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February 4, 2000

Alison A. Hess, C.P.G.
U.S. Environmental Protection Agency
290 Broadway, 19th Floor
New York, NY 10007-1866

RE: LOWER HUDSON RIVER ECOLOGICAL RISK ASSESSMENT – COMMENTS

Dear Ms. Hess:

Enclosed are the comments of the General Electric Company (GE) on the U.S. Environmental Protection Agency's (EPA) "Volume 2E – A Baseline Ecological Risk Assessment For Future Risks in the Lower Hudson River" (December 1999).

Unfortunately, our comments submitted to EPA on the Upper Hudson River Ecological Risk Assessment on September 7, 1999 were not considered in the development of this report, as a result it suffers from many of the same flaws as the Upper Hudson River Ecological Risk Assessment. This ecological risk assessment is best described as a "screening" analysis that one would perform to determine if a site-specific assessment was needed. In addition to other problems, the report relies on overly conservative assumptions concerning toxicity and exposure; fails to consider a significant amount of field data; and fails to use the weight-of-evidence method in a useful way.

Without significant revisions, the ecological risk assessment findings are too unreliable to guide development of remedial objectives or to predict what impact a remedy will have on the river ecology.

Please place a copy of this letter and associated comments in the site administrative record.

If you have any questions on these comments, please let me know.

Yours truly,

J G Haggard

John G. Haggard

JGH/bg
Enclosure

cc: Richard Caspe, U.S. EPA
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COMMENTS OF GENERAL ELECTRIC COMPANY ON

Hudson River
PCBs Reassessment RI/FS
Phase 2 Baseline Ecological
Risk Assessment for Future Risks
in the Lower Hudson River

February 4, 2000

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1.0 Executive Summary and Introduction

General Electric Company (GE) submits these comments on the *Hudson River PCBs Reassessment RI/FS Phase 2 Baseline Ecological Risk Assessment for Future Risks in the Lower Hudson River (Future Risk ERA),* issued by the U.S. Environmental Protection Agency (EPA) on December 29, 1999.

PCBs have been present in the Hudson River environment for 50 years, and at significantly higher levels than are found today. For the last 25 years, PCB concentrations in fish and wildlife in the Hudson River have been declining. During this period, other pollutants in this river have generally declined and the management of wild populations, particularly fish, has materially improved. EPA has studied and analyzed Hudson River PCBs for the last 10 years and, even before this reassessment began, the Agency was fully familiar with the river's aquatic resources through its involvement in the issuance of the first water discharge permits to power plants on the Lower Hudson River in the 1970s.

As a result of public, scientific and regulatory interest in the environmental health of the Hudson River, volumes of data on fish, wildlife, sediment and water quality have been collected over the last 25 years. The data documenting conditions in the Lower Hudson for this period are particularly rich for fish.

When it began its ecological risk assessment for the Lower Hudson, EPA had at its disposal the entire record of a living river laboratory, a quarter century in length. These data, collected at a time when PCB levels were higher, provided an unusual opportunity to explore relationships between PCB levels and the sustainability of populations of fish, birds, and mammals. For a number of animal populations, there was sufficient data for EPA to examine the potential for impacts due to PCBs and to determine whether at lower future levels it is reasonable to suggest that animal populations would be affected.

EPA could have built on this extensive historical record to produce a first-class ecological risk assessment. Unfortunately, the Agency did nothing to collect data on wildlife or biotic populations in the Lower Hudson over the past 10 years and disregarded the mine of data which it examined in the 1970s power plant cases and which has grown larger with new data in each year since. EPA likewise ignored the extensive work of the U.S. Fish and Wildlife Service and the National Marine Fisheries Service in addressing the most obvious, large-scale, Hudson-related biological emergency of the last 25 years – the late '70s-early '80s crash of the coastal striped bass population, to which the Hudson stock contributes, an event for which PCBs were considered, but rejected, as a cause, before the real cause, overfishing, was established (Atlantic States Marine Fisheries Commission [ASMFC], 1990).

What EPA produced is superficial, theoretical speculation that implies future risks to wildlife populations without providing evidence of past effects and while ignoring clear evidence that key wildlife populations are, in general, healthy and the communities diverse. For many of the fish and wildlife species evaluated by EPA, the facts clearly contradict EPA's conclusions. For example, the facts demonstrate that:

- The white perch population of the Lower Hudson River is relatively stable and that the striped bass and shortnose sturgeon populations have increased dramatically since the 1970s. The upward trend in striped bass is especially important because EPA has concluded that risks to this species are especially high.

- Although EPA predicts that PCB levels in kingfishers range from 4 to 280 times the level EPA says may pose a risk, a kingfisher population is documented by EPA as successfully reproducing in the Lower Hudson.

According to reports from various sources, including the New York State Department of Environmental Conservation (NYSDEC), the U.S. Fish and Wildlife Service (USFWS), the Audubon Society and others, the populations of other species are present and growing, including bald eagles, which have returned to the Hudson after an absence of more than 100 years and, contrary to EPA statements, are successfully reproducing in the Lower Hudson River; mallard ducks, whose population is characterized as "demonstrably secure," great blue herons, and raccoons. In some cases, EPA's report does not even acknowledge these facts, and where it does, it discounts the data for no legitimate reason.

EPA's approach, including selective use of data, discounting information in a manner that is inconsistent with the Agency's guidance and scientifically defensible practices, and uncorroborated speculation about risks for which no site-specific evidence exists, is highly misleading to the public and fails to provide regulators with a risk assessment that is useful for choosing the most appropriate, scientifically defensible management options for the Upper Hudson River. There is no sound basis to accept EPA's analytical approach as plausible when it at dramatic variance with the facts.

The objective of the risk assessment should be to provide data and analysis on which to base remedial decisionmaking for the Upper Hudson River. To the extent that an examination of risks in the lower river is appropriate, the assessment must be useful to the remedial manager as:

- A sound and reliable description of the effects of current and future PCB exposures emanating solely from the Upper Hudson on biota in the Hudson River Valley.
- A foundation for projecting the responses of those biota to alternative remedies taking into account the effects of chemicals other than PCBs and PCBs whose source is not the Upper Hudson River.
- A sound technical underpinning for comparing the ecological benefits gained through remediation to the ecological costs of implementing remedial actions.

Like EPA's Baseline Ecological Risk Assessment (BERA), the Future Risk ERA is simply a screening-level assessment. As such, it does not reflect acceptable scientific practice, is excessively conservative, and is insufficient for use in determining the effect of a remedy or selecting an appropriate remedy.

The Future Risk ERA repeats critical flaws identified by GE and others in the BERA including:

- Inadequate consideration of population vs. individual-level effects.
- Ignoring or dismissing site-specific data.
- Failure to use a weight-of-evidence approach correctly.
- Use of excessively conservative assumptions concerning exposures and effects.
- Interpretation of exceedances of Sediment Effects Concentrations and other sediment quality guidelines as measures of actual effects.
- Inappropriate use of the TEQ approach.
- Failure to evaluate the usefulness of or even cite the expert review of PCB effects on fish prepared for NOAA.
- Mathematical errors.

Rather than altering the assessment procedures to minimize or eliminate the identified flaws, EPA used exactly the same approach in the Future Risk ERA. Consequently, this assessment suffers from the same flaws as the BERA.

In the following sections, GE provides comments on EPA's Future Risk ERA, specifically addressing:

- The Future Risk ERA does not provide the information necessary to support remedial action decisions.
- EPA has repeated critical flaws identified in previous reviews of the BERA.
- The Future Risk ERA does not conform to best scientific practice.

- The models used to project future PCB concentrations in media have been inadequately reviewed and are seriously deficient.
- Available data on ecological resources of the Lower Hudson River were not used and directly contradict EPA's conclusions.
- EPA's approach to effects assessment for fish and wildlife is excessively conservative, relies on a small subset of the available data, and ignores or improperly interprets key studies.

