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September 7, 1999

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

RE: 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 – Baseline Ecological Risk Assessment Hudson River PCBs Reassessment RI/FS" (BERA).

Given the scale of the Upper Hudson River site, EPA should strive to bring the best science to bear to understand the risks to ecological receptors. This, however, is not reflected in the recently released report. The 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; misrepresents important conclusions for two field studies; 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;

John G. Haggard /TGE

John G. Haggard

Encl:

10.2806

cc: Richard Caspe, U.S. EPA
William McCabe, U.S. EPA
Douglas Fischer, U.S. EPA (ORC)
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Comments of General Electric Company on Volume 2E – Baseline Ecological Risk Assessment Hudson River PCBs Reassessment RI/FS

September 7, 1999

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1.0 Introduction And Executive Summary

General Electric Company (GE) submits these comments on the Phase 2 Report – Review Copy, Further Site Characterization and Analysis, Volume 2E – Baseline Ecological Risk Assessment Hudson River PCBs Reassessment RI/FS (BERA) which was released by the U.S. Environmental Protection Agency (EPA) on August 4, 1999.

GE's comments are premised on the understanding that the objective of the BERA is to support remedial decisionmaking for the Upper Hudson River.[1] To achieve this objective, the assessment must provide:

- a sound and reliable description of the effects of current PCB exposures on biota in the Hudson River Valley;
- a foundation for projecting the responses of those biota to alternative remedies; and
- a sound technical underpinning for comparing the ecological benefits gained through remediation to the ecological costs of implementing remedial actions.

The scale of the sociological, ecological and economic impacts of a remedy for a large, complex ecosystem such as the Hudson River dictate that the best science be employed to reduce uncertainty in decision making. The assessment should reflect best scientific practice in ecological risk assessment as described in EPA's Guidelines for Ecological Risk Assessment (EPA 1998a) and exemplified in ecological risk assessments that have been published in the peer-reviewed scientific literature. EPA's assessment does not reflect best scientific practice. It is excessively conservative because it relies on screening level benchmarks. It is deficient both because of EPA's failure to collect relevant data over the last ten years and because of its failure

[1] The Upper Hudson River is the 40 mile stretch between Hudson Falls and the Federal Dam at Troy. For reasons explained previously to the Agency, GE maintains its position that the Hudson River PCBs Superfund Site encompasses only these 40 miles and does not extend to the Lower Hudson River.

to examine and utilize existing site-specific data. It is grossly insufficient for use in determining the need for a remedy or selecting a remedy.

<u>**The Approach Used by EPA is Inconsistent with Best Scientific Practice**</u>.

Best scientific practice in ecological risk assessment differs in two fundamental respects from best practice in human health risk assessment. First, although there are limited circumstances, such as protection of endangered species, in which adverse effects on individual organisms are sufficient to warrant management action, effects on populations and communities are the prime ecological focus and should be the basis for analysis (EPA 1998b). Second, whereas most human health risk assessments must be based on predictions from models, ecological risk assessments can be based on observed exposures and effects measured in well-designed, site-specific studies. EPA's work fails to meet either of these basic benchmarks. The hallmark of this assessment is its repeated use of literature-based screening values to project effects on individual organisms.

<u>**EPA's Assessment Focuses on Individuals, Not Populations or Communities**</u>.

With the exception of the analysis of benthic invertebrates, EPA's assessment endpoints address risks to individual organisms, not populations. No data or methods are presented that either evaluate effects on populations or communities directly or provide a basis to extrapolate from individual level effects to population effects.

<u>**EPA Failed to Collect Ecological Information on the Hudson and Its Assessment Ignores or Dismisses Substantial and Valuable Site-Specific Data**</u>.

Despite spending ten years on this Reassessment, EPA has failed to examine the wild populations of the River and its Valley with the exception of benthic invertebrates. This is - indefensible. Moreover, EPA's assessment repeatedly ignores or dismisses the substantial and valuable data that have been collected about the biota of the Hudson over the last thirty years and which provide both probative evidence as to the health of the wildlife populations and a mechanism to test the results derived from generic or hypothetical analyses. To give two examples, the New York State Department of Environmental Conservation (NYSDEC) has examined macroinvertebrate populations in the Hudson and could not identify any adverse effects from the exposure to PCBs. Extensive data on the fish populations of the Lower Hudson are available but were not analyzed.

EPA Misstates the Results of the Site-Specific Studies.

EPA relies on two Hudson-specific studies: EPA's own study of benthic invertebrates and the Fish and Wildlife Service examination of tree swallows. EPA's Risk Characterization, in the body of its report, correctly concluded that the benthic invertebrate community analyses could not distinguish any clear effects from PCBs. The BERA's conclusions misstated the result of this study by claiming that the analysis showed a reduced macroinvertebrate community with potential risk due to the site. The tree swallow study was unable to show a dose-response relationship between tree swallow reproduction and PCB exposures. The behavioral responses that were identified are not correlated with reproductive success. The Assessment inaccurately claims that the study showed decreased reproductive success related to PCB exposures.

Available Population and Community Data Conflict with EPA's Conclusions.

In addition to the two site-specific studies that were misstated by EPA, other available data on the status of Hudson River biological resources conflict with EPA's conclusions. The New York State Department of Environmental Conservation (NYSDEC) has examined macroinvertebrate populations in the Hudson and could not identify any adverse effects from exposure to PCBs. National Marine Fisheries Service (NMFS) and the Fish and Wildlife Service analyzed the effects of PCBs on the striped bass population under the Atlantic Striped Bass Conservation Act and concluded that PCBs were not the cause of declines in the Hudson or coastal striped bass populations. Data available to EPA demonstrate that populations of striped bass, shortnose sturgeon, and other Hudson River fish species have increased in recent years. NYSDEC has examined the growing number of eagles in the Hudson Valley and throughout the state. Breeding Bird Survey data document healthy populations of many other bird species in the

Hudson Valley. These data and other similar data reflect the actual health of the wild animal populations of the Hudson. These are the facts that count.

<u>EPA's Assessment Fails to Use the Weight-of-Evidence Approach In a Sound and Meaningful Manner.</u>

Because any single study can produce ambiguous results, multiple lines of evidence should be developed using different types of data. Each line of evidence should be evaluated, and all the lines together should be used to draw conclusions concerning the existence, causes, and magnitudes of risks. Evaluation criteria are discussed in the Guidelines for Ecological Risk Assessment (EPA 1998a), and in the refereed scientific literature (Suter and Loar 1992, Suter 1993, Menzie et al. 1996, Suter et al. 1999) This is not a simple process of counting up a number of studies and keeping score of the findings. The results of 10 bad studies cannot be compared on an equal footing with the results of one high quality, relevant study. The quality and relevance of each study must be closely evaluated.

While the BERA claims to have developed and analyzed several lines of evidence for a wide variety of species, in fact, the BERA reflects a basic misunderstanding of how to perform a weight-of-evidence assessment. Most of the assessment endpoints are addressed using only one line of evidence: comparison of measured or modeled exposure concentrations to generic, non-specific toxicity benchmarks, particularly Toxicity Reference Values (TRVs) and Sediment Effect Concentrations (SECs). EPA failed to collect the information required to implement the weight-of-evidence approach properly. EPA began its reassessment almost ten years ago; its failure to collect site-specific data and to examine existing data closely is indefensible. Beginning a "field survey" two months before releasing the BERA by making phone calls to collect anecdotal information is no substitute for the comprehensive data collection demanded by a site of this size and complexity. EPA's cavalier attitude toward factual evidence cannot be reconciled with a true weight-of-the-evidence analysis.

EPA's Assessment is Excessively Conservative.

The approaches used for exposure assessment and effects assessment result in overestimates of actual exposures and risk. In the exposure assessment, unnecessarily conservative assumptions are made concerning (1) treatment of samples in which a target chemical was not detected yet was still assumed to be present, (2) diet composition and food consumption rates, and (3) habitat utilization. The effects assessment relies on screening-level criteria and Toxicity Reference Values (TRVs). These values are intended to identify the lowest doses that could potentially affect organisms, not the values at which a population will exhibit adverse effects at relevant ecological endpoints. The Toxicity Quotients (TQs) developed from these exposure and effects estimates greatly inflate the ecological risks of PCBs present at the Hudson River site.

Since the ultimate question for the risk manager is what effect an array of possible remedial actions will have on wildlife populations, the assessment should reflect prudent realism rather than conservatism. Use of excessively conservative assessment calculations will lead to a misrepresentation of site conditions and result in the prediction of excessively beneficial results from various remedial actions, which will not be borne out in fact. EPA policy on this point was articulated by Administrator Browner in her cover letter on EPA's Guidance for Risk Characterization: "while I believe that the American public expects us to err on the side of protection in the face of scientific uncertainty, I do not want our assessments to be unrealistically conservative. We cannot lead the fight for environmental protection into the next century unless we use common sense in all we do." EPA's Assessments does not follow this basic Agency policy.

The SECs are not Reasonable Estimates of Effects of PCBs on Benthic Invertebrates.

For benthic invertebrates, EPA relies on SECs which operate as TRVs. These also are screening-level criteria that do not reflect effects on benthic invertebrates demonstrably caused by PCBs. The SECs incorporate the assumption that the supposed effects on benthic invertebrates will be reflected in adverse effects on fish populations, threatened and endangered species, and the ability of particular habitats to support sustainable, healthy animal populations.

There is no demonstration that an exceedance of SEC values for PCBs has any identifiable adverse effect on other biotic populations.

EPA's Assessment Should Not Rely on the TEQ Approach Because It Is Not Sufficiently Developed and Has Been Applied Improperly in the BERA.

The Toxicity Equivalence (TEQ) approach, used by EPA as one method for assessing the risks of PCBs to exposed fish and wildlife, converts concentrations of "dioxin-like" organic chemicals to equivalent concentrations of dioxin. The Toxicity Equivalency Factors (TEFs) used by EPA are, according to their developers, order-of-magnitude approximations (Van den Berg et al. 1998). The analytical methods used by EPA to measure concentrations of individual congeners are not sensitive enough to distinguish biologically significant and insignificant concentrations in fish tissue. EPA's treatment of data below the minimum quantification level for these congeners produces highly inflated estimates of both exposures and effects. Moreover, according to an expert review performed for NOAA, information on the relative sensitivities of different fish species to dioxin-like compounds is insufficient to support application of the TEQ approach to Hudson River fish species. This technique is not developed to the point where it is an effective tool for realistic risk assessment.

EPA's Use of the Upper Hudson Food-Chain Bioaccumulation Model is Premature.

GE has previously noted significant deficiencies in the Upper Hudson River model used by EPA to quantify the bioaccumulation of PCBs in fish tissue. These deficiencies have not yet been addressed by EPA, and the model still predicts higher tissue concentrations than are actually observed. The Agency has properly elected not to use the Thomann-Farley model for a risk assessment of the Lower Hudson until it has been fully vetted and reviewed. The same logic applies to EPA's Upper Hudson River model: it should not be used for risk assessment until it is validated against field data, the public comments have been addressed, and it has undergone a rigorous peer review.

* * *

Each of these major limitations and deficiencies is described more fully in the text which follows. Another way to summarize the deficiencies in the BERA is to compare it against the standards for admissibility of expert scientific evidence established by the Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). When such a comparison is made, it is clear that the BERA falls far short of these standards for sound science and would not be admitted for consideration by a jury deciding a scientific question to which it was allegedly relevant. By the same token, it should not be used for decision-making in this Reassessment.

