few individual areas and the attainment of levels within or below the IMPG range in all other areas is more than sufficient to ensure the maintenance of a healthy local benthic invertebrate community. Moreover, the exceedance of the IMPG for piscivorous mammals in the PSA would not affect the local population of those mammals, as represented by mink, for two reasons: (1) As discussed in Section 2.1, the alternate IMPG itself is conservatively based on a dietary concentration (3.7 mg/kg) that GE has shown was a no-effect level in the mink feeding study, and hence even individual mink would not be expected to experience adverse effects at that level; and (2) in any event, as discussed in Section 2.2, the local population of mink extends beyond the PSA to other, nearby areas outside the Site and thus would likely not be adversely affected by an exceedance of the IMPG level in prey items within the PSA. In addition, the absence of any significant impact of SED 2/FP 1 on the overall wildlife community in the Rest of River area is illustrated by EPA's and GE's field surveys and other field information on the PSA, which have showed that the wildlife community in the PSA consists of numerous, diverse, and thriving species (including many rare species) despite the presence of PCBs in that area for over 70 years.

Furthermore, as noted above, it is critical that any uncertain risks that may be evidenced by IMPG exceedances be weighed against the certain adverse impacts associated with implementing further remedial efforts aimed at achieving the ecological IMPGs. In this case, implementation of SED 2/FP 1 would avoid such adverse impacts, whereas all of the alternatives involving removal would cause substantial short-term and long-term ecological harm, as shown in the Revised CMS Report. In these circumstances, SED 2/FP 1 would meet the standard of providing overall protection of the environment.

As shown in Section 3.1, SED 3/FP 3 would achieve levels within the range of the alternate ecological IMPGs for all receptor groups and all areas, and, where the IMPGs consist of ranges, would achieve the lower bounds of those ranges in all or most areas. On the other hand, as discussed in detail in the Revised CMS Report (Sections 8.2.4.3 and 8.2.7), implementation of that combination of alternatives would result in substantial short-term and long-term adverse impacts of the environment as a result of the removal and capping of sediments throughout Reach 5A, the bank stabilization in Reaches 5A and 5B, the thin-layer capping in portions of Reach 5C and Woods Pond, and the removal or disturbance of approximately 93 acres of the floodplain in the PSA, including mature floodplain forest, vernal pools, and other wetlands. These activities, which would impact a total of approximately 230 acres of ecological habitats in the PSA, would have long-lasting, and in some instances permanent, negative consequences for the plants and animals that use those habitats. As stated by EPA (2005d, p. 6-6), "it is important to determine whether the loss of a contaminated habitat is a greater impact than the benefit of providing a new, modified but less contaminated habitat." That is the situation for SED 3/FP 3. As a result, SED 3/FP 3 would not meet the standard of providing overall protection of the environment.

As also shown in Section 3.1, SED 10/FP 9, would achieve levels below or within the range of the alternate IMPGs for all ecological receptors in all averaging areas, with the exception of benthic invertebrates in 2 of the 32 averaging areas. Again, those limited exceedances would not have an adverse effect on the local benthic invertebrate community for the same reasons discussed above for SED 2/FP 1. Moreover, as explained in the Revised CMS Report (Sections 8.2.4.3 and 8.2.7), this combination of alternatives has been designed to minimize the extent and severity of adverse habitat impacts. In particular, compared to SED 3/FP 3 and the other combinations of alternatives that include extensive sediment and soil removal, SED 10/FP 9 would impact substantially less of the aquatic riverine habitat, the riverbanks, the forested floodplain, and the wetlands in the PSA, and would not directly affect any vernal pools. This combination would affect a total of approximately 90 acres of ecological habitats in the PSA. As a result, the impacts of this combination on the habitats of the PSA would be much more limited in areal extent and less severe than those of SED 3/FP 3 (as well as the larger remediation alternatives) and would not be expected to cause widespread harm to the overall environment in the PSA. For these reasons, SED 10/FP 9 would provide overall protection of the environment.

4. Summary

As discussed in Section 1, due to EPA's use in its HHRA of the animal-based toxicity values for PCBs, together with its use of a number of unrealistic exposure assumptions, the HHRA and the application of the human health IMPGs based thereon (as presented in the Revised CMS Report) substantially overstate the risks that PCBs might cause cancer and adverse non-cancer effects in humans. In fact, the scientific evidence shows that exposure to PCBs at environmental levels does not cause such adverse human health effects. This evidence shows that the combination of SED 2/FP 1 (as well as the other combinations of remedial alternatives under evaluation) would be protective of human health.

The evaluations presented in this document illustrate the impact of using sound assumptions and interpretations of the ecological studies and data used in EPA's ERA on attainment of the ecological IMPGs by remedial alternatives and on the extent to which those alternatives would provide protection of the environment. Specifically, these evaluations have examined the impact of using scientifically supportable ecological IMPGs and averaging areas instead of those that EPA required be used in the Revised CMS Report. As discussed above, the evaluations using those scientifically supportable inputs demonstrate that both SED 2/FP 1 and SED 10/FP 9 would provide overall protection of the environment (although SED 10/FP 9 would cause some negative habitat impacts). Moreover, these evaluations confirm that SED 3/FP 3 (as well as remedial alternatives requiring more extensive sediment and floodplain soil remediation) would not provide overall protection of the environment since they are not necessary to protect ecological receptors from the purported effects of PCBs and would cause severe long-term and, in some cases, permanent adverse ecological impacts on the habitats in the PSA and the plants and animals that use them.

In short, since SED 2/FP 1 would protect both human health and the environment, there is no need or justification for requiring additional remedial actions in the Rest of River area, with the attendant unavoidable ecological damage that would result from remedial construction activities in the River and floodplain.

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