By concluding that PCBs may or may not pose risks to wildlife populations and offering no evidence of past effects from PCBs, EPA failed to abide by the most fundamental tenet of its own internal guidance -- it did not quantify impacts on wildlife populations. The Agency failed to use realistic exposure scenarios, failed to consider effects that might be attributable to contaminants other than PCBs, and failed to distinguish PCBs from the Upper Hudson and those originating in the mid-Hudson or elsewhere. This final point is most important. EPA is preparing to make a remedial decision for the Upper Hudson River. If it intends to assert that its decision would benefit lower parts of the river as well as the Upper Hudson, it must be able to show that it has the ability to distinguish between one PCB source and another. There is no indication in this report or any report that the agency has thus far produced for this project, that EPA can do that with any scientific certainty.

Therefore, this report should be given no weight in the Agency's deliberations over the appropriate remedial strategy for the Upper Hudson River.

2.0 The Future Risk ERA does not provide the information necessary to support remedial action decisions

As we have previously explained, it is inappropriate for EPA to base a remedial decision for sediments in the Upper Hudson on risk reduction to biota in the Lower Hudson.[1] Should EPA nevertheless persist in examining risks in the Lower Hudson, it is clear that, like the BERA, the Future Risk ERA in its present form will not provide useful information for the risk manager.

To support remedial action decisions for the Upper Hudson River, the Future Risk ERA must be based on an objective evaluation of all available information concerning the risks to ecological resources posed by present and future exposures to PCBs. As described in the following sections of GE's comments, this information should include:

- Site-specific data concerning PCB and other chemical exposures and effects on populations and communities based on a variety of independent lines of evidence.

- Estimates of concentrations of PCBs in sediment, water, and biota based on properly calibrated and verified models.

- A thorough review of all available data.

The Future Risk ERA fails to include any of the above information. It is based on inadequately verified models, excessively conservative Toxicity Quotients (TQs) based on a limited evaluation of literature-derived test data, a focus on individual organisms, and a failure to consider important and relevant site-specific data. Therefore, the Future Risk ERA cannot support scientifically sound decisions about remedial actions on the Hudson River.

[1] See Nov. 6, 1997 letter from Angus Macbeth to Richard Caspe; May 5, 1998 letter from Angus Macbeth to Douglas Fischer.

3.0 EPA has repeated critical flaws identified in GE's and others' review of the Baseline ERA

GE's and other's comments on the BERA identified a number of critical flaws, which render the document inadequate for supporting remedial decisionmaking for the Hudson River. In the Future Risk ERA, EPA has not addressed *any* of these flaws.

3.1 Inadequate consideration of population vs. individual-level effects

As noted in GE's comments on the BERA, decisions concerning remedial action needs for the Hudson River must consider:

(1) Whether the sustainability of exposed biological populations and communities is being threatened by the presence of PCBs in Upper Hudson River sediment.

(2) Whether the positive effects of a particular remedy will be greater than any negative ecological effects of carrying out the remedy. EPA's Risk Management Guidance clearly states that populations are the appropriate level of ecological organization for assessment. (EPA 1999a, Ecological Risk Assessment and Risk Management Principles for Superfund Sites. USEPA Office of Solid Waste and Emergency Response, Washington, D.C., Directive 9285.7-28P).

A focus on populations rather than individuals is necessary because compensatory mechanisms that operate in all biological populations permit these populations to sustain themselves in spite of the death or impairment of some individuals that occurs due to natural and anthropogenic stressors. Even if statistically significant reductions in survival, growth and reproduction of some individuals are observed, such data alone cannot be used directly to estimate adverse effects to populations, communities, or ecosystems (Forbes and Calow, 1999). Survival, growth, and reproductive rates are interrelated in complex ways, and apparent adverse changes in one of these factors (e.g., a reduction in fecundity) are often offset by compensatory changes in others (e.g., increased growth and survival of young).

In the Future Risk ERA, EPA indicates that it considers population-level effects by comparing the magnitudes of TQs over the 25-year modeling period to the life spans of the receptor species (p. 9). EPA asserts that population-level effects are more likely if the TQ exceeds 1 for the life span of a species. This approach does not consider compensatory processes and is not supported by any published studies. In fact, EPA did not even implement the approach described on page 9. The risk characterization in Section 5 does not even discuss the life spans of the various receptor species, much less compare them to the duration of the modeling period.

3.2 Ignoring or dismissing site-specific data

GE's comments on the BERA noted that EPA had not examined or incorporated site-specific data such as biological surveys, whole-media toxicity tests, or reproductive effects studies. According to Suter (1999), site-specific ecotoxicological studies "can provide a firm basis for decision making, often resulting in savings in remedial costs far beyond the cost of performing the studies." This is particularly true where, as in the Lower Hudson, PCB concentrations in biota have been declining over a long period of time. GE's previous comments included a comparison between the data used by EPA and the data collected by the Department of Energy for the Clinch River ecological assessment. Table 1 presents a similar comparison between the Future Risk ERA and the Clinch River ERA. Whereas the BERA included limited site-specific data concerning the effects of PCBs on Hudson River biota, the Future Risk ERA includes *no* data specific to the Lower Hudson River.

Like the BERA, the Future Risk ERA ignores or discounts existing site-specific data. For the Lower Hudson, extensive data on the condition of ecological resources are available, especially for fish. As in the BERA, EPA explicitly discounts these data for risk assessment, arguing on page 45 that reproduction and recruitment of fish might be impaired by exposure to PCBs, even though populations are increasing. The implication is that only comparisons between measured or modeled exposures and Toxicity Reference Values (TRVs) are relevant. This conflicts with established principles of ecological risk assessment (e.g., Suter, 1993) and with EPA's own Superfund guidance (EPA, 1997a).

3.3 Use of excessively conservative assumptions concerning exposures and effects

In its comments on the BERA, GE noted that, even accepting the proposition that the TQ approach provides useful information for an assessment, EPA's application of TQs in the BERA provides highly inflated risk estimates that are not useful in remedial decisionmaking. Both the exposure assessment and the effects assessment used by EPA employed data, models, and assumptions that are inappropriate for site-specific assessments.

Like the BERA, the Future Risk ERA employs water and sediment-quality guidelines designed to be protective such that exposure concentrations *below* the criteria can be confidently presumed to be safe. Site-specific studies of the type EPA chose *not* to perform (such as those used in the Clinch River ERA) are required to determine whether exposures that exceed the guidelines are actually causing any adverse effects. Similarly, in selecting TRVs for use in assessing effects on fish and wildlife, EPA consistently chose the lowest value from the range of available test results, and often adjusted those values even lower with 10x uncertainty factors. The resulting TRVs are generally lower than any exposure concentrations at which effects have been observed in any test system. We may be confident that exposures that are lower than the TRVs will have no adverse effects, but additional information – again, information that EPA chose not to collect – is required to determine whether adverse effects will occur at the exposure levels actually seen in the lower Hudson.

3.4 Interpretation of exceedences of Sediment Effects Concentrations and other sediment quality guidelines as actual measures of effects

GE's comments on the BERA included an extensive discussion of the lack of validity of NOAA's Sediment Effects Concentrations (SECs) as measures of actual effects on benthic invertebrate communities. GE provided a thorough review of the inherent limitations of the SECs and other generic sediment quality guidelines, including statements from the *developers of the guidelines themselves* that these values are intended as screening values, not as measures of effects. In the Future Risk ERA, EPA continues to use generic sediment-quality criteria as the primary measure of risks to benthic invertebrates.

3.5 Inappropriate use of the TEQ approach

GE previously noted that the toxicity equivalency (TEQ) approach, in its current state of development, is a screening approach rather than a primary assessment approach. The developers of the approach themselves have expressed caution concerning improper use of the TEQs. EPA has inappropriately handled non-detect readings of PCB congeners by using full detection limits for non-detect values, even though standard risk assessment practice typically involves using one-half of the detection limit for non-detects and in the human health risk assessment a value of 0 was used for non-detect. As noted by GE in comments on the BERA, EPA has assumed that nondetects of BZ#126 are present at the detection limit. This results in the TEQ-based risk assessments being driven by a chemical not even detected (non-quantified concentrations of BZ#126).

In the case of fish, the review performed for NOAA of the TEQ approach concluded that, because of insufficient understanding of inter-species variations in sensitivity to dioxin-like compounds, the approach should not be applied to Hudson River fish species (NOAA, 1999).