2.0 The Ecological Risk Assessment Does Not Conform To Best Scientific Practice

EPA's ecological risk assessment is based principally on "Toxicity Quotients" (TQs), i.e., comparisons between measured or modeled exposure concentrations and concentrations believed to be potentially harmful to organisms. Conservative, "screening-level" data and assumptions are used to define both the exposures and the effects. Screening-level data and models, such as those used by EPA, are deliberately designed to be conservative, i.e., to minimize the possibility that any potential adverse effects will be missed. They 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 screening-level data "would not be technically defensible." A scientifically defensible ecological risk assessment should be based on the methods described below, not on TQs.

A wide variety of techniques for measuring and characterizing ecological risks at contaminated sites are described in EPA's Guidelines for Ecological Risk Assessment (EPA 1998) and Ecological Risk Assessment Guidance for Superfund (EPA 1997). These include:

- 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.

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.

These methods are described in available EPA guidance documents and in the refereed scientific literature. Experience and practice at the other comparable sites demonstrates the inadequacy of EPA's BERA for the Hudson River.

The assessment performed for the Clinch River Study Area in Tennessee is a particularly appropriate example of an approach consistent with best scientific practice because: 1) it involved a study area similar in scale to the Hudson River, and 2) sediment-derived PCBs were a major concern. The Clinch River ecological risk assessment was documented recently in a series of peer-reviewed articles in *Environmental Toxicology and Chemistry* (Volume 18, no.4, 1999, pp.579–654). Table 1 compares the assessment endpoints, data types, and assessment methodologies used in these two assessments.

Both assessments address risks of sediment-derived PCBs to benthic macroinvertebrates, fish, birds, and mammals. However, far more information was used in the Clinch River assessment. Whereas the Hudson River BERA primarily relies on TQs, the Clinch River assessment employed a wide variety of site-specific data. In addition to TQs, 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. The draft assessment for the Clinch River was completed in 1995 and the final assessment was issued in 1996. EPA had ample time to perform similar studies for the Hudson River. The Hudson River BERA repeatedly cites lack of data on population trends or parameters but never offers an explanation for why such data were not collected. EPA's attempt to patch this glaring omission by making phone calls to collect anecdotal information beginning two months before releasing the BERA (Tables 5-67 and 5-85) falls far short of the mark.

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The Assessment Endpoints for Fish and Wildlife Receptors Pertain to Effects on Individuals, not Populations

EPA's assessment endpoints for fish and wildlife refer to protection and maintenance of "survival, growth, and reproduction" of individual organisms rather than to the sustainability of populations.

The *Guidelines for Ecological Risk Assessment* (EPA 1998A) permit assessment endpoints to be defined at any level of biological organization including the individual organism. This latitude is necessary because the guidelines are intended to be applicable to all of EPA's regulatory activities. Many of these activities (e.g., development of water-quality criteria and registration of new chemicals) do not employ site-specific data and cannot directly address effects of chemicals on populations and communities. In making decisions concerning remedial action needs for the Hudson River, however, decisionmakers must determine (1) whether the sustainability of exposed biological populations and communities is being threatened by the presence of PCBs in Hudson River sediment, and (2) whether the positive effects of a particular remedy will be greater than any negative ecological effects of carrying out the remedy.

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 impacts to some individual organisms. Even if there were statistically significant reductions in survival, growth and reproduction of individuals, such data alone cannot be used directly as surrogates for evaluating adverse effects to populations, communities, or ecosystems. Survival, growth, and reproduction rates are interrelated in complex ways, and the contribution of each factor to eventual population indices depends on the life history of the organism and compensatory mechanisms at the population and community levels. EPA's draft Risk Management Guidance clearly states that populations are the appropriate level of ecological organization for assessment. (EPA 1998b)

Large numbers of the fish and wildlife species are routinely harvested for recreation or human consumption without threat to stock abundance. EPA's focus on the individual organism is inappropriate since it does not rest on a showing that effects on individuals will be reflected in effects on the relevant populations. Consequently, it cannot support a reasoned remedial action decision for the Hudson River.

An appropriate example of an assessment endpoint for fish or wildlife is provided in the *Ecological Risk Assessment Guidance for Superfund* (1997, Highlight I-2, p. I-6; emphasis added): "[s]ufficient rates of survival, growth, and reproduction *to sustain populations of carnivores typical for the area.*"

The Assessment Endpoint for Habitat As Presently Stated is Meaningless

EPA lists "Protection of significant habitats" as an assessment endpoint. No definition of "habitat" is provided, and generic water and sediment quality criteria are the only measures employed by EPA to evaluate effects on habitat. Because some of the remedial actions (i.e., dredging of sediment) being considered by EPA would destroy the contaminated habitat, it is important to define and examine this endpoint realistically so that the adverse ecological effect of such remedies can be weighed and taken into account in considering remedial alternatives.

It is also important to note that no one has alleged that levels of PCBs found in these "significant habitats" are causing damages to the habitat. The question should be directed at whether the organisms supported by the habitat are adversely impacted by PCBs. This illustrates another basic flaw with the BERA; EPA has made no attempt to map habitats and determine how different species utilize different habitats.

EPA's Measurement Endpoints Are Not Predictive of Population or Community Effects

With the exception of the benthic invertebrate community survey, all of the measurement endpoints used by EPA are generic toxicity benchmarks: sediment-quality criteria, water-quality criteria, and TRVs derived from the most conservative single-species toxicity tests available. These benchmarks cannot be validly used to infer the existence of adverse effects on populations or communities.

To support a remedial action decision for the Hudson River, the measurement endpoints used in the assessment must either (1) directly address the abundance and distributions of populations and communities, or (2) provide an appropriate line of evidence regarding effects on populations and communities. Quantitative biological surveys can provide information to assess effects on populations and communities directly. Supporting lines of evidence can be developed from data such as site-specific toxicity tests, histopathological and biochemical studies of exposed populations, and dose-response data from all relevant laboratory tests. Models are available that can potentially be used to quantify effects of chemicals on exposed populations (Barnthouse 1993). Even if data on the dynamics of exposed populations are insufficient to support quantitative modeling, the above measurement endpoints can be used to estimate the fraction of a population that could potentially be impaired by exposure to PCBs.

EPA's Assessment is Based on Screening-Level Models and Ignores, Discounts, or Misinterprets Empirical Data

EPA's Assessment does not examine and incorporate site-specific data such as biological surveys, whole-media toxicity tests, or reproductive effects studies. In fact, with the exception of the TRVs for tree swallows that were based on field studies, none of the benchmarks are based on site-specific data. 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." As documented in Table 1, a wide variety of site-specific data were collected for the Clinch River BERA. Generic criteria and TRVs provided only one of many lines of evidence used in the assessment.

EPA's use of water and sediment-quality criteria as measurement endpoints for the BERA is inappropriate and redundant with earlier uses of the same criteria in the screening assessment performed for the Phase 1 investigation (EPA 1991). The SOW for the BERA correctly notes that comparisons of exposure concentrations to ambient water quality criteria and sediment quality guidelines merely indicates that there is a "potential for risk" to aquatic organisms. Notwithstanding this admission, EPA uses these criteria as separate lines of evidence for *every assessment endpoint* addressed in the assessment, and using these criteria concludes for each that actual risks are present. This is not a substitute for a site-specific ecological risk assessment.

Rather than measuring exposures of birds and mammals to PCBs, EPA calculates exposure using biota-sediment accumulation factors (BSAFs) and the FISHRAND model, which simulates the bioaccumulation of sediment-derived PCBs in aquatic food chains. Where data is available it should be used. For instance, EPA should have directly estimated avian exposures using measured concentrations in eggs. PCB concentrations in fish for the period 1993–1996 were computed by the model; data is available for this period and should have been used.

EPA ignores or discounts other existing site-specific data. In addition to the benthic community data collected by EPA and used in the assessment, data on benthic community structure are available from NYSDEC (1993) and Exponent (1998 a,b). These data were not used.

EPA ignores the large quantity of fish population data available for the Lower Hudson River from surveys conducted by NYSDEC and the Hudson River utility companies. Abundance trends for striped bass are reported by NOAA and are used in stock assessments performed by the Atlantic States Marine Fisheries Commission (NMFS 1998a). Estimates of the abundance of shortnose sturgeon in the Hudson River are available for the 1970s (Dovel et al. 1992) and the 1990s (Bain et al. 1995); these studies are summarized in the Final Recovery Plan for shortnose sturgeon (NMFS 1998b).

EPA acknowledges (p. 129) the growth in the white perch population in the lower Hudson, but discounts the significance of this growth on the grounds that "it is possible that PCBs could influence rates of reproduction and recruitment to a degree that is not manifested in recent populations trends." A similar argument is made in discussing the continued presence of apparently healthy fish populations in the upper Hudson, and of apparently healthy bird and mammal populations in both the upper and lower Hudson valleys. It appears that EPA's position is that a decline in abundance would indicate an adverse effect due to PCBs; an increase indicates only that the adverse effects (which are purportedly demonstrated by the TQs) are being masked by other factors. This argument is obviously contrary to established principles of scientific inference.

Data on population trends and reproductive success in bald eagles and other bird species are available but were not considered by EPA. NYSDEC has been monitoring the winter use and breeding activity, tissue contaminant concentrations, and reproduction of bald eagles in New York State and in the Hudson River area for many years. In addition to these reproductive data, the collection of prey from eagle nests by NYSDEC provides empirical, site-specific information on the diets of bald eagles that should have been used by EPA to improve the realism of its exposure model. Peter Nye of NYSDEC found remains of grebes, eels, pickerel, bullhead, herring and carp in eagle nests. In addition, NYSDEC collected unhatched eggs which could be analyzed. Information on the PCB concentrations in some of these prey, including bullhead and eels, are available (Secor 1997). Other data for bird populations are available from the U.S. Fish and Wildlife Service (USFWS 1997), NYSDEC (1997), and the North American Breeding Bird Survey (Sauer et al. 1997). EPA used none of these data.

Finally, as discussed in Section VI of these comments, the benthic community study and tree swallow reproduction study performed to support EPA's assessment were misinterpreted as supporting EPA's conclusions, even though adverse effects that could be validly attributed to PCBs were not detected in either study.

EPA Improperly Applies the Weight of Evidence Approach

EPA claims (p. 167) to have used a "weight of evidence" approach to "assess the potential for adverse reproductive effects in the receptors of concern as a result of exposure to PCBs in the Hudson River." EPA's assessment, however, presents virtually no lines of evidence other than screening-level TQs and fails to present a framework for resolving conflicting lines of evidence.[2] Many of the so-called "lines of evidence" are based on the same or similar data and are not truly independent. For example, TQs for fish and wildlife are presented using TRVs based alternatively on total PCBs and TEQs. Both approaches to TRV-development are based on the

[2] EPA's failure to present a framework for resolving conflicting lines of evidence is remarkable in light of its statement in the Responsivenss Summary for the Ecological Risk Assessment Scope of Work: "The quality of each measurement endpoint will be evaluated according to the attributes identifed by Menzie et al. (1996) and will be discussed in ERA. USEPA notes that Dr. Menzie will be directly involved for the Hudson River PCBs Reassessment ERA" (Responsiveness Summary at 19).

same types of data; they simply have different theoretical foundations and use different exposure estimates. Similarly, the same water and sediment-quality-based TQs are cited as evidence for risks to every receptor group. In reality, most of the assessment endpoints are addressed using only one line of evidence: comparison of measured or modeled exposure concentrations to generic toxicity benchmarks. In contrast, appropriately defined multiple lines of evidence would include completely independent study designs, such as: (1) benchmark comparisons; (2) field evaluations of community structure or reproduction; and (3) toxicity bioassays. (Suter et al. 1999, Jones et al. 1999)

EPA simply failed to collect the information required to implement the weight-of-evidence approach properly. For at least a decade, the "sediment quality triad" approach (Chapman et al. 1997) has been recognized in assessments of effects of chemicals on benthic invertebrate communities. The triad approach has been used in other large-scale ecological risk assessments, including both the Clinch River assessment and the assessment performed for the Clark Fork River, Montana (Canfield et al. 1994). EPA did not collect the data needed for such an examination. Similar concepts should have been used to evaluate all receptors of interest on the Hudson River. For example, rather than limiting evaluation of birds to literature-based TQ comparisons, multiple lines of evidence for effects on bird populations can be generated through quantitative field studies of reproductive success, density and diversity. Likewise, site-specific, field based community structure and reproductive studies on small mammals are relatively straightforward to execute and would support a true evaluation of multiple lines of evidence.