In these circumstances, the Future Risk ERA should not employ the TEQ approach.

3.6 Failure to cite the expert review of PCB effects on fish prepared for NOAA

In its previous comments, GE noted that NOAA commissioned a review by Dr. Emily Monosson of effects of PCBs on fish, with specific reference to Hudson River fish populations (NOAA, 1999). The review concluded that adverse effects on early life stages of Hudson River fish species might occur at tissue concentrations exceeding 5 ppm (whole body, wet weight), and that physiological effects on adult fish might occur at tissue concentrations exceeding 12.5 ppm (whole body, wet weight). One might question these values in light of the site-specific data, but in any event, they are far higher than the TRVs used by EPA in both the BERA and the Future Risk ERA.

This review was published by the same NOAA office that published the report on Sediment Effects Concentrations that EPA used in its assessment of risks to benthic invertebrates. Both reports were issued in March, 1999. There is no indication that EPA evaluated the applicability of the Monosson study. EPA's failure to examine the Monosson review violates common sense and the Agency's own guidelines, which require the EPA to consider all relevant evidence when performing its risk assessments. Will EPA choose the results that give the lowest possible acceptable PCB levels regardless of the quality of the data? This is scientifically indefensible.

4.0 The ERA for Future Risks does not conform to best scientific practice

Like the BERA, the Future Risk ERA relies almost exclusively on "Toxicity Quotients" (TQs), i.e., comparisons between measured or modeled exposure concentrations and concentrations believed to be potentially harmful to organisms. Such screening-level data and models, as applied by EPA, are deliberately designed to be conservative, i.e., to minimize the possibility that any potential adverse effects will be missed. They necessarily overstate the actual effects of most chemicals at most sites. The Ecological Risk Assessment Guidance for Superfund (EPA, 1997) explicitly states that decisions to require remedial action based solely on the screening-level calculations performed by EPA "would not be technically defensible." As noted by GE in comments on the BERA, a scientifically defensible ecological risk assessment should use a variety of independent techniques for measuring and characterizing ecological risks, e.g.:

- Measurements of the abundance, diversity, and other characteristics of exposed invertebrate, fish, and wildlife communities.
- Measurements of reproductive success in fish, birds, and mammals.
- *In-situ*, whole-media, and dietary toxicity tests using selected receptors or appropriate surrogate species.

These techniques are described in EPA's Guidelines for Ecological Risk Assessment (EPA, 1998) and Ecological Risk Assessment Guidance for Superfund (EPA, 1997). Each type of measurement typically requires knowledge of and data relevant to the population dynamics of the species for appropriate use in assessing risks to wild populations. Measures of effects on individual organisms must be interpreted in the context of the distribution, abundance, and temporal dynamics of the exposed populations.

As noted in GE's comments on the BERA, these techniques have been successfully applied at other large Superfund sites such as the Clark Fork River (Canfield et al., 1994) and the Clinch River Study Area, Tennessee (Cook et al., 1999). Table 1 contrasts the assessment performed for the Clinch River Study Area to the EPA's Future Risk ERA. In addition to the TQ approach used by EPA, the Clinch River assessment used site-specific toxicity tests, histopathological studies, avian reproduction studies, a mink dietary toxicity test, and local/regional fish and benthic macroinvertebrate surveys. In contrast with the deterministic TQs used in the Hudson River assessment, Monte Carlo analyses and other probabilistic approaches were used in the Clinch River risk assessment to characterize the likelihood that adverse effects might occur as a result of exposure to PCBs and other chemicals.

Data collection to support the Clinch River assessment began in 1989, the same year EPA initiated its reassessment of PCBs in the Hudson River. EPA had ample time to perform similar studies for the Hudson River, but chose not to do so.

EPA's approach to evaluating the small amount of field data that were discussed in the Future Risk ERA also fails to meet accepted standards of scientific inference. In the Clinch River assessment, all of the lines of evidence were considered together in making determinations concerning the existence and magnitude of risks. Lack of concordance between different types of evidence relevant to a given endpoint was taken to indicate that the risk assessment was inconclusive. In the Future Risk ERA, EPA discounted all lines of evidence other than TQs, arguing that the failure of field data to support the TQs simply showed that other factors were masking the adverse effects caused by exposure to PCBs. Such an approach is scientifically indefensible.

5.0 The models used to project future PCB concentrations in water, sediment, and biota have been inadequately reviewed and are seriously deficient

All three of the models used by EPA in the exposure assessment component of the Future Risk ERA have deficiencies that compromise their value for projecting future PCB concentrations in sediment, water, and biota. Two of these models – EPA's HUDTOX and FISHRAND models – were recently revised, and it is the modified models that were used in the risk assessments. Our comments are based on oral presentations of the modified models to the peer reviewers of EPA's Baseline Modeling Report (BMR), and we reserve our right to supplement these comments after further review of the revised BMR, which EPA just released in late January 2000.

5.1 EPA Upper Hudson River model (HUDTOX) used to predict PCB loads to the Lower Hudson River

The use of the EPA Upper Hudson River model (HUDTOX) to predict PCB load passing Troy to the Lower Hudson River relies on the presumption that this model accurately predicts the time trends of PCB concentrations at Troy. As detailed in GE's Comments on the BMR (GE, 1999), GE has concerns that HUDTOX has not been properly and fully developed and is inadequate for predicting future PCB concentrations. One of the most significant of these concerns relates to the model's ability to describe PCB fate downstream of the Thompson Island Dam (TID). The equations and coefficients describing sediment transport in the 34 miles between the TID and Troy are inconsistent with the equations and coefficients used in the Thompson Island Pool and inaccurately represent the processes critical to PCB fate in the river (GE, 1999).

The inaccuracy of the HUDTOX-predicted PCB load to the Lower Hudson River is exacerbated by the necessity to convert the HUDTOX PCB metric (PCBs with 3 or more chlorine atoms; tri+) to the homolog characterization of PCBs used in the Farley et al. (1999) Lower Hudson River model. This conversion was made using factors that may not be generally applicable because they were developed from 1993 TID and Waterford data that were influenced by the 1991-1993 elevated upstream source.

The ratio of each PCB homolog to tri+ was calculated in two steps. The first step was to calculate the seasonal averages of these ratios for all of the measurements made at the GE TID West sampling station between 1991 and 1998. The second step was to convert these ratios to equivalent ratios at Waterford. This step was accomplished using the differences in PCB composition between the TID and Waterford observed in the 1993 EPA Phase 2 sampling program. This assumes that the differences observed in 1993 apply over all times, a presumption that was never tested. There are several reasons why the presumption may be invalid. First, the 1993 EPA Phase 2 TID station was located along the west shoreline 200 feet upstream of the GE TID West station. Both stations provide poor representations of the overall PCB flux passing TID and they are not replicate locations. Second, the 1993 EPA Phase 2 data reflect a period in which PCB load from the vicinity of Hudson Falls was a significant component of the PCBs passing the TID. This condition is not representative of the entire 1991 to 1998 period; a period over which conditions have transitioned from one in which the Hudson Falls source dominates to one in which sediment sources dominate. Thus, a ratio developed from a snapshot in time may not be applicable to the full historical period or to the future.

5.2 Farley et al. Lower Hudson River model used to predict Lower Hudson River water and sediment PCB concentrations

EPA has used the Farley et al. (1999) Lower Hudson River model without having conducted a critical review to determine its validity and accuracy. EPA has not developed an understanding of the veracity of the predicted water and sediment PCB concentrations and the relationship of those concentrations to the various PCB sources. Because the predictions are the basis for the risk calculations, the lack of understanding of model veracity undermines the utility of the risk assessment.

Concerns about model veracity are pertinent in view of apparent deviations between the model and site data. These deviations raise questions about the ability of the model to accurately describe the relative contributions of external and sediment PCB sources and to accurately predict time trends.

The model is biased toward lower chlorinated PCBs relative to the observed PCB composition. For example, data indicate that dichlorobiphenyl constitutes about 20 percent of the sum of di- through pentachlorobiphenyl present at river mile 125, whereas the model computes that it constitutes about 40 percent. (See Figure 3-2 of Farley et al. 1999). Dichlorobiphenyl is a reasonable tracer of the Upper Hudson River source and the upward bias of the model may indicate underestimation of the rate at which the Upper Hudson River source declines as water moves downstream.