Both EPA's Hudson River Assessment and the Clinch River assessment addressed risks of sediment-derived PCBs to benthic macroinvertebrates, fish, birds, and mammals. However, far more information was used in the Clinch River ERA (Table 1). Five independent lines of evidence were developed for fish, three were developed for benthic invertebrates, and two were developed for piscivorous birds and wildlife. Ample time was available for EPA to perform similar studies, however, virtually no ecological data beyond those available for the Phase I assessment were collected.[3]

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[3] Clearly, use of the best available science involves development of a report that is free of mathematical errors. While time constraints prevented completion of a detailed mathematical review of all calculations,

3.0 The Ecological Risk Assessment is Excessively Conservative

Even if, arguendo, the TQ approach can, in principle, provide information that is useful in a baseline ecological risk assessment, EPA's application of the TQ approach provides highly inflated risk estimates that are not useful in remedial decisionmaking. Both the exposure assessment and the effects assessment employ data, models, and assumptions that are, at best, appropriate for screening.

The Exposure Assumptions Employed by EPA Result in Overestimates of Actual Exposures

In contrast to assumptions used in the companion human health risk assessment, the BERA assumes that samples with non-detect values contained PCBs at levels equal to the detection limit. No explanation is provided to support this assumption. The use of detection limits as estimates of concentrations actually present is an acceptable practice in screening assessments, but is not acceptable for use in a baseline assessment. The guidance prepared by EPA Region 3 (available at http://www.epa.gov/reg3hwmd/risk/guide3.htm) states that the approach used in the BERA "always produces a mean concentration which is biased high, and is not consistent with Region 3's policy of using best science in risk assessments." Less conservative and more acceptable approaches either (1) assume that nondetects are present at one-half the detection limit, or (2) if the data set contains a high proportion of positive detects (typically, greater than 50%), use a statistical estimation procedure to estimate the distribution of concentrations below the detection limit. At low detection levels one must also recognize the contribution of

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Tables 3-26 through 3-65 appear to contain an important miscalculation that leads to erroneous predictions of egg concentrations and predicted risks to avian embryos. Tables 3-26 through 3-65 calculate the predicted egg concentrations (in mg/Kg) for each of the bird species by multiplying the total average daily dose (in mg/Kg/day) by the biomagnification factor (BMF) (apparently unitless per page 55 of the BERA). Clearly the units in this equation do not cancel out. Either the units of the BMF were inadvertently not reported in the text (and should be mg/kg/day) or it is necessary to convert the total average daily dose of a concentration in food (in mg/Kg) prior to applying the BMF. Because BMFs usually reflect the ratio of the concentration of a chemical in the diet to the concentration in tissue, the latter error is the more likely of the two. In that case, the reported egg concentrations in all of these tables are erroneous, and the resultant predicted risks to avian embryos are also reported in error.

"background" PCBs which do not originate from the site and will not be addressed by any conceivable site remedy.

The BERA fails to consider realistically the influence of migratory behavior, home range, and landscape pattern on the distribution of exposures within fish and wildlife populations. For example, all avian receptors are assumed to have a home range (modifying value of 1.0) consisting solely of the Hudson River. For species that can exploit wetlands or other nonriverine habitats, this assumption is excessively conservative when applied to entire populations rather than to maximally exposed individuals. Piscivorous birds, such as blue heron, would be expected to forage in ponds and tributary streams as well as in the Hudson River itself and to obtain a significant fraction of their diets from sources other than fish (Henning et al. 1999). Similarly, insectivorous birds, such as tree swallows, can be expected to obtain part of their diets from terrestrial insects and to exploit insect emergences from ponds and tributary streams. Biomagnification factors (BMFs) reported by Giesy et al (1995) and employed by EPA to predict egg concentrations of piscivorous birds are 4 to 15 times greater than site-specific BMFs for tree swallows. Mink live primarily in wetland areas, and raccoons are abundant in hardwood swamps, flood plain forests, fresh and salt marshes, mesic hardwood stands, cultivated and abandoned farmlands, and suburban residential areas (Kaufman 1982). EPA could and should have studied habitat availability and utilization by avian and mammalian receptor species.

Anadromous and semianadromous fish species, such as striped bass and white perch undergo complex seasonal migrations that limit their exposures to PCBs. Individuals of both species range widely throughout the lower Hudson, and, in the case of striped bass, along the Atlantic coast from North Carolina to Maine. NYSDEC's data have consistently shown that the adult striped bass with the highest PCB tissue concentrations are collected in the vicinity of the Federal dam at Troy. Secor and Baker (1999) have shown that these fish are predominantly males that remain in freshwater for most or all of their lifetimes. Concentrations of PCBs in these fish are not representative of concentrations found in spawning females (or most Hudson striped bass) which are migratory and have much lower exposures to PCBs.

Differences in professional judgment regarding specific exposure parameter values can often be resolved through the use of probabilistic analyses, such as Monte Carlo analysis. By using distributions to represent the full range of values for exposure, both the most extreme and the most likely values are incorporated into the assessment, to a degree commensurate with the actual distribution in the population. Such an approach would have been far more scientifically defensible than the use of only the most conservative exposure assumptions in a deterministic analysis.

The Effects Assessment Relies on Excessively Conservative TRVs and Criterion Values

EPA's approach to developing TRVs (pp. 79-80) is unnecessarily conservative and, in many cases, results in the use of TRVs that are many times lower than the lowest concentration or dose ever observed to affect exposed organisms. The approach develops a single value rather than a range of values for each receptor species. In all cases where studies are not available of the taxonomic family or order of interest, the lowest applicable No Observed Adverse Effect Level (NOAEL) is used to define the TRV. NOAELs are appropriate for screening because they define a dose or exposure concentration below which no effects should occur; they are inappropriate for baseline assessments because they do not define a concentration or dose above which effects are likely. The approach used in the Clinch River assessment (Sample and Suter 1999) would be more appropriate for a baseline assessment. In the Clinch River assessment, NOAELs and Lowest Observed Adverse Effect Levels (LOAELs) for each receptor species were used to define ranges of exposures associated with negligible (dose lower than NOAEL), possible (dose exceeds NOAEL), and probable (dose exceeds LOAEL) effects on individual organisms.

The TRVs used by EPA to address risks to fish are whole body concentrations ranging from 0.5 mg/Kg to 15 mg/Kg. These values are inconsistent with values developed in two recent reviews of the literature on toxicity of PCBs to fish. NOAA (1999b) performed a review of the literature on reproductive, developmental, and immunotoxic effects of PCBs in fish. This review was published in March 1999 and is cited in the BERA (NOAA 1999a). According to NOAA's evaluation of the toxicity of Aroclor 1254, the threshold for occurrence of physiological and biochemical changes related to reproduction in adult fish is a liver concentration of approximately 25 ppm (equivalent to a whole-body concentration of approximately 12.5 ppm).

This review implies that a valid screening benchmark for Aroclor 1254 and related PCB mixtures in fish tissue (whole body) would be no lower than 12.5 ppm. Actual reductions in egg production or viability may require even higher exposure levels. Using actual reductions in survival or reproduction rather than physiological and biochemical endpoints, Niimi (1996) concluded that the weight of evidence from numerous species indicated that adverse reproductive effects are typically observed at whole body concentrations >100 mg/kg wet weight. Similarly, adverse effects on growth and survival of the progeny have generally been observed at whole body concentrations > 50 mg/kg wet weight. Only one of the TRV's used by EPA to calculate TQs is greater than NOAA's screening benchmark (spottail shiner, 15 mg/kg).

Similar reviews of the PCB toxicity literature are unavailable for birds and mammals. However, EPA's use of the lowest measured NOAEL, rather than the full range of available NOAELs and LOAELs, is an excessively conservative approach to assess the effects of PCBs on exposed species and does not provide a realistic description of risk. In many cases, laboratory studies provide the basis for the only TRV derived despite the many limitations in the ability of laboratory studies to simulate actual field conditions. Laboratory studies generally overestimate potential adverse effects. In the wild, organisms are exposed to widely fluctuating dose rates, temperatures, environmental stresses, competition, and food availability.

Regardless of the relative merits of field and laboratory study designs, we disagree with EPA's selection of studies on which to base TRVs (always the most conservative study, unless a study is available on a species of the same taxonomic family or order), as well as its interpretation of the studies selected. When sufficient data are available from both laboratory and field-based studies to generate TRVs, the BERA provides no information as to which TRV (laboratory or field-based) is actually used to predict risks. These multiple sources of conservatism are further compounded by the use of several ten-fold uncertainty factors to account for interspecies differences and subchronic-to-chronic exposure durations.

A notable problem with the EPA's Assessment relates to the use of gallinaceous birds (e.g., chickens) to evaluate the effects of PCBs on all avian receptors in the Hudson River region. This assumption is overly conservative; other data sources should be considered. For example, the

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site-specific tree swallow studies eliminate the need to predict PCB effects from the extrapolation of laboratory data. As a second example, in the analysis of mallards, three studies were examined for PCB toxicity data, and the TRV was based on the study with the lowest NOAEL; when there is more than one equally valid NOAEL, the highest value should be selected to provide the most realistic estimate of the effects threshold. In a third example, the analysis of great blue herons included the addition of an uncertainty factor due to the relatively short length of the study (Scott 1977). Longer term studies than the one chosen are available and would eliminate the need for an uncertainty factor. Fourth, despite the availability of field data on bald eagles and related predatory birds (Elliot et al. 1996), the TRV was developed using data from chicken studies. A far more representative laboratory study was conducted on screech owls (McLane and Hughes 1980), which are similar in feeding guild and taxonomy although they are not in the same family or order as bald eagles.

For bats and raccoons, EPA based TRVs on a laboratory study of rats conducted by Linder et al. (1974), despite the many limitations associated with the use of a laboratory species to evaluate wild species. EPA should have based TRVs for bats and raccoons on studies of wild species, such as Linzey (1987) and McCoy et al. (1995), which would not be subject to such extreme extrapolations. Even if there were a defensible basis for using Linder et al. (1974) instead of Linzey (1987) or McCoy et al. (1995), the uncertainty factor used by EPA to derive a TRV is overly conservative. For example, Sample et al. (1996) used Linder et al. (1974) to derive a NOAEL of 0.4 mg/kg-d, a value more than ten-fold higher than EPA's TRV of 0.032 mg/kg-d for bats.