The water column and sediment model-data comparisons were limited to a single year (1993), an inadequate duration to test the model's ability to predict time trends accurately. Water column data for comparison to the model were available for only 3 locations over the more than 150 miles of river. The model predicts PCB levels that compare poorly with these data. The model's predictions are significantly lower than the summer data and do not predict the extent of concentration decline from Troy to the mid-river in April (Figure 3-5 of the Future Risk ERA report). These differences suggest that the model underestimates sources within the lower river (probably local sediments) and under estimates the loss rate of Upper Hudson River PCBs. The comparison of model and surface sediment data (Figure 3-7 of the Future Risk ERA report) excludes important data (i.e., the USEPA Phase 2 high resolution cores) that indicate that the model under predicts 1993 surface sediment PCB levels.

5.3 Models used to predict PCB concentrations in Lower Hudson River fish (FISHRAND and Farley et al.)

PCB concentrations in fish in the Lower Hudson River were computed using two models, FISHRAND (EPA, 1999b) and Farley et al., (1999). Each model was used to predict

PCB concentrations in selected species in the Lower Hudson River (Table 2). These models are similar, in that they are mechanistic bioenergetic-based simulation models of bioaccumulation in aquatic organisms. However, they differ in some of the formulations used to describe the key processes, and the impacts of these differences have not been evaluated. In addition, as mentioned above, EPA has used the Farley, et al., (1999) Lower Hudson River model without having conducted a critical review to determine its validity and accuracy. Thus, the validity of the predicted fish PCB concentrations has not been fully evaluated, undermining the utility of the risk assessment.

A preliminary review of Farley et al. (1999) and FISHRAND (EPA, 1999b) has revealed several weaknesses in parameterization and calibration of the models. These are divided into three categories: food web structure, calibration, and other issues associated with model development.

5.3.1 Food web structure

FISHRAND and Farley are inconsistent in their characterization of the food web.

Fish can accumulate PCBs from both the surface sediments and the water column. PCB concentrations in the sediments and water column may exhibit different rates of natural recovery and different responses to remedial activities. Thus, the realism of the projected fish concentrations is affected by the accuracy of the presumed food web. The two bioaccumulation models of the Lower Hudson River are inconsistent in their descriptions of contaminant sources to the food web. FISHRAND includes both sediment- and water column-associated food webs for the resident fish and the striped bass, based on the fact that the striped bass concentrations are computed from the largemouth bass concentrations, and the statement that the parameterization of FISHRAND is the same as in the Upper Hudson River. In contrast, Farley includes only a water column source to the food web of the striped bass. To develop reliable projections, this inconsistency must be reconciled, and the final food web structure must be considered in light of the available information.

Striped bass migration patterns are described inaccurately.

Largemouth bass is a resident fish, while striped bass is migratory. Because predicted largemouth bass PCB concentrations are used to estimate striped bass concentrations, the contribution to the striped bass of PCBs originating south of Region 1, that is, in the estuary, is underestimated in the ERA. Projected concentrations in the striped bass are determined by the changes in the loads from the various PCB sources in the Lower Hudson River. Migratory striped bass migrate between the coastal ocean, the river and the Harbor and are therefore exposed to PCBs from many sources. Inaccurate description of the relative contributions of each source can therefore lead to inaccurate projections.

5.3.2 Calibration

Farley does not compute realistic temporal trends in striped bass PCB levels.

Computed total PCB concentrations in striped bass ages 6-16 years are consistently lower than the data prior to 1992 and generally greater than the data after 1992 (Figure 3-9 of the Future Risk ERA report). This is important because it indicates that the rate of natural recovery is not being accurately modeled. It may be due to inaccuracies in the food web structure, in particular the contribution of sediment and water column PCBs, or to inaccurate temporal trends in water column PCBs computed by the fate model.

Response of model fish at RM 152 to the events of 1991 is unrealistic.

At river mile (RM) 152, lipid-based PCB concentrations in largemouth bass, white perch, brown bullhead and yellow perch increased in 1992 following the Allen Mill event and decreased thereafter (Figure 3-12a of the Future Risk ERA report). In contrast, model calculations for these fish exhibit no response to these events. This suggests that exposure concentrations and food web structure may be inaccurate.

FISHRAND computations on a wet weight and lipid basis are inconsistent.

For largemouth bass and white perch at RM 152, wet weight-based concentrations computed by the model run through the error bars and exhibit limited bias with respect to the data. In contrast, lipid-based levels are generally lower than the data (Figure 3-12a of the Future Risk ERA report). This suggests that the lipid contents are not representative of the fish for which PCB data are available.

5.4 Other model development issues

Size of fish modeled may not reflect consumption patterns by ecological receptors.

To develop a relationship between largemouth bass and striped bass concentrations, EPA compared concentrations in fish greater than 25 centimeters (cm) in length, because those are consumed by anglers. It is unclear what size classes are used in the model calculations. Size classes consumed by wildlife should be used.

Fish growth rates are not site-specific.

Fish growth rates can control the computed PCB concentrations. For example, if growth rates are unrealistically high, then the predicted degree of bioaccumulation is likely to be unrealistically low. To calibrate a model with less bioaccumulation, the exposure concentrations must be increased. This is done, for example, by increasing the contribution to the food web from more contaminated sources. Thus, realistic growth rates are needed to characterize the contaminant sources to the food web as accurately as possible. It is our understanding that FISHRAND employed generic growth rates; site-specific data should be used when available.

6.0 Available data on ecological resources of the Lower Hudson directly contradict EPA's conclusions

Substantial data are available concerning the condition of the ecological resources of the Lower Hudson River. Information concerning long-term trends in the abundance of various fish species, including three of the receptor species considered in the Future Risk ERA, are especially complete. This information directly contradicts EPA's conclusions concerning the risks posed by future exposures to PCBs.

6.1 Benthic macroinvertebrates

Based on the comparison of modeled Lower Hudson River PCB surface water and sediment concentrations with screening criteria and guidelines, EPA contends that there is the potential for adverse effects on benthic organisms. As noted in GE's comments on the BERA, NYSDEC (1993) found that the abundance of pollution-intolerant filter-feeding macroinvertebrates has increased throughout the Hudson River as a result of improved water quality since 1972. Hudson River macroinvertebrate communities are comparable in structure to those in other New York rivers, and currently considered slightly impacted based on the type of species present in the river (Plafkin et al., 1989; NYSDEC, 1993).

In addition to improvements at several sites in the Upper Hudson River, NYSDEC (1993) noted improvements in macroinvertebrate populations in the Lower Hudson River over the last two decades. The number of pollution-sensitive species increased below Troy Dam at Castleton and Saugerties between 1973 and 1983. Numbers declined from 1983 to 1991, but 1991 values were still higher than those of the early 1970s. These data demonstrate that: (1) the benthic community improved even in the presence of PCB concentrations greater than levels currently exhibited; and (2) changes in species composition appear to occur independent of changes in PCB levels.

There is more evidence that the improvements in macroinvertebrate communities of the Hudson River noted by NYSDEC (1993) are likely independent of any changes in PCB concentrations. Exponent (1998a,b) found that the macroinvertebrate communities of the Upper Hudson River had abundant populations and high species richness (i.e., total number of taxa), in areas with higher PCB concentrations. These results together with the results of macroinvertebrate surveys conducted by EPA (as reported in the BERA) suggest that PCBs currently have no major impact on macroinvertebrate communities of the Hudson River. Because it is highly unlikely that PCB concentrations in the Lower Hudson River reach the high concentrations in study area sediments sampled by Exponent (1998a,b), it can be concluded that there is no apparent risk, present or future, from GE-associated PCBs to macroinvertebrates of the Lower Hudson River.

6.2 Fish

The Hudson River utility companies recently completed a comprehensive assessment of the impacts of power plants on the biological resources of the Hudson River (Central Hudson Gas & Electric Corporation et al., 1999) as part of a Draft Environmental Impact Statement (DEIS). The assessment summarizes 25 years of data on the distribution and abundance of the major fish populations inhabiting the Lower Hudson. Trends in the abundance of 16 fish species were evaluated, including striped bass, white perch, and shortnose sturgeon. The major conclusions from the DEIS are summarized below.