For mink, the most scientifically defensible basis for a TRV is provided by Auerlich and Ringer (1977), rather than Heaton et al. 1995), which was used by EPA. Auerlich and Ringer (1977) fed mink Aroclor 1254 at multiple dose groups over a 4.5 month period. This period included critical life stages, so that no subchronic-to-chronic uncertainty factor should be necessary. Heaton et al.'s (1995) field study was confounded by the concurrent exposures of mink to other chemicals, and was of shorter duration than Auerlich and Ringer (1977) (4 months vs. 4.5 months). The most defensible TRV for mink would be based on Auerlich and Ringer (1977), without the factor-of-ten adjustment.

EPA's use of water quality criteria is similarly over conservative. As described by EPA (EPA 1986), water-quality criteria for the protection of aquatic life are intended to protect 99% of the individuals in 95% of the species exposed to a toxic chemical. Chemicals present at concentrations lower than the criterion clearly should not harm any exposed population. Concentrations above the criterion, however, do not necessarily imply that any of the exposed populations at a site are being adversely affected.

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4.0 The Sediment Effect Concentrations (SECs) are not Reasonable Estimates of PCB Toxicity to Benthic Invertebrates Either Individually or As a Population

Because the BERA claims to address benthic invertebrates at the population level, we address the SECs used as TRVs for benthic invertebrates in greater detail. The deficiencies discussed in this section are illustrative of problems found in many of the other TRVs used in EPA's Assessment.

EPA relies on SECs developed by NOAA (1999b) as TRVs for benthic invertebrates. These SECs are used in assessments of the likelihood that PCBs are impacting benthic invertebrate populations, fish populations, threatened and endangered species and the ability of particular habitats to support sustainable, healthy populations of biota. The presumption is that exceedance of SEC values is evidence that some unspecified toxic effect is occurring to benthic invertebrates and that this direct effect results in secondary effects to fish, threatened and endangered species and other organisms.

This presumption lacks scientific merit for two reasons:

- The SEC values have no causal basis.
- Direct relationships between benthic community productivity and the productivity of higher trophic level populations cannot be demonstrated.

The SECs developed by NOAA (1999b) and termed "Consensus-Based" SECs are the geometric means of pre-existing SECs developed from correlating measurements of sediment chemical concentrations and the results of sediment bioassay tests. The meaning and utility of the pre-existing SECs is the subject of considerable scientific debate (for example, see the discussion by O'Connor in the January 1999 issue of SETAC News). The principal arguments center on the lack of consideration of cause and effect. Absent an understanding of the agents responsible for observed toxicity and in the presence of the typical co-variation among sediment contaminants, it is inappropriate to use simple bivariate correlations to ascribe threshold concentrations for individual chemicals. This difficulty is compounded by the aggregation of data from sites that differ physically and in the suite of chemicals present. As indicated by Swartz and DiToro (1997) "correlation of chemical concentration and biological response only establishes potential exposure. The effects assessment must be based on independent evaluation of causality." This limitation makes SEC values appropriate for use only in the problem formulation stage of an ecological risk assessment (Chapman and Mann, 1999).

Authors of several of these methods have warned against their use as risk assessment tools. Long and Morgan (1991) and Long et al. (1995), who developed the current effects-range approach, have clearly stated the limits of these Sediment Quality Values (SQVs) in their primary publications. Long et al (1995): "The numerical guidelines should be used as informal screening tools in environmental assessments. They are not intended to preclude the use of toxicity tests or other measures of environmental effects." Like these scientists, Cubbage et al. (1997) inform the reader that their SQV (the PAET used by NOAA 1999b) have not been peer reviewed. These authors warn managers that the freshwater SQV "delineate a level below which biological effects are unlikely to occur…stations above these levels could be tested with bioassays to substantiate implied deleterious effects." The authors of the TEL/PEL values promulgated by the Ontario Ministry of the Environment (Smith et al. 1996) repeat this warning for their users: "[T]he guidelines are intended to be used in Canada as an indication that no adverse effects on aquatic organisms are expected if the measured concentrations of substances in sediments are equal to or lower than the recommended sediment quality guidelines. In contrast, measured concentrations of substances in sediments that are higher than the recommended sediment quality guidelines indicate only that there is the potential for adverse biological effects to occur." The use of these values to derive SECs and the subsequent use of SECs to *predict biological effects* in a baseline risk assessment is completely inconsistent with the intent of the basic SQVs as stated by their authors.

A key problem in the SEC approach is that no-effects data are not properly considered. The distribution of no-effects data is important because it is only in no-effects samples that *all* chemicals must be present below toxic levels, including the chemical of interest. Therefore the no-effects distribution defines a concentration range over which the chemical of interest assuredly has no toxic effect. The converse, however, is not true of the distribution of effects data; the effects distribution does not define a concentration range over which the chemical of interest assuredly produces a toxic effect because virtually all environmental samples are mixtures of chemicals. Where an effect is observed in a chemical mixture, a variety of measured and unmeasured chemicals could be responsible for the observed toxic effect: the effect cannot be positively attributed to any single chemical. Measured toxic effects have a high probability of being attributed to the wrong chemical(s).

The authors of the NOAA (1999b) SECs argue that the central tendency of the various pre-existing SECs for PCBs "reflect(s) causal rather than correlative effects ... and account for the effects of contaminant mixtures." There is no logical basis underlying the idea that causation exists in the central tendency of numbers that do not reflect causation. If ten researchers independently demonstrate and quantify correlations between the frequency of skin cancer and annual average air temperature, the central tendency of those studies does not provide evidence that skin cancer is caused by exposure to high air temperature. Correlation does not define causation, and multiple studies of correlation cannot overcome this fact. (See Appendix B).

The pre-existing SEC values are mostly based on data from sediments for which PCBs have not been shown to be the dominant or only contaminant of concern. For example, of the nine sites used to develop the Ingersoll et al. (1996) SEC values, only one (Waukegan Harbor) or possibly two (Saginaw River) could even be considered as primarily dominated by PCBs. The others contain substantial quantities of metals, PAHs, and/or petroleum hydrocarbons. As a result, the data set used to assign SEC values includes observations of toxicity at relatively low PCB concentrations. However, it is incorrect to infer that PCBs cause toxicity if these low concentrations are exceeded. Because the BERA does not present an evaluation of the studies on which each SEC is based, it fails to demonstrate that the SEC values have any meaning with regard to PCB toxicity. In fact, a recent analysis of field data (Anid and Connolly 1998), has shown that such evaluations can significantly alter the interpretation of SEC values. This analysis suggests that existing SEC values significantly over-estimate PCB toxicity because of the co-variation of PCBs and other chemicals.

The significant overstatement of PCB toxicity by the SEC values is illustrated by the spiked sediment toxicity study of Swartz et al. (1988) that NOAA (1999a) improperly uses as a validation of the SEC values. This study used sediment with a TOC content of about 0.25 percent. Most sediments contain a TOC content in the range of 1 to 4 percent. The fine sediment of the Thompson Island Pool has an average TOC of about 2 percent. Based on the relationship between the bioavailability of organic chemicals in sediments and sediment TOC that forms the basis of EPA's Sediment Quality Criteria (USEPA, 1993), the Swartz et al. toxicity results would have to be adjusted by about a factor of 8 to be applicable to the Hudson River. Thus, the applicable LC_{50} and LC_{10} values for comparison to the SEC values are 86 and 54 mg/kg DW. For argument sake, accepting the acute-to-chronic ratio of 11 cited in NOAA (1999b), PCBs would not *begin* to cause chronic toxicity to amphipods until concentrations exceeded about 8 mg/kg DW. In comparison, the NOAA (1999b) SEC values indicate the threshold is 0.04 mg/kg and that extreme effects are expected if the sediment concentration exceeds 1.7 mg/kg.

5.0 EPA's Assessment Should Not Rely on the TEQ Approach Because It Is Not Sufficiently Developed and Has Not Been Applied Properly

The Toxicity Equivalence (TEQ) approach converts concentrations of "dioxin-like" organic chemicals to equivalent concentrations of dioxin. EPA has used the TEQ approach as a method of assessing the risks of PCB exposure to fish and wildlife, in spite of its substantial limitations. The TEQ approach provides only order of magnitude estimates of toxicity. Moreover, the analytical methods used by EPA cannot accurately measure PCB congeners in fish or animal tissue. EPA has inappropriately handled non-detect readings of these congeners.

In addition, the TEQ calculations in the BERA are not well-documented. The procedure for estimating individual congener concentrations and TEQs is unclear and poorly justified. The report does not provide enough information to permit one to recheck the calculations. For these reasons, EPA's presentation of its analysis is markedly below the standard of "best practices."

The TEFs are Improperly Applied

EPA seems to consider the use of total PCB and PCB TEQ as equally valid means of assessing risks, regardless of the species and endpoint being evaluated. Given its current state of development, the use of the TEQ approach should be considered as a screening level filter rather than as a primary assessment approach. This reflects the cautions issued by the scientists who have contributed to the development of the TEQ approach for PCBs (Van den Berg et al. 1998; Tillit et al. 1991; Safe 1990, 1994). The TEFs used to convert coplanar congener concentrations to dioxin-equivalents are, at best, order-of-magnitude approximations useful primarily for screening purposes.

The stringent data requirements and the lack of a comprehensive toxicological database currently preclude the routine application of the approach to all receptor species. With the possible exception of mink, insufficient information is available concerning the species addressed in the BERA for TEQs to provide defensible risk estimates. For example, results of field studies for fish indicate that expression of PCB exposure in TEQs does not improve correlations between exposure and adverse effects (Giesy et al. 1994). In reviewing the applicability of the TEQ approach to Hudson River fish species, NOAA (1999a) concluded that "it is currently not possible to evaluate the risk to Hudson River fish larvae from exposure to coplanar PCBs using the TEQ method."

As a second example, the calculations of some TEFs are based on enzyme induction studies, notably BZ#81, one of the two most potent TEQ congeners to avian species (Van den Berg, et al. 1998). However, Yorks, et al. (1998) clearly demonstrated the lack of induction in tree swallows when dosed with PCBs and likewise observed a lack of metabolic activity in field studies, thus negating the TEQ approach for this species.

The Analytical Data are Inadequate

The analytical data for individual congeners in biota are inadequate for calculating TEQs. In particular, the practical quantitation limit (PQL) for BZ#126 was too high to permit reliable measures of its concentration in biological samples. These TEQ values are based on non-detect concentrations. EPA assigned the PQL to concentrations of BZ#126 below the quantitation limit and then used those values in the risk assessment. This deficiency is critical to the assessment because, based on EPA's calculations, BZ#126 comprises from 52 to 85 percent of the PCB TEQ in fishes from the Hudson River (BERA Table 3-1). Furthermore, the BERA implies that this overestimate of BZ#126 is compensated for by the fact that BZ#81 was not measured. The BERA provides no justification for its unusual assumptions but states that the magnitude of error associated with the omission of BZ#81 and the use of the detection limit for BZ#126 is within an order of magnitude at most. There is no basis for this conclusion. The end result of this assumption is that the TEQ-based risk assessments are driven by non-quantified concentrations of BZ#126.

6.0 EPA Has Misstated the Results of Field Studies

EPA considered two site specific field studies as part of the BERA: the USFWS tree swallow reproduction study (Secord and McCarty 1997, McCarty and Secord 1999a, 1999b), and EPA's study of the benthic macroinvertebrate community in Thompson Island Pool (Appendix H of the BERA). EPA concluded that both studies support a finding of significant risks related to PCB exposures. Neither study supports this conclusion.

The Tree Swallow Study Did Not Demonstrate PCB-Related Reproductive Effects

According to EPA's assessment, McCarty and Secord (1999a) observed "decreased reproductive success relative to reference areas and the occurrence of unusual parental and/or nesting behavior relative to reference areas" (BERA at p. 175). EPA states that "the behavioral endpoints have been shown to be statistically related to PCB exposures." EPA's inference from these results is that "PCB exposures may have significant effects on tree swallow nesting behavior. Alterations in behavior may also be reflected in changes in reproductive success of this species over time."

These statements are misleading. McCarty and Secord have been unable to demonstrate a dose-response relationship between tree swallow reproduction and PCB concentrations. The differences in reproductive parameters between the Ithaca and Hudson River tree swallow population are very likely due to the natural and temporal variation of these parameters between populations. The behavioral responses, although statistically related to PCB doses, are not correlated with reproductive success.

The theory of a relationship between PCB contamination and reproductive effects in tree swallows is not supported by the 1995 data set (McCarty and Secord 1999a). No significant differences in reproductive success of tree swallows nesting on the Hudson River in 1995 were found when comparing to the Ithaca reference data. Reproductive success was not related to PCB dose in either data set. The behavioral endpoints mentioned in the Hudson River BERA and measured by McCarty and Secord (1999b) are nest quality metrics; these metrics were not correlated with reproductive success.

Problems with reference site selection severely compromise all of McCarty and Secord's results. Both reference sites chosen for comparison with the Hudson River sites are inadequate. The original reference site was located on Champlain Canal. However, the tree swallow eggs at the Champlain reference site were determined to contain high concentrations of PCBs (Secord and McCarty 1997). Moreover, space limitations at this site forced the researchers to place tree swallow nest boxes much closer together (10-15 meters apart) than at all other Hudson River sites (30 meters apart) (Secord and McCarty 1997). Robertson and Rendell (1990), Muldal et al. (1985) and others have found that tree swallows prefer distantly spaced nests; adverse effects of close spacing confound effects of PCBs on tree swallows nesting at this site.

Data collected at a site in Ithaca during McCarty's thesis studies at Cornell University (McCarty 1995), were chosen as an alternative reference data set. However, the Ithaca study was conducted prior to 1994, and very limited information is provided regarding the site. Although the field methods used at Ithaca are reported to be the same as those used at the Hudson River sites, other factors that affect reproductive success, such as weather conditions, habitat characteristics, and tissue residue levels, have not been documented. The dissimilarities (i.e., the years sampled and habitats represented) between the Ithaca and Hudson River sites greatly weaken the already ambiguous conclusions that can be drawn from these studies.

The Benthic Macroinvertebrate Study Did Not Demonstrate PCB-Related Effects

In presenting conclusions from the benthic macroinvertebrate study documented in Appendix H to the BERA, EPA states that "[t]he analysis shows a reduced macroinvertebrate community, indicating the potential for risk above regional conditions due to site-related influences" (BERA at p. 167). This statement contradicts the statement in the Risk Characterization section (p. 121) that the benthic invertebrate community analyses could not distinguish any clear effects from PCBs in the Upper or Lower Hudson River (BERA at 121).

In fact, EPA's benthic macroinvertebrate study did not employ a design capable of separating effects of PCBs from effects of environmental variables such as site depth, grain size, total organic carbon (TOC), and other potentially toxic chemicals. The results presented in Appendix H, Table H-6 show that concentrations of PCBs, TOC, cadmium, chromium, lead, and mercury all co-vary at the five stations studied. Hence, although benthic community metrics differ between Stations 5 and 7 (higher PCB concentrations) vs. Stations 3, 4, and 6 (lower PCB concentrations), it is not possible to infer that PCBs are responsible for the differences in macroinvertebrate community metrics between these two groups of sites.

These results flatly contradict claims made by EPA, (pp. ES-6, 167) that PCBs are adversely affecting benthic macroinvertebrate populations in the Upper Hudson River.

7.0 Available Population and Community Data Conflict With EPA's Conclusions

Many studies of the biological resources of the Hudson River and Valley have been carried out over the last 25 years. As a result, many sources of field data on the status of benthic communities and of fish and wildlife populations are available. EPA failed to use these data. They generally demonstrate the presence of healthy populations and communities in the upper and lower Hudson in spite of exposures to PCBs.

Benthic Macroinvertebrates

No effects of PCBs have been seen in Hudson River benthic macroinvertebrate communities as evidenced by the increase in abundance of pollution-intolerant filter feeders (NYSDEC 1993) over a 25 year period.

Fish

Fish population data are available for the Lower Hudson River from surveys conducted by NYSDEC and the Hudson River utility companies. Abundance trends for striped bass are reported to NOAA and are used in stock assessments performed by the Atlantic States Marine Fisheries Commission. These data, reported in the 1998 striped bass stock assessment (NMFS 1998a) clearly show (Figure 1) that the abundance of young-of-the-year striped bass has remained stable since 1980 and that the abundance of the spawning stock in the Hudson River has increased over the same period. There is no evidence of any adverse effects due to PCB exposure. Following the decline of the coastal striped bass stock in the mid-1970s, the National Marine Fisheries Service and the U.S. Fish and Wildlife Service investigated the possible causes of the decline. Those agencies did not find that PCBs posed a threat to the striped bass population and they concluded, given the restrictions on striped bass fishing in the Hudson, that the "Hudson River striped bass stock is likely to increase to near the maximum level supportable by that ecosystem." (Atlantic States Marine Fisheries Commission, 1990).

EPA also neglected the documented positive trends in the populations of shortnose sturgeon in the Hudson River. Two studies have generated estimates of the adult shortnose sturgeon population using mark-recapture methods. Dovel et al. (1992) used recapture counts from 1975 to 1980 to estimate the shortnose sturgeon population size in the Hudson River at 13,000 adult fish. In 1995, Bain et al. used comparable methods to estimate the shortnose sturgeon population at 38,024 (standard error = 7,199). According to Bain et al. (1995), both studies probably underestimate the sturgeon population because the samples did not cover the full range of habitat used by sturgeon in the Hudson River. Nonetheless, these studies suggest that the numbers of shortnose sturgeon are increasing in the Hudson River.

Wildlife

NYSDEC has been monitoring the winter use and breeding activity, tissue contaminant concentrations, and reproduction of bald eagles in New York State and the Hudson River area for many years. Statewide, there are approximately 45 breeding pairs, and the recent wintering population includes 200–250 individuals (Nye 1999, pers. comm.). Since 1990, bald eagle productivity in the state has ranged from 0.55 to 1.3 fledglings per occupied territory (NYSDEC 1999). Production has been greater than 0.7 (the minimum for a stable population [Sprunt et al. 1973]) in eight out of nine years, and greater than 1.0 in six out of nine years (the rate assumed for a healthy population by USFWS (1997). In 1996, 37 young (including one introduced chick) were fledged in the state; 43 eaglets (including 3 introduced chicks) fledged in 1997; and 40 eaglets (including 1 introduced chick) fledged in 1998.

Nesting attempts in three bald eagle territories on the Hudson resumed in 1992, and fledglings were successfully produced in 1997 (Nye 1999, pers. comm.). Four eaglets were fledged from Hudson River nests in 1998.

In addition to these reproductive data, the collection of prey from eagle nests by NYSDEC provides empirical, site-specific information on the diets of bald eagles that should have been used by EPA to improve the realism of its exposure model. Peter Nye of NYSDEC found remains of grebes, eels, pickerel, bullhead, herring and carp in eagle nests. Information on the

PCB concentrations in some of these prey, including bullhead and eels, are available (Secor 1997). Remaining samples are being stored with the plasma and egg samples for analysis of organochlorines. EPA should have worked with NYSDEC to measure the PCB concentrations in these samples. Measured PCBs in eggs could have been used to calibrate the rough estimate provided by the biomagnification factor (BMF) approach in EPA's risk assessment, improving the reliability of the BCF model, and could have been considered as an indicator of exposure on their own. Measured PCBs in prey items could have been used to calibrate the food web exposure model.

Other data for bird populations that relate directly to EPA's risk models, are available and should have been included in EPA's analysis. 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.

8.0 Conclusion

The BERA is significantly flawed. It does not reflect best scientific practice, is excessively conservative, and is grossly insufficient in determining the need for or selecting a remedy. These weaknesses make the assessment of little use for the remedial decision maker.

- The BERA is deficient because its assessment endpoints inappropriately focus on risks to individuals, not populations or communities, and it is insufficiently based on observed exposures and effects measured in well-designed, site-specific studies. EPA had ample time – nearly 10 years – to collect the necessary data to perform a defensible and valid ecological risk assessment.

- The BERA ignores a wealth of valuable site-specific data and misrepresents the two site-specific studies on which it relies. Available population and community data, in fact, contradict the BERA's conclusions.

- The BERA fails to use the weight-of-evidence approach in a sound manner. Although EPA claims to have examined several lines of evidence, most of its assessment endpoints are addressed using only one line of evidence: comparison of measured or modeled exposure concentrations to generic, non-specific toxicity benchmarks. Other, more probative lines of evidence are ignored.

- The BERA contains a number of assumptions and approaches that are excessively conservative. These include, employing generic screening values such as TRVs and SEC as predictors of site-specific risk; treating non-detects as if they show the presence of a chemical; and mistaken and unrealistic assumptions about diet composition, food consumption rates and habitat utilization. The BERA should not have relied on the TEQ approach, which is insufficiently developed and was misapplied.

- The BERA should not have used EPA's food-chain bioaccumulation model, which is flawed, undergoing changes and has not yet been peer-reviewed.

EPA should ignore this assessment when making a remedial decision for the Site.

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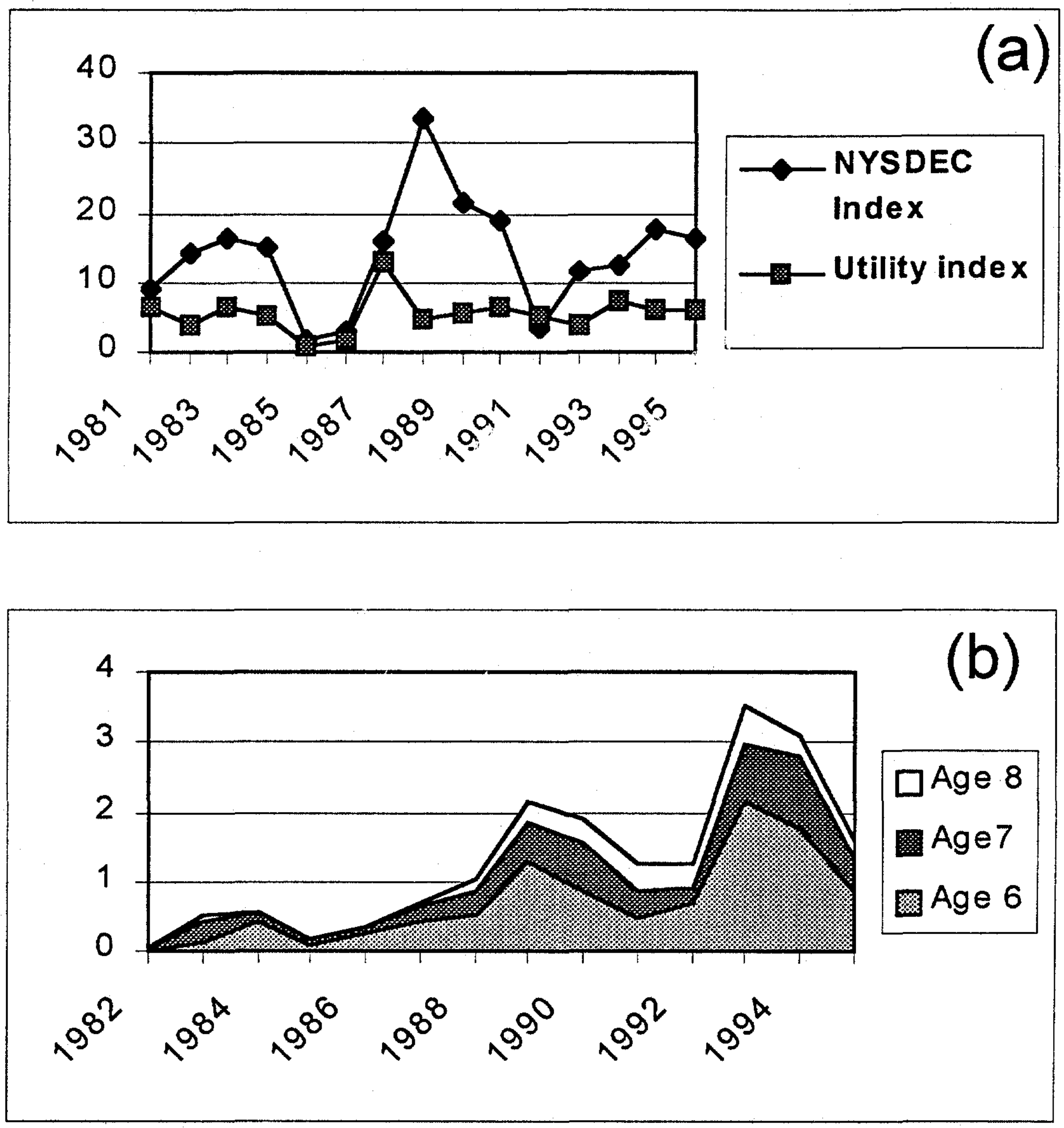