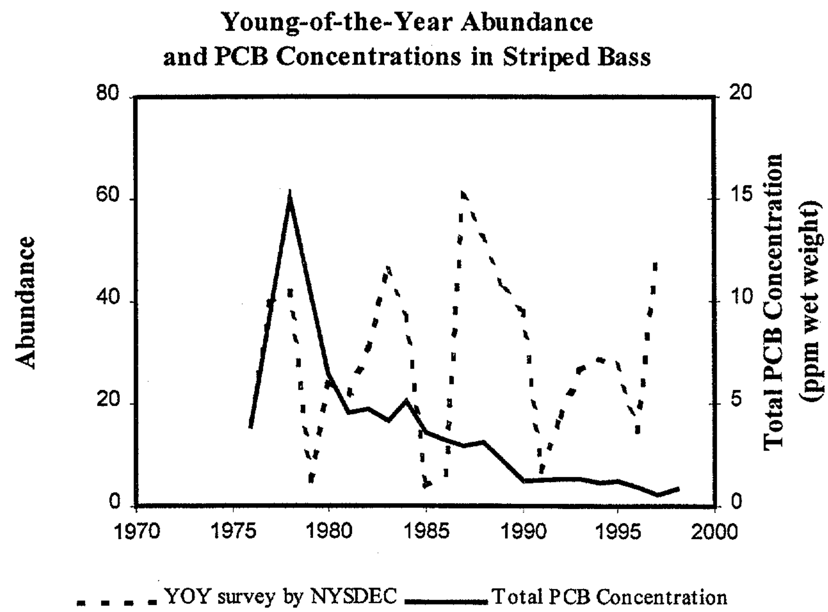
6.2.1 Striped bass

Information on the abundance of striped bass life stages in the Lower Hudson is available from sampling programs conducted both by the utility companies and by NYSDEC. These data include a river wide ichthyoplankton sampling program, two beach seine surveys, a trawl survey, and a mark-recapture program. NYSDEC also samples striped bass in 7 bays around western Long Island Sound, conducts a haul seine survey to obtain information on the length, age, sex distribution, and mortality rates for the adult population, and monitors the striped bass bycatch in the American shad fishery. The data derived from these programs represent one of the most extensive data sets available for any estuarine fish species.

As documented in the DEIS, large year classes of striped bass, as measured by the utility and NYSDEC beach seine surveys, were produced in 1977, 1978, 1983, and 1984. When these fish reached reproductive age in the mid and late 1980s, numbers of striped bass larvae collected in the utilities' river wide ichthyoplankton survey increased dramatically. Correspondingly strong year classes, as measured in the beach seine surveys, were produced in four consecutive years, from 1987 through 1990. The abundance of adult striped bass increased steadily from 1980 through the mid-1990s. According to the DEIS, the Hudson River striped bass population may now have reached its carrying capacity. Striped bass are, according to the DEIS, now a dominant predator in the estuary, controlling the abundance of many other fish species.

In addition to the utility-sponsored studies, research on the migratory behavior of striped bass has shown that adult striped bass collected immediately below Troy Dam (RM 152) appear to be a cohort of nonmigratory male fish that have resided in fresh water for their entire lifetimes (Secor, 1999). These fish, which frequently have higher PCB body burdens, are unrepresentative of the population as a whole. Fish that migrate annually between marine and fresh water, and probably dominate the spawning stock, have much lower body burdens. The adult females sampled by NYSDEC in April and May, in the mid and lower estuary, provide the most relevant data concerning PCB concentrations in spawning female striped bass and are the only data that should be used for risk assessment.

Figure 1 compares time trends in PCB concentrations in adult female striped bass, collected during the spawning season in the mid and lower Hudson, to trends in the NYSDEC striped bass juvenile index. This index, which is a measure of the density of juvenile striped bass present in the Hudson River estuary during the late summer and early fall, has been accepted by the Atlantic States Marine Fisheries Commission (ASMFC) as a valid indicator of year-class production in the Hudson River striped bass population and is used in the ASMFC's annual striped bass stock assessments. From 1976 through 1997, the annual production of young striped bass from the Hudson has fluctuated without trend; PCB concentrations in the spawning females that produced these fish have declined steadily over the same period. The ASMFC concluded that "[g]iven the very healthy status of the Hudson River stock, which is well documented to have relatively high tissue concentrations of PCBs, it would appear that such levels ... may not pose a threat to striped bass from a population biology perspective" (ASMFC, 1990). Clearly, there is no evidence that high maternal PCB concentrations in the late 1970s adversely affected striped bass recruitment. The obvious implication of this result is that future, lower maternal concentrations will similarly have no effect on striped bass recruitment.



Total PCB Concentration: Average +/- 2SE for female striped bass (>1000g, April/May, fillet)

Source: hudorg.dbf, NYSDEC database

Abundance: Geometric mean number per 200' seine haul for 6 week sampling period +/- 2 SE

Source: Draft Environmental Impact Statement, December 1999

Figure 1. Total PCB Concentration and Young-of-the-Year Production for Striped Bass in the Lower Hudson River

6.2.2 White perch

White perch are sampled in many of the same programs that sample striped bass. The abundance of white perch larvae and juveniles increased rapidly in the late 1970s, but has fluctuated and generally declined since the mid-1980s. A variety of factors may have contributed to the decline; however, the DEIS concluded that competition with young striped bass and predation by older striped bass are the most likely cause (Central Hudson Gas & Electric Corporation et al., 1999). In addition, the re-growth of large beds of water chestnut in the upper estuary following cessation of herbicide treatments in 1976 is believed to have reduced the quality of the habitat for juvenile fish and may also have contributed to the recent decline (Central Hudson Gas & Electric Corporation et al., 1999).

6.2.3 Shortnose sturgeon

Published mark-recapture studies discussed in GE's comments on the BERA show a large increase in the abundance of shortnose sturgeon in the Lower Hudson between the 1970s and the 1990s. These studies indicate that the size of the spawning stock of shortnose sturgeon in the Hudson has increased fourfold, from approximately 14,000 fish to 60,000 fish during that interval. These studies are supported by data on the abundance of yearling shortnose from the utilities' monitoring program. The utilities' data show a substantial increase in abundance of young sturgeon since 1990. In light of these data, NMFS has recommended that the status of the population be changed from "endangered" to "threatened."

6.2.4 Atlantic Tomcod

The Atlantic tomcod is relevant to the Future Risk ERA because studies performed in the in the 1970s found liver tumors in 80% of the adult tomcod examined (Klauda et al., 1981). Exposure to PCBs was suggested as a possible cause; however elevated levels of PAH-sensitive biomarkers in Hudson River tomcod suggest increased exposure to polycyclic aromatic hydrocarbons (PAHs), consistent with previous studies (Wirgin et al., 1994). Thermal stress to tomcod during warmer months and the potential occurrence of a genetically distinct population of tomcod in the Hudson River that is predisposed to neoplasia may also contribute to the prevalence of tumors (El-Zahr, et al., 1993; Schultz et al., 1993; Wirgin et al., 1991). Despite the tumors, population trends in this species have been relatively stable, with abundance increasing somewhat from 1983-1989 and decreasing somewhat from 1989 through 1997. The DEIS concludes that improved sewage treatment in the lower estuary, resulting in reduced food availability and increased competition, may be responsible for the recent decline. Data collected during the 1995-1996 spawning season indicate that the incidence of liver tumors has dropped to less than 2%.

6.2.5 Summary of Risks to Fish Community of the Lower Hudson River

Changes in the fish community as a whole, measured by the number of species present, appear to have been determined by three factors based on analyses performed by experts in fisheries biology (Central Hudson Gas & Electric Corporation et al., 1999):

(1) Improved water quality in the Lower Hudson, which increased the number of marine species entering the lower estuary.

(2) Increased abundance of striped bass, which reduced the abundance of many species throughout the lower estuary.

(3) Increased abundance of water chestnut, which has reduced the availability of habitat for freshwater fish in the upper estuary.