Indices of striped bass abundance in the Hudson River. (a) Young-of-the-year indices from beach seine surveys conduced by the Hudson River utilities and the NYSDEC. (b) CPUE for age 6 through 8 striped bass caught as bycatch in the gillnet fishery for American shad. Data from SARC (1998).

Table 1: Comparison of Hudson River 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.	**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 benthic community study, water and sediment-quality criteria, Chronic TRVs (reproduction endpoint) for fish, birds, and mammals	**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	
Measured concentrations of aroclors and PCB congeners in fish (whole body), water, and sediment Modeled oral doses (aroclors 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 subarea), using (1) conservative exposure assumptions, and (2) Monte Carlo analysis of all exposure parameters

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Effects Assessment	
Hudson River ERA	**Clinch River ERA**
TRVs for PCB and TEQ concentrations in fish tissue Field-derived (tree swallow) or literature-derived (other species) TRVs for fish, birds, mammals Analysis of local-scale benthic community diversity	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

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Risk Characterization	
Hudson River ERA	**Clinch River ERA**
All assessment endpoints: Comparison of water and sediment concentrations to water and sediment-quality criteria **Benthic Invertebrates**: Correlation of local-scale benthic community diversity with PCB concentrations in sediment **Fish**: Comparison of aroclor and TEQ concentrations in fish tissue to literature-derived NOAEL TRVs Overview of population trends for selected species **Birds**: Comparison of modeled oral doses and egg concentrations (aroclors and TEQs) to field-derived (tree swallow) or literature-derived (other species) TRVs Qualitative overview of occurrence data for various species **Mammals**: Comparison of modeled doses (aroclors 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

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Exhibit A

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Appendix A

Critique of Analyses Presented in Appendix K of EPA's Ecological Risk Assessment

Appendix K to EPA's Baseline Ecological Risk Assessment (BERA) is not relevant to the risk assessment itself. In addition, there are significant problems associated with several of the conclusions. In particular, the usefulness of the "Principal Components Analysis" (PCA) set out in the Appendix rests on the analyst's ability to understand the biological or physical meaning behind the components. EPA presents little analysis of the interpretation of component 2 and therefore leaves open the question of the meaning of differences or similarities among samples. Appendix K should not be included in the BERA, and its conclusion should be disregarded. Below, we comment specifically on several points brought up in Appendix K.

Impact of Upstream Remediation Between 1993 and 1995

Appendix K suggests that remediation of upstream PCB sources will not lead to significant reductions in fish PCB levels. This conclusion is unwarranted, is contradicted by other lines of evidence, and is not relevant to the ecological risk assessment.

In Section K.6 of Appendix K, EPA compares the 1993 and 1995 fish congener data collected by NOAA and EPA using PCA. From this analysis, EPA concludes that "little difference was evident between the two fall sampling events, suggesting that little had occurred (such as GE remediation of the Hudson Falls releases) to affect the congener patterns, and, by inference, the basic routes of exposure in fish." BERA (p. 68 of Book 1).

Although Section K.6 presents several comparisons between fish collected in fall 1993 and fall 1995, EPA states that most of the comparisons cannot be used because of confounding variables. In fact, the differences seen in the fall 1993 and 1995 samples are due in part to differences between juvenile and adult fish (Figure K-41). When age class is not considered, EPA states that for striped bass "there may actually be a discernable difference between the Fall 1993 results and the Fall 1995 results since there is a portion of both data sets based on the same life-stage which appear to be different" (p. K-19). For white perch and yellow perch, life-stage does not appear to influence the comparison, and based upon Figure K-40, EPA concludes that there is no difference between fall 1993 and fall 1995. In fact, these comparison provide little support for EPA's conclusion of no difference: for yellow perch, there are only five values presented for fall 1995. These are tightly clustered and lie within the range of the Fall 1993 values. However, all but four of the values for fall 1993 lie below and to the right of the Fall 1995 values (Figure K-40), suggesting that the populations as a whole may in fact be different.

This leaves only the white perch data (Figure K-40) to support the conclusion of no effect. The 1993 and 1995 values data do indeed overlap. However, the white perch data must be balanced against the results seen in the striped bass and yellow perch. In short, EPA's conclusion that there are no differences in the fall 1993 and fall 1995 fish data is very weak.

In addition, no data for the fall 1995 collection above RM 152 were used (page K-18), so any conclusions drawn must relate only to the Lower Hudson River.

Finally, it is unclear what EPA means by effects on the "basic routes of exposure." The most likely meaning is that the PCB composition of the source did not change. However, this does not mean that remediation activities upstream of Thompson Island Pool had no impact on PCB levels. It simply means that either there was no change in the composition of the source to the fish during this period or that the tool used was too imprecise to tell potentially different sources apart.

The most direct way to assess the impact of upstream remediation on fish PCB levels is to analyze fish PCB levels. For example, lipid-based levels in largemouth bass, pumpkinseed and brown bullhead in Thompson Island Pool declined from 1993 to 1995 (Figure 1), consistent with a decrease in exposure level.

In conclusion, the analysis presented in Section K.6 does not support EPA's assertion that site-based remediation had no effect on fish levels. The limited number of data points, the scatter observed in the PCA, the fact that only a qualitative appraisal of the results was presented, the differences among species in apparent trends from 1993 to 1995, and the limitation of the data to the Lower Hudson River all undermine EPA's conclusion that remediation of the Hudson Falls releases did not affect the basic routes of exposure in fish. This conclusion also is contradicted, at least in Thompson Island Pool, by the more direct analysis of PCB levels in fish.

Sources of PCBs to the Fish in the Freshwater Portion of the Lower Hudson River

In discussing spatial patterns in the congener composition in fish, EPA, referring to the freshwater portion of the Lower Hudson River, states that "additional, substantive, higher molecular weight PCB load to this region is not in evidence" (p. K-10). This conclusion is based upon analyses presented in the DEIR, but is contradicted by the data presented by EPA.

EPA states that PCB concentrations decrease from the Thompson Island Pool to the Lower Hudson River, but that there is a "trend to a nearly constant average value for each feeding guild in the Lower Hudson" (p. K-11), presumably referring to the fact that the decline in lipid-based total PCB concentrations in fish observed in the Upper Hudson River and in the upper portion of the Lower Hudson River stops, and concentrations in the lower portion of the Lower Hudson River do not decline towards the mouth (Figure K-18). In fact, total PCB concentrations in foragers in Figure K-18 actually increase towards the mouth downstream of approximately mile 120. Over this region, concentrations would be expected to decline due to dilution. This is shown in the bottom panels of Figures 2a and 2b, each of which contains a line indicating the expected degree of dilution by freshwater inflow (mile 153 to approximately mile 60), and by tidal mixing (mile 60 to the mouth). On each plot, the value on the Y-axis represents relative concentration and is set to 1.0 at mile 153. For example, PCBs in the water at Troy are expected to be diluted by 80% at the mouth of the river due to freshwater inflow and tidal

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mixing. Comparison of calculated dilution with the observed lack of gradient in forage fish total PCB levels downstream of approximately mile 120 (Figure K-18) suggests that lower river sources may be affecting PCB levels even above the salt wedge, perhaps as far north as mile 120.

This conclusion is brought out more clearly by studying spatial patterns in the concentrations of individual congeners in fish collected by EPA and NOAA in 1993 (Figures 2a-2b). Above approximately mile 100, concentrations of each congener decline more rapidly than expected by dilution. Below the region between mile 90 and 110, concentrations of all PCBs do not decline as fast as expected by dilution, and concentrations of higher chlorinated PCBs actually increase. Note that actual concentrations (mg/kg lipid) are plotted here, not weight proportion. This provides evidence for a higher molecular weight PCB load to the region of the freshwater Lower Hudson River downstream of the region between mile 90 and 110. Thus, EPA's conclusion is contradicted by the available data it presents.

Use of Congener Ratios to Explore PCB Sources to the Fish

EPA concludes that the use of congener ratios provides "little clue as to the nature of the source" of PCBs to the fish (p. K-30-31). This is based upon variation in spatial trends among media (fish, sediment and water) as well as variation among fish. EPA's analysis is focused on assessing the relative importance of upper and lower river sources to the fish. Interpretation of these ratios for the purposes of Appendix K is difficult, but EPA's conclusion is too broad. These ratios can provide useful information concerning PCB sources to fish in other contexts, as demonstrated in QEA (1999).

QEA used these ratios to answer a different question: are the fish in the Upper Hudson River exposed to dechlorinated PCBs or relatively undechlorinated PCBs? The observation that the average ratio was more similar to surface sediments than buried dechlorinated sediments was very clear (Figure 5-15 of QEA 1999).

On a related point, EPA concludes that because the value of the ratios is greater in the particulate phase, the partition coefficient for BZ#49 is greater than the congeners used in the numerators (p. K-28). The opposite is true, and indeed the K_{OW} values of the congeners used in the numerators are approximately a factor of two greater than BZ#49 (Hawker and Connell 1988).

In conclusion, the statement that congener ratios provide little clue as to the nature of PCB sources is too broad and is contradicted by data. A more correct statement would be that the analysis presented in Appendix K does not lead to definitive conclusions concerning variation in PCB sources with river mile.

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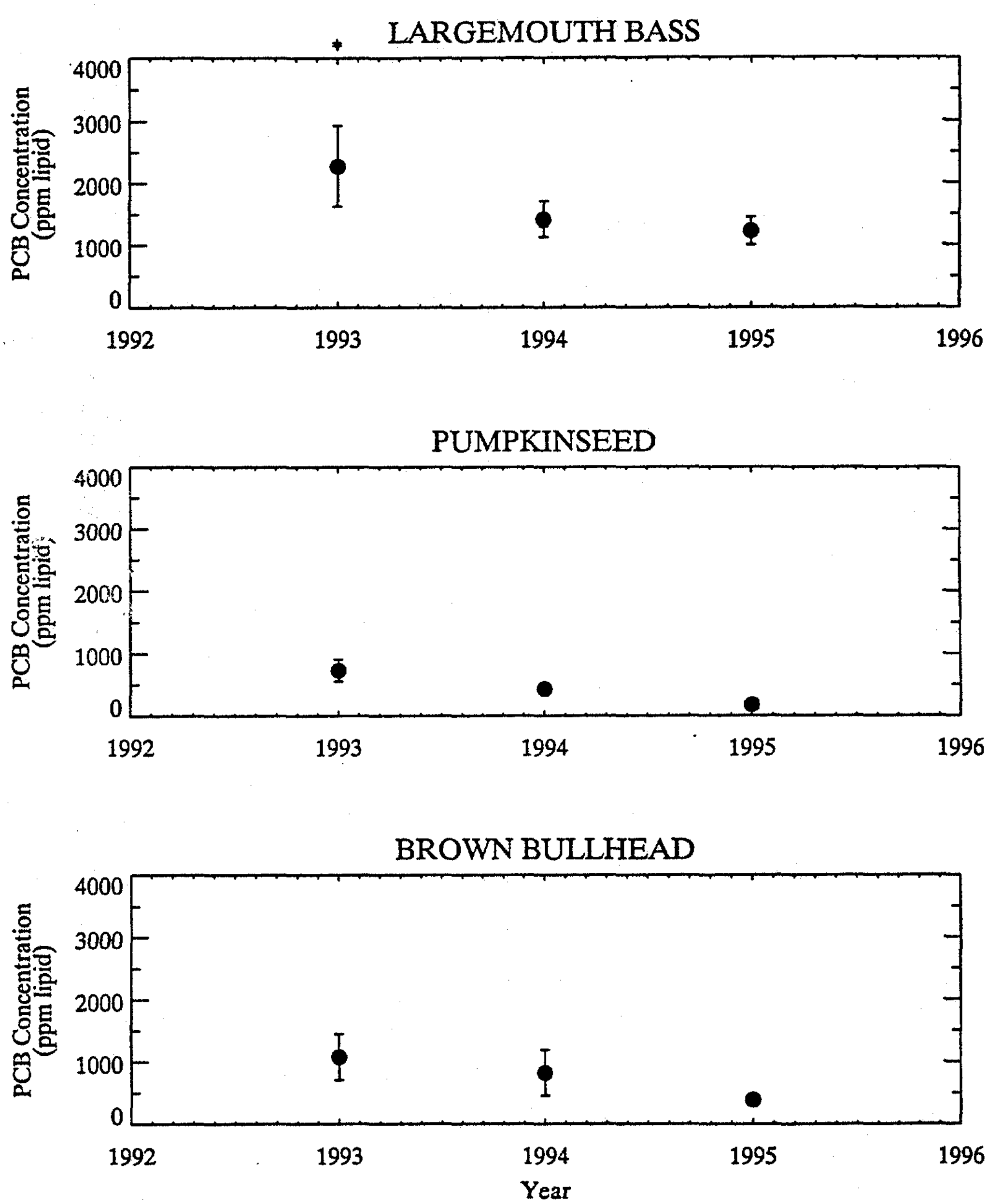

Data are arithmetic means +/- 2 standard errors.
NYSDEC Data

Figure 1. Lipid-normalized PCB concentrations in largemouth bass, pumpkinseed and brown bullhead collected from Thompson Island Pool.

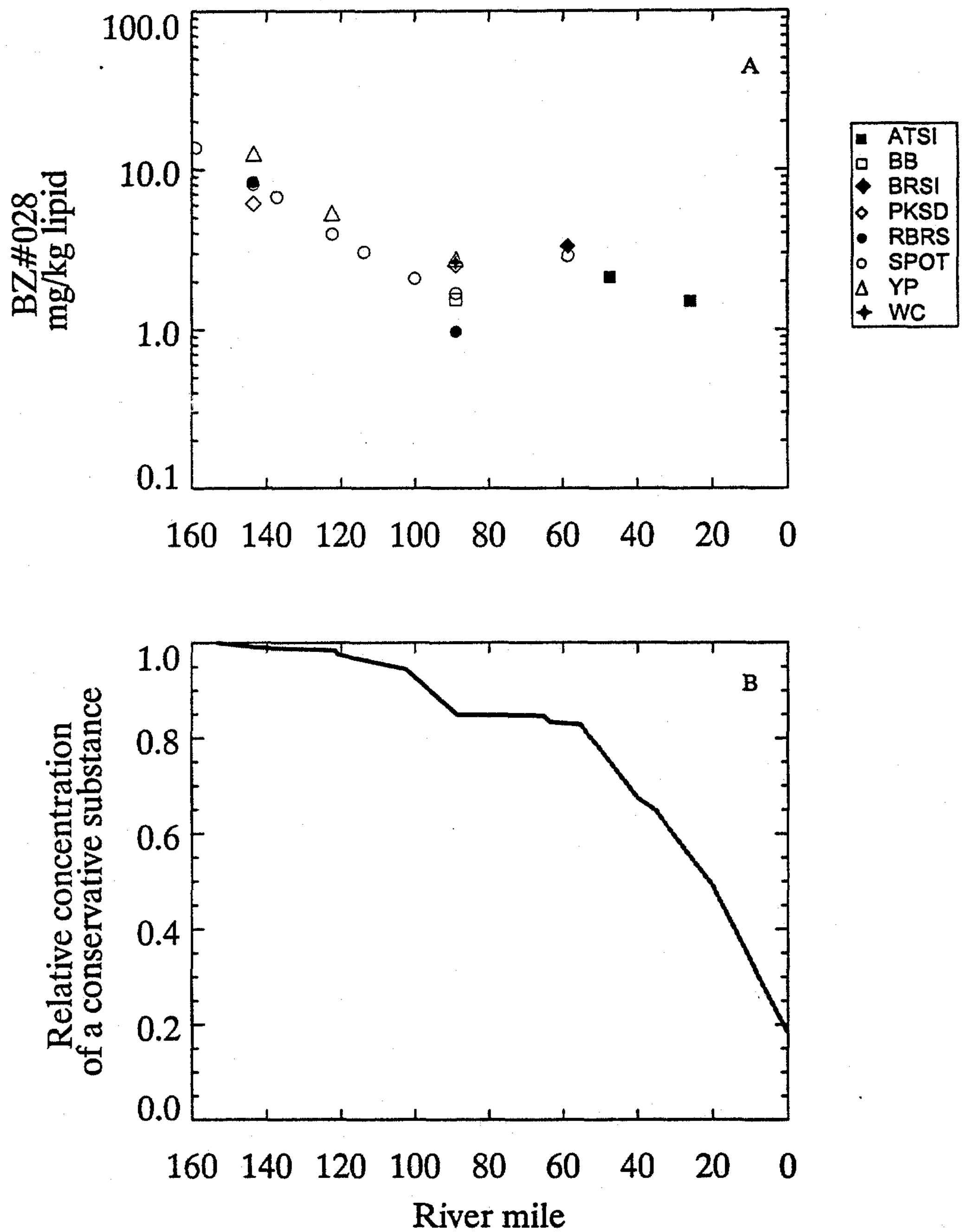

Figure 2a. Spatial Gradients in Concentration of PCB Congener BZ#028 in Fish from the Hudson River Compared With Gradients Expected Due to Dilution of PCBs Originating Upstream.

A: Species Specific Average Concentration of BZ#028
B: Concentration of a Conservative Substance Relative to MP153.
Dilution estimated based upon tributary inflow above MP60 and tidal mixing below MP60.
Data: EPA Phase II and NOAA, 1993

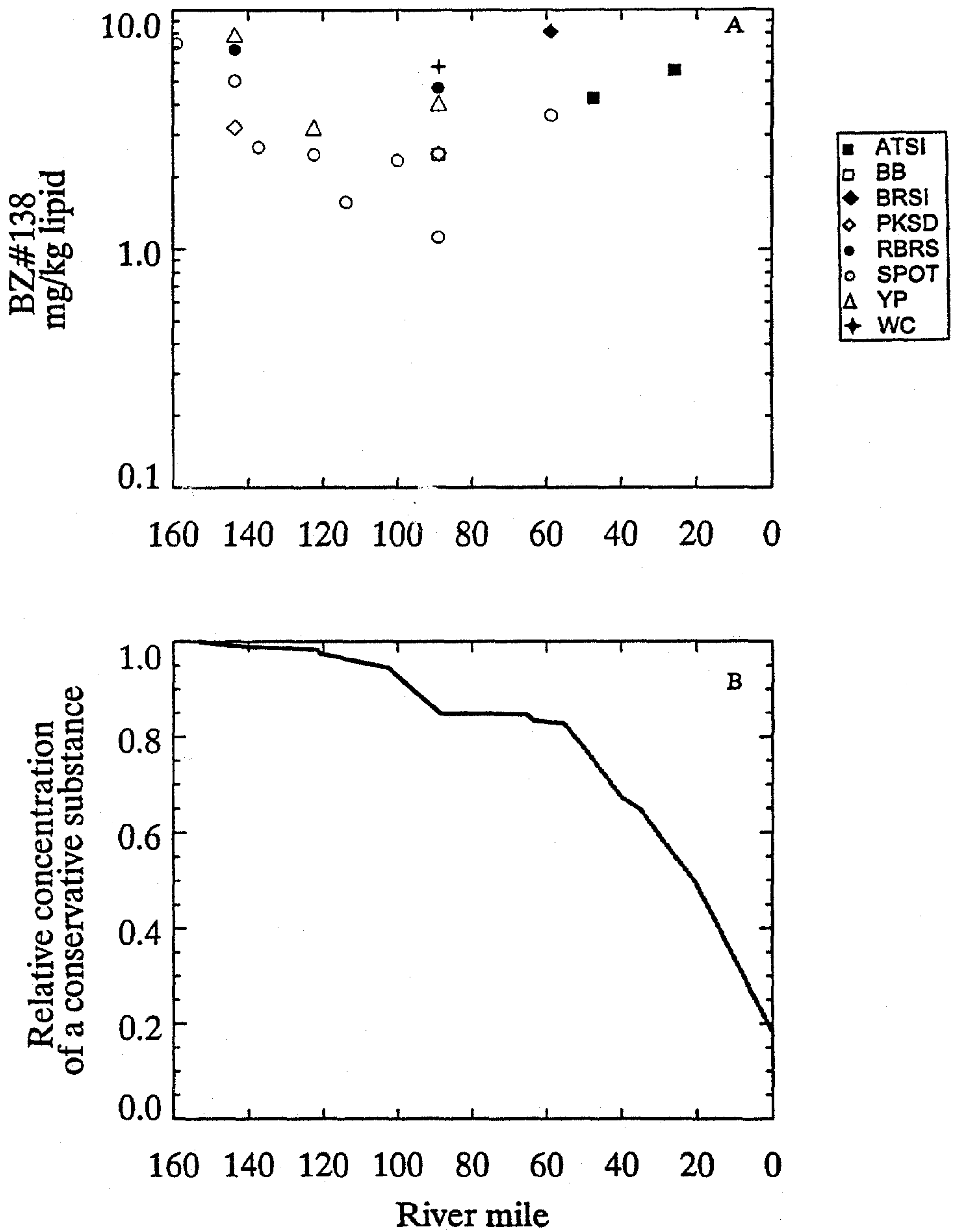

Figure 2b. Spatial Gradients in Concentration of PCB Congener BZ#138 in Fish from the Hudson River Compared With Gradients Expected Due to Dilution of PCBs Originating Upstream.