PCB exposures, which have declined steadily over the entire period covered in the DEIS, do not explain any of the observed changes. The observation of increasing, i.e., recovering, populations of fish occurring in previous periods of relative high PCB concentrations suggests that PCBs are unlikely to have a significant impact on population dynamics in the future when PCB levels are expected to decline.

6.3 Birds and Mammals

As noted by GE in comments on the BERA, data demonstrating the health of bird and mammal populations throughout the Hudson Valley are available from a variety of sources. For example, data show that mallards are "demonstrably secure" throughout the New York Bight watershed and are "widespread, abundant and secure in the state of New York" (USFWS, 1997). NYSDEC (1997) reports that, on the basis of breeding surveys, the mallard population using the Hudson River estuary is "stable to increasing." Mid-winter counts of waterfowl show generally increasing numbers of mallards and other species with a peak in 1995 of more than 16,000 birds (NYSDEC, 1997). North American Breeding Bird Survey data (analyzed in Sauer et al., 1997) indicate that populations of mallard ducks have significantly increased at a rate of 5.7 percent per year within the region that includes the Hudson River (i.e., the Ridge and Valley Province) since 1966.

The Future Risk ERA itself acknowledges that Audubon Society Christmas bird counts and other sources of local information on the bird species present in the Lower Hudson Valley show that:

(1) Tree swallows are present throughout the Lower Hudson Valley.
(2) Waterfowl are extremely abundant.
(3) Belted kingfishers and great blue herons are breeding throughout the Lower Hudson.
(4) Bald eagles are returning.

EPA's statement that the eagles have not successfully reproduced is incorrect. In fact, the Hudson River bald eagle population has become reestablished in recent years. The first bald eagle nesting attempt on the Hudson River in over 100 years occurred in 1992 along the Lower Hudson River, but no fledglings were successfully produced at this nest until 1997 (Nye 1999, pers. comm.). Since then, three bald eagle territories have been active on the Lower Hudson River. Four eaglets were fledged from these territories in 1998, including three from a single nest in Columbia County. Four eaglets were also fledged in 1999, including three from a single nest in Green County.

The Future Risk ERA also acknowledges that raccoons are abundant throughout the Lower Hudson Valley, and that mink and river otter are present. EPA discounts the significance of the occurrence of raccoon populations on the grounds that raccoons likely obtain food from sources other than the Hudson River. In the 1960s, the Hudson River Valley Commission (HRVC, 1966) reported that the raccoon, cottontail rabbit, gray squirrel, muskrat, skunk, and beaver were plentiful along the Hudson River. Numerous localized studies of biota in wetland and riparian areas along the Lower Hudson River reported the presence of mammalian species that are common throughout the eastern U.S., including raccoon, muskrat, beaver, and white-tailed deer (Kiviat, 1986, 1997; Kiviat and Tashiro, 1987; Kiviat and Stapleton, 1987).

7.0 EPA's approach to effects assessment for fish and wildlife is excessively conservative, relies on a small subset of the available data, and ignores or improperly interprets key studies.

All of GE's comments on the TRVs used in the BERA apply equally to the Future Risk ERA, because in almost all cases the same TRVs are used in both documents. The only exception is the study of Bengsston (1980), for which EPA apparently *lowered* the NOAEL and LOAEL in response to comments from NOAA on the BERA. In addition to its previous comments, GE believes it is important to emphasize that the effects assessment component of the Future Risk ERA is based on a mere handful of studies that are treated in an excessively conservative manner. Therefore, not only does EPA make inappropriate use of an overly conservative screening-level approach, its approach is further compromised by a biased treatment of the available literature-derived toxicological data.

7.1 Benthic Community Structure

EPA states that the assessment endpoint to be used for evaluation of risks to the benthic community is benthic community structure,[2] but the measurement endpoints selected were (1) comparison of modeled water column chemical concentrations to water quality criteria and (2) comparison of modeled sediment chemical concentrations to guideline values. Neither of these endpoints that were actually used is directly representative of benthic community structure. These methods are suitable only for screening assessments. The Future Risk ERA should rely on direct measurement of the abundance, diversity, and other characteristics of invertebrate communities. Data on benthic community structure are available from EPA (1993) (reported as part of the BERA), Exponent (1998a,b), and NYSDEC (1993).

[2] The text of the Future Risk ERA uses the ambiguous phrase "benthic community structure as a food source"—whether this is intended to mean community structure or biomass is unclear, but in either case, the measurement endpoints used are inappropriate.

Water and sediment quality criteria (or guideline values) are inappropriate measurement endpoints for assessment of benthic community structure. Criteria values are derived from toxicity tests on individuals, and do not represent community-level effects.

7.2 Fish

The following studies provided *all* of the TRVs for the eight fish species evaluated:

- Bengtsson (1980), effects of exposure to Clophen A50 on the minnow *Phoxinus phoxinus.*
- Walker et al. (1994), effects of dioxin on lake trout eggs and fry.
- Adams et al. (1989, 1990, 1992) study of redbreast sunfish (*Lepomis auritus*) exposed to multiple chemicals in the field.
- Olivieri and Cooper (1997), study of effects of dioxin on the fathead minnow (*Pimephales promelas*).
- Elonen et al. (1998), study of the effects of dioxin on channel catfish (*Ictalurus punctatus*).
- Westin et al. (1993), study of effects of PCBs on larval striped bass (*Morone saxatilis*).

The study by Bengtsson (1980) was the source of laboratory-derived TRVs for 7 of the 8 fish species. The TRVs for 6 of these species were derived by applying 10x uncertainty factors to the NOAEL and LOAEL calculated in the paper. The study by Walker et al. (1994) was the source of TEQ-based TRVs for 6 of the 8 species. No uncertainty factors were applied to results from this study; however, because salmonids appear to be uniquely sensitive to dioxin compared to other tested taxonomic groups, the relevance of the study to Hudson River fish species is questionable. The NOAELs derived from the two field studies used by EPA (Adams et al., Westin et al.) are *unbounded* NOAELs, meaning that no effects on survival, growth, or reproduction attributable to PCBs were actually observed.

The review performed by Monosson (NOAA, 1999) for NOAA, which evaluated all available literature on the toxicity of Aroclor 1254 to fish, concluded that adverse effects could be expected at exposure concentrations of approximately 25 ppm in the livers of adult fish (equivalent to approximately 12.5 ppm in fillets of Hudson River fish) or approximately 5 ppm (whole body) in larvae. The NOAA value for adult fish is nearly an order of magnitude higher than the LOAEL TRVs EPA used for pumpkinseed, brown bullhead, yellow perch, white perch, largemouth bass, striped bass, and shortnose sturgeon. As noted in Section 2 of these comments, EPA ignored the report's conclusion that the TEQ approach should not be applied to Hudson River fish species.

As noted in GE's comments on the BERA, the values developed in the Monosson report are still conservative: a review by Niimi (1996) concluded that even higher exposures may be required before actual reductions in survival or reproduction are observed in typical fish species. Thus, EPA's approach to evaluating the toxicity of PCBs to fish is highly selective and superficial and the effects predicted by EPA's TQs have not been observed in the exposed populations themselves.

7.3 Birds

For birds, the following laboratory studies on gallinaceous birds (*e.g.*, chickens and pheasants) provided a large fraction of the TRVs used by EPA:

- Scott (1977), effects of PCBs on the chicken.
- Nosek et al. (1992), effects of dioxin on the pheasant.
- Powell et al. (1996), effects of PCB congeners on the chicken.

EPA acknowledges that gallinaceous birds, such as chickens and pheasants, are extremely sensitive to PCBs. The use of TRVs derived from these studies is therefore expected to significantly overstate the actual risks of PCBs to wild birds. Alternative data sources more relevant to avian receptors at the Hudson River which avoid this overprediction are discussed in the following sections.

As GE explained in its comments on the BERA, EPA's use of the lowest available NOAEL when multiple studies were available is inappropriate. Because a NOAEL can be considerably lower than an effects threshold, selection of the *highest* NOAEL for the species of interest or a surrogate will minimize the gap between the NOAEL and the actual threshold for observable effects.

The derivation of TRVs in the Future Risk ERA also follows an outdated "margin-of-safety" method in applying uncertainty factors which introduces unnecessary conservatism into the risk assessment. Rather than using default uncertainty factors of 10, human health risk assessors (Dourson et al., 1996) use a method that considers values from 1 to 10 where appropriate, depending on the availability of data for the chemical in question. Ecological risk assessors seem to be following suit, particularly with regard to interspecies extrapolations (e.g., EPA Region 10, 1997 [EPA, 1997b]; Hoff and Henningsen, 1998). EPA's ERA guidelines (EPA, 1998) note that "uncertainty factors can be misused, especially when used in an overly conservative fashion, as when chains of factors are multiplied together without sufficient justification."

In several instances, EPA considers a 10-week exposure period to be subchronic, and a subchronic-to-chronic uncertainty factor of 10 is applied to the NOAEL. This is the case for the tree swallow, mallard, great blue heron, bald eagle, and belted kingfisher's dietary TEQ-based TRV. However, according to Sample et al. (1996), 10 weeks is considered the transition point from a subchronic to a chronic exposure duration for avian species, rendering such a large uncertainty factor unnecessary.

7.3.1 Tree Swallow

The field studies conducted by the U.S. Fish and Wildlife Service which addressed effects of PCBs at concentrations higher than likely to be found in the Lower Hudson make it irrelevant to predict PCB-related effects on the basis of extrapolations of data from laboratory studies. Ample field data have been collected from areas adjacent to the

Hudson River (Secord and McCarty, 1997; McCarty and Secord, 1999 a,b). These data indicate that the reproductive success of tree swallows is not being affected by PCBs in the Hudson River. EPA's statements regarding these studies are misleading. McCarty and Secord have been unable to illustrate a dose-response relationship between tree swallow reproduction and PCB contamination. The differences in reproductive parameters between the Ithaca and Hudson River tree swallow populations fall within the natural variation observed elsewhere in tree swallow populations. Likewise, the behavioral data referred to by EPA do not correlate with reproductive parameters.

7.3.2 Mallard

Out of the three studies that have examined PCB toxicity in mallards, EPA selected the study with the *lowest* NOAEL for TRV development. As shown above, this approach is erroneous. The NOAEL found by Risebrough and Anderson (1975), based on a dietary Aroclor 1254 dose of 40 ppm, is recommended as the TRV. Risebrough and Anderson (1975) did not measure PCB concentrations in eggs associated with this level of exposure. However, Heath et al. (1972) established a NOAEL for Aroclor 1254 at a slightly lower dose (25 ppm), and measured a corresponding egg concentration of 45 ppm. Additionally, because these two studies used exposure durations of 150 and 511 days (Risebrough and Anderson, 1975; Heath et al., 1972, respectively), should not apply a subchronic-to-chronic uncertainty factor as it did for the Custer and Heinz (1980) study.

7.3.3 Great Blue Heron

The studies selected by EPA for TRV development for the great blue heron were less appropriate than other available studies and were incorrectly interpreted. Speich et al. (1992) examined potential effects of environmental concentrations of PCBs, from both pristine and industrialized areas, on great blue heron reproduction in western Washington State. The authors noted that they were unable to detect any PCB-related effects on egg mortality that would have been predicted on the basis of chicken studies. Therefore, the egg concentration of 16 ppm (wet weight), representing the highest reported mean egg concentration in a reproductively healthy colony, could be considered an unbounded NOAEL. This concentration is 48-fold higher than the TRV (0.33 mg/kg egg) derived by EPA on the basis of effects in chickens.

Field data in Sanderson et al. (1994) are used to derive a TEQ-based TRV in great blue heron eggs. However, the authors reported an improvement in the reproductive success of the colony with the highest measured TEQ concentrations. Though EPA used an egg concentration of 0.5 ug TEQ/kg egg as a LOAEL based on a reduction in body weight, Sanderson et al. (1994) did not find reduced body weights in the birds.

7.3.4 Belted Kingfisher

Species-specific studies are not available for the kingfisher; however, the studies selected by EPA for TRV development were less appropriate than other available studies for species similar to the kingfisher. As indicated above, there are available studies for species with similar feeding habits to those of the kingfisher (e.g., great blue heron) which would provide more representative TRVs than those derived using gallinaceous bird studies.

7.3.5 Bald Eagle

The TRV for total PCB concentrations in bald eagle eggs - 3.0 mg/kg - is based on a field study of population productivity and egg contaminant concentrations for a large number of sites (Wiemeyer et al., 1993). This value is inappropriate for two reasons:

(1) Wiemeyer et al. (1993) report that productivity was not statistically different in eggs in three concentration ranges: <3.0, 3.0 - <5.6, 5.6-<13 (Wiemeyer et al., 1993 Table 10). Productivity was significantly reduced for PCB concentrations >13 mg/kg. Thus, based upon these data, a NOAEL of 13 mg/kg is more appropriate.

(2) Wiemeyer et al. (1993) could not demonstrate impacts of PCBs on productivity because of the strong correlation between PCB and DDE levels. Thus, a LOAEL cannot be determined, and the degree of conservatism in the NOAEL of 13 mg/kg is unknown.

DDE concentrations in fish collected recently near Catskill, New York average approximately 0.27 ppm whole body (NYSDEC database: HUDORG.dbf). Using an egg/fish DDE ratio of 22 (Giesy et al., 1995), an egg level of approximately 6 mg/kg is estimated. This is greater than the NOAEL of 3.6 mg/kg estimated by Wiemeyer et al. (1993) for DDE in bald eagles. This suggests that DDE may be having an impact on bald eagle productivity in the Lower Hudson River.

EPA also ignored or discounted two other field studies on potential effects of PCBs on bald eagles. Elliot et al. (1996) evaluated hatching success and morphological, physiological, and histological parameters in bald eagle eggs collected near pulp mills in British Columbia. Laboratory hatching success did not differ between eggs from pulp mill sites and from reference locations, though Elliot et al. (1996) did find positive associations between PCB exposure and biochemical and morphological responses. The unbounded NOAEL for hatching success based on this data is >400 pg/g TEQ (wet weight) in eggs. Additionally, Donaldson et al. (1999) studied reproductive success of breeding bald eagles along Lake Erie in Canada from 1980 to 1996. The author concluded that the reproductive success of the colony was not impaired, and found an unbounded NOAEL of >26.4 mg/kg total PCBs (wet weight) in eggs based on nest reproductive success. Both of these NOAELs are significantly higher than those selected by EPA.

7.4 Mammals

As noted in GE's comments on the BERA, the TRVs for little brown bat and raccoon are based on laboratory studies of rats (Murray et al. 1979; Linder et al. 1974). The study by Murray et al. (1979) was also used to derive TEQ-based dietary TRVs for mink and river otter. EPA calculated TRVs by applying 10x uncertainty factor to the LOAELs and NOAELs from these studies.

The very limited available data concerning effects of PCBs on mammalian species other than rodents and mink indicate that EPA should be very cautious about basing remedial decisions on TQs calculated for these species. Data sources and approaches that EPA could use to more appropriately assess potential effects of PCBs on mink and river otter are described below.

7.4.1 Mink

EPA used a field study by Tillett et al. (1996) to derive both a NOAEL and a LOAEL for TEQs in the diet of mink at Lake Michigan. However, the method used to administer PCBs to the test animals did not exclude other environmental toxicants known to be present in Great Lakes fish (Giesy, et al. 1994), the study is inappropriate for use in deriving a LOAEL. On page 34 of the Future Risk ERA, EPA states that "because of the potential contribution of other contaminants (e.g., metals, pesticides, etc.) to observed effects in field studies, [this] ERA and ERA Addendum use field studies to establish NOAEL TRVs, but not LOAEL TRVs." According to EPA's own selection criteria, this study should not have been used to derive a LOAEL TRV.

Mink laboratory studies that investigate the reproductive effects of Aroclor 1254 resulting from chronic dietary exposure are typically considered relevant and scientifically sound for the development of protective mink NOAEL and LOAEL values for PCBs. EPA's choice of the study by Aulerich and Ringer (1977) is consistent with Sample et al. (1996); however, it should be used similarly to derive a TRV. While EPA applies a subchronic-to-chronic uncertainty factor of 10 to the NOAEL and LOAEL, Sample et al. (1996) states that because the treatment period extended before and throughout the reproductive stage, the study should be considered chronic in duration. As a result, the NOAEL and LOAEL should not be conservatively adjusted to account for the exposure duration.