A: Species Specific Average Concentration of BZ#138
B: Concentration of a Conservative Substance Relative to MP153.
Dilution estimated based upon tributary inflow above MP60 and tidal mixing below MP60.
Data: EPA Phase II and NOAA, 1993

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Exhibit B

Appendix B

Critique of the Evaluation of the Predictive Capability of the NOAA (1999) SEC Values

NOAA (1999) used three approaches to evaluate the predictive capability of their Sediment Effect Concentration (SEC) values:

- Comparison to field data from numerous freshwater and estuarine/marine sites
- Comparison to the results of a laboratory spiked-sediment bioassay
- Comparison to screening level sediment quality criteria developed by New York State Department of Environmental Conservation (NYSDEC) using equilibrium partitioning

All of these approaches are flawed and do not validate the use of the SEC values as reasonable predictors of PCB toxicity.

1.0 Comparison to Field Data

This evaluation of SEC predictive capability was conducted using a data set that included the results of studies from eight freshwater bodies, eleven estuarine or marine sites and the Environmental Monitoring and Assessment Program (EMAP) Virginia Province. These data were used to test the frequency at which the SEC values correctly predicted the presence or absence of toxicity. This testing contained the following flaws:

- The data set was not independent of the data used to develop the SEC values
- It is not likely that PCBs were the toxic agent at most of the sites
- Comparison over multiple sites does not test the predictive capability at individual sites

1.1 Lack of Independence of the Validation Data Set

The pre-existing SEC values used by NOAA are not independent of the SEC validation data to develop the "Consensus-based" SEC values. For example, the Ingersoll et al. (1996) SECs were developed using data from 5 of the 8 freshwater sites that form the testing data set (i.e., Indiana Harbor; Saginaw River; Trinity River; Upper Mississippi River; Waukegan Harbor).

1.2 Lack of Relevance to PCB Toxicity

A validation of the relevance of the SEC values to PCB toxicity in the Hudson River would be best achieved by comparison to data from sites in which PCBs are the probable toxic agent. No attempt was made to use such a criterion in site selection. Five of the freshwater sites in the validation data set clearly fail to meet this criterion. Two of the water bodies (Trinity River and Upper Mississippi River) had little or no PCB present, as indicated by the overwhelming frequency of non-detect concentrations. Three of the water bodies contain chemicals other than PCBs that could account for all of the observed toxicity (Indiana Harbor; Grand Calumet River; Potomac River). In fact, the reference cited for the Grand Calumet River data (Hoke et al. 1993) states that "... ammonia, polycyclic aromatic hydrocarbons, metals, petroleum hydrocarbons, and bicarbonate ion appear to be the major contaminants of environmental significance to benthic invertebrates within the study area." A sixth site (Saginaw River) is also problematic because it contains significant concentrations of several heavy metals (Moll et al., 1995) and significant TCDD TEQ values that are attributable mostly to dioxin and furan congeners (Gale et al., 1997).

All of the estuarine or marine sites in the validation data set fail the PCB dominance criterion. Most of the sites contain relatively high concentrations of PAHs. Some contain significant amounts of pesticides or metals. For example, toxicity in Tampa Bay was significantly correlated with trace metals, pesticides, PAHs and ammonia in addition to PCBs (Carr et al., 1996). Similarly, as shown in Figure B-1, amphipod mortality in the Hudson-Raritan Estuary and LA Harbor exhibited no evident dose-response relationship to PCBs, but did show such a relationship for PAHs (Anid and Connolly, 1998).

1.3 Lack of Predictive Ability at Individual Sites

The two freshwater studies in which PCBs are perceived to be a primary contaminant demonstrate that the SEC values lack predictive ability. The Lower Fox River and Green Bay data exhibit 86 percent false positives for the Extreme Effect Concentration (EEC) and 84 percent false positives for the Medium Effect Concentration (MEC). Although all but one of the Waukegan Harbor samples are classified as toxic, neither the mortality or growth endpoints exhibit a dose-response relationship with PCBs. Further, the one non-toxic sample had the third highest PCB concentration in the data set (7.4 mg/kg DW).

2.0 Comparison to the Laboratory-Spiked Sediment Bioassay

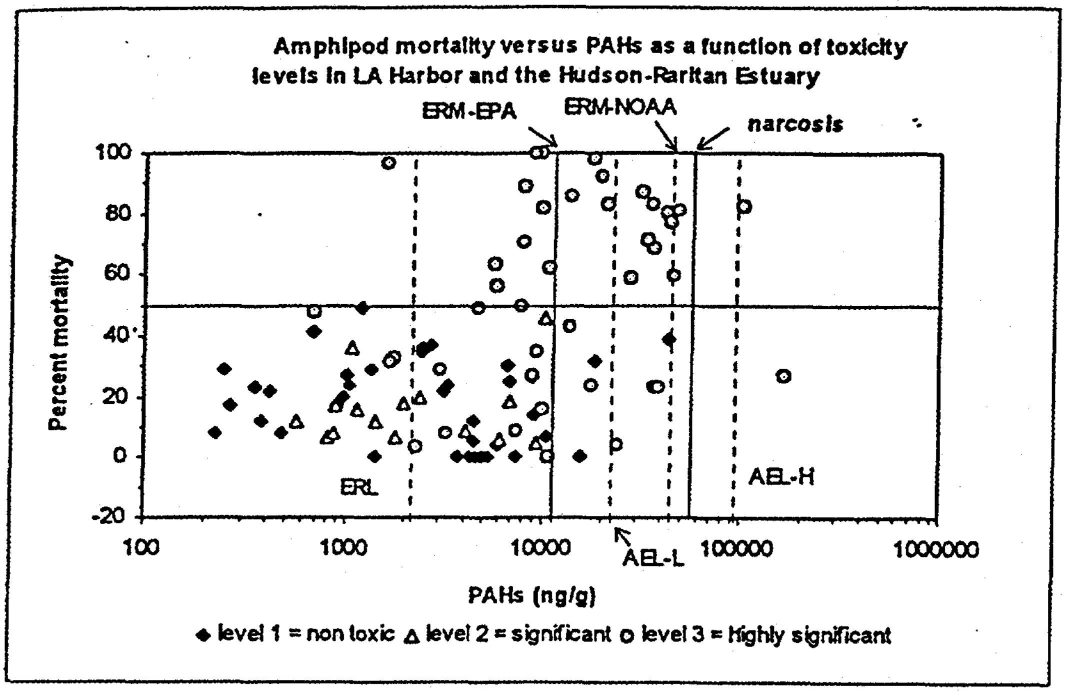
The Swartz et al. (1988) spiked sediment toxicity study cannot be compared to the SEC values. This study used sediment with a TOC content of about 0.25 percent. Most sediments contain a TOC content in the range of 1 to 4 percent. The fine sediment of the Thompson Island Pool has an average TOC of about 2 percent. Based on the relationship between the bioavailability of organic chemicals in sediments and sediment TOC that forms the basis of EPAs Sediment Quality Criteria (EPA, 1993), the Swartz et al, toxicity results would have to be adjusted by about a factor of 8 to be applicable to the Hudson River. Thus, the applicable LC_{50} and LC_{10} values for comparison to the SEC values are 86 and 54 mg/kg DW. For arguments sake, accepting the acute-to-chronic ratio of 11 cited by NOAA (1999) and assuming the validity of this study, one would at most conclude that PCBs would not even *begin* to cause chronic toxicity to amphipods until concentrations exceeded about 8 mg/kg DW.

3.0 Comparison to Screening Level Sediment Quality Criteria Developed using Equilibrium Partitioning (EqP)

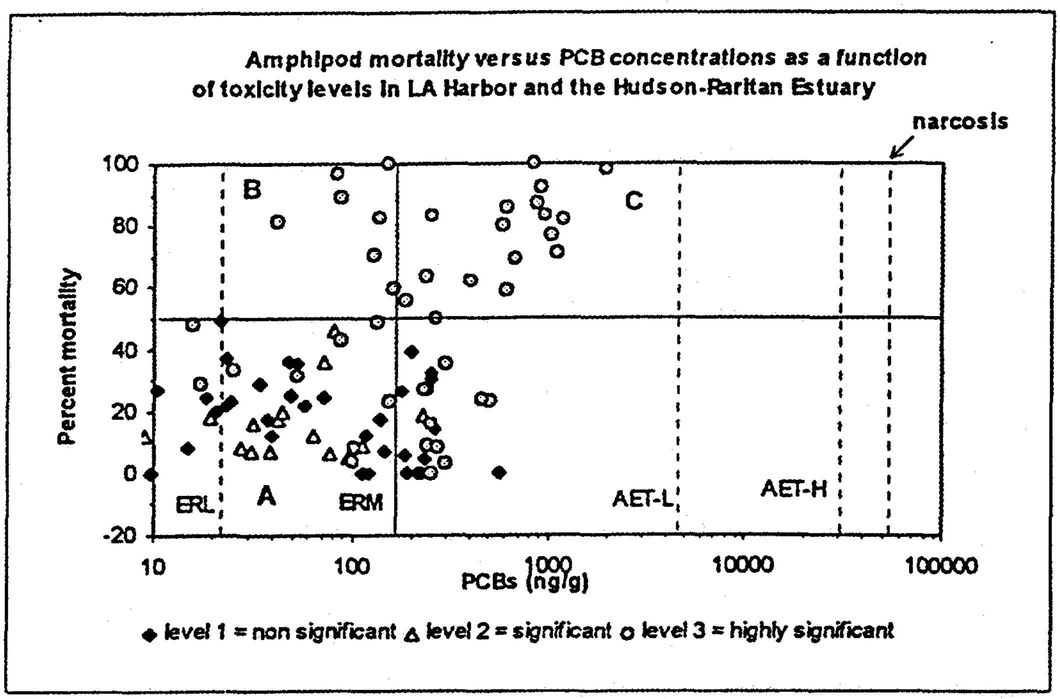
EqP sediment quality criteria are by definition sediment concentrations at which no effect is expected. They are derived using two conservative assumptions. The first is that sediment chemical is fully bioavailable. It is well accepted that some fraction of the chemical in the sediments is not bioavailable. The second is that the water quality criterion is the maximum allowable pore water concentration. The water quality criterion is determined using procedures that ensure that it is protective, i.e., it is not a toxicity threshold and may be significantly below a toxicity threshold. It is for these reasons that sediment quality criteria are best used as screening values. Sediment concentrations lower than the EqP are presumed safe. Concentrations greater than the EqP may, or may not, indicate toxicity.

The NYSDEC (1993) sediment quality guidelines were calculated using the EPA 1991 water quality criterion and an organic carbon normalized partition coefficient (K_{oc}) of $10^{6.14}$. The chosen partition coefficient is generic and not necessarily applicable to the Hudson River. In fact, Hudson River field data indicate a K_{oc} about a factor of 3 to 4 lower than the generic value (QEA 1999). Thus, the NYSDEC numbers provide no validation of the SEC values.

10.2871



Amphipod mortality versus PAHs as a function of toxicity levels in LA Harbor and the Hudson-Raritan Estuary
ERM-EPA
ERM-NOAA
narcosis
Percent mortality
ERL
AEL-H
AEL-L
PAHs (ng/g)
◆ level 1 = non toxic △ level 2 = significant ○ level 3 = Highly significant



Amphipod mortality versus PCB concentrations as a function of toxicity levels in LA Harbor and the Hudson-Raritan Estuary
narcosis
Percent mortality
B
C
A
ERL
ERM
AET-L
AET-H
PCBs (ng/g)
◆ level 1 = non significant △ level 2 = significant ○ level 3 = highly significant

10.2872

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