An alternative approach to TRV development based on dietary levels of PCBs is the determination of critical body residues of PCBs developed from dose-response relationships. A study by Leonards et al. (1995) evaluated dose-response relationships for PCB body burdens and mink reproductive parameters from nine feeding studies. Leonards et al. (1995) proposed critical body residues of 1.2 ug/g total PCBs (wet weight) and 160 pg/g TEQ (wet weight) based on effects on mink litter size. Because PCB whole-body concentrations in mink were more closely correlated with reproductive effects than PCB concentrations in food, these critical whole-body residue levels should serve as PCB TRVs. EPA should use the results of ongoing residue studies for furbearers by NYSDEC in conjunction with these TRVs.

7.4.2 River Otter

EPA selected TRVs for the river otter using NOAEL and LOAEL TRVs for mink, based on the assumption that because the two species are in the same phylogenetic family, they must be similarly sensitive to PCBs. Recent data examining reproductive health in mustelids found that river otters were not as susceptible to PCB-induced effects as mink (Harding et al., 1999). The Agency should take account of this information.

7.5 General Limitations of TRVs and the TQ Approach

As previously indicated, the TQ approach, which incorporates the TRVs, is a highly conservative screening-level approach that is inappropriate for use in an ecological risk assessment of the scale of the Hudson River assessments. Since this approach focuses on potential risks to individuals, it is not sufficient to demonstrate a significant risk at the population, community, or ecosystem level. EPA's selective treatment of the available scientific literature and overly conservative application of uncertainty factors in deriving TRVs further negates any use this approach has on decisions regarding remedial actions.

8.0 Conclusions

In its *Baseline Ecological Risk Assessment for Future Risks in the Lower Hudson River,* EPA relied exclusively on models and ignored site-specific data demonstrating that PCBs have not adversely affected ecological resources of the Lower Hudson River in the past, and will not do so in the future. The models used by EPA to predict future concentrations of PCBs in water, sediment, and fish tissue contain many deficiencies and have been inadequately reviewed to date. The Toxicity Reference Values used by EPA to estimate risks to fish and wildlife are conservative, screening-level values selectively derived from the scientific literature. EPA's conclusions, which are that important fish and wildlife species in the lower Hudson are presently at risk and will in the future continue to be at risk, are unambiguously contradicted by a wealth of data on the past and present status of those species. Data that were available to EPA show that:

- The reproductive success of the Hudson River striped bass population, as measured by the number of juvenile fish produced each year, was as high in the 1970s, when PCB concentrations in adult female striped bass were at their highest measured levels, as in recent years, when concentrations are much lower. The abundance of adult striped bass has increased dramatically over that same period, as has the abundance of shortnose sturgeon.

- The Lower Hudson River Valley supports healthy, reproducing populations of the wildlife populations addressed by EPA. These include piscivorous birds such as the kingfisher, for which EPA predicted that reproductive effects would occur as a result of PCB exposures.

- Bald eagles are now successfully reproducing in the Lower Hudson River Valley, for the first time in 100 years.

EPA's failure to properly consider these facts in the Future Risk ERA is inconsistent with best scientific practice in ecological risk assessment and with the agency's own guidelines.

This assessment *does not* provide a sound and reliable description of the effects of current and risks of future PCB exposures on biota in the Hudson River Valley. It does not provide a scientifically valid foundation for either estimating the responses of the biota of the Lower Hudson River to alternative remedies that would reduce inputs of PCBs from the upper Hudson or for comparing the ecological benefits gained through remedial actions to the ecological costs of implementing remedial actions.

The report should not be used by EPA in making decisions regarding remedial actions in the upper Hudson River.

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Table 1. Comparison of Lower Hudson River Future Risk ERA and Clinch River ERA

Hudson River ERA	Clinch River ERA
Problem Formulation	
Assessment endpoints: Maintenance of benthic community structure; protection and maintenance of local fish, insectivorous birds, waterfowl, piscivorous birds, and wildlife; protection of threatened and endangered species; protection of significant habitats Measurement endpoints: Water and sediment-quality criteria, Chronic TRVs (reproduction endpoint) for fish, birds, and mammals	Assessment endpoints: Reductions in benthic community richness or abundance; reductions in fish species richness or abundance; increased frequency of gross pathologies in fish communities; reduced abundance or production of piscivorous and insectivorous wildlife **Measurement endpoints:** Near-field and far-field biological survey data (fish and benthic invertebrates), whole-sediment toxicity tests; whole-water toxicity tests, fish histopathology, water and sediment-quality criteria; chronic TRVs for fish, birds, and mammals, blue heron reproductive success, mink dietary toxicity studies
Exposure Assessment	
Modeled concentrations of PCBs (tri+) and TEQs in fish Modeled oral doses (tr+ and TEQs) to avian and mammalian receptors using conservative exposure assumptions; modeled egg concentrations in birds	Measured concentrations of Aroclors in fish (whole body), water, and sediment Measured concentrations of Aroclors in great blue heron eggs and chicks Modeled oral doses to avian and mammalian receptors (by sub-area), using (1) conservative exposure assumptions, and (2) Monte Carlo analysis of all exposure parameters

Effects Assessment	
Hudson River ERA	**Clinch River ERA**
TRVs for PCB and TEQ concentrations in fish tissue Field-derived (tree swallow and bald eagle) or literature-derived (other species) TRVs for fish, birds, mammals	TRV for PCB concentrations in fish tissue (whole body, adult) Literature-derived TRVs for birds and mammals Site-specific assessment of fish histopathology and reproductive condition Whole-sediment toxicity tests Whole-water toxicity tests Analysis of fish and benthic community composition at local and regional scales Site-specific mink dietary toxicity study Site-specific study of great blue heron reproductive success

Risk Characterization	
Hudson River ERA	**Clinch River ERA**
All assessment endpoints: Comparison of water and sediment concentrations to water and sediment-quality criteria **Fish**: Comparison of tri+ and TEQ concentrations in fish tissue to literature-derived TRVs Overview of population trends for selected species **Birds**: Comparison of modeled oral doses and egg concentrations (tri+ and TEQs) to field-derived (tree swallow and bald eagle) or literature-derived (other species) TRVs . Qualitative overview of occurrence data for various species **Mammals**: Comparison of modeled doses (tri+ and TEQs) to literature-derived TRVs	**Benthic Invertebrates**: Comparison of maximum sediment concentration to sediment-quality criteria; comparison of empirical distribution functions for sediment toxicity to cumulative distribution of measured sediment concentrations Whole-sediment toxicity tests **Fish:** Comparison of observed concentration in fish tissue to TRVs Whole-water toxicity test results Comparison of frequencies of histopathological and reproductive condition indicators in study area to observed values in unexposed upstream reservoir Canonical discriminant analysis of fish community composition (reservoir scale); analysis of species richness (reservoir scale and local scale) **Birds:** Comparisons of modeled dose distributions (cumulative frequencies from Monte Carlo analysis) to TRVs Comparison of blue heron reproductive success in on-site and off-site rookeries; comparison of osprey reductive success in nests adjacent to site to observed range of North American values **Mammals:** Comparisons of modeled dose distributions (cumulative frequencies from Monte Carlo analysis) to TRVs Comparison of toxicity observed in mink dietary study to toxicity predicted from exposure model and literature-derived TRVs

Table 2. Computation of PCB Levels in Fish - Future Risk ERA

Species	Location (River Mile)	Method of estimation	Sediment exposure	Water column exposure
Largemouth bass, White perch, brown bullhead, pumpkinseed, yellow perch, spottail shiner	60-152	FISHRAND	✓	✓
White perch	113,152 Region 1 (60-152)	FISHRAND FARLEY	?	? ✓
White perch	Region 2 (12-60)	FARLEY		✓
Striped bass	113	FARLEY		✓
Striped bass	152	Largemouth bass from FISHRAND multiplied by a data-based STB/LMB ratio	✓	✓