United States Department of the Interior

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Peer Review Panel
Housatonic ERA
Lenox, MA

Thank you for the opportunity to provide comments on the Ecological Risk Assessment for the General Electric (GE)/Housatonic River Site, Rest of River, July 2003, as prepared by Weston Solutions for the US EPA and the US ACOE.

This ERA is the most comprehensive Risk Assessment ever conducted in the Northeast. We recognize and commend EPA, ACOE and all associated contractors for the completion of a very complex, and challenging ERA. The ERA represents the compilation and analysis of an enormous amount of data from field and laboratory studies conducted over the last several years along with extensive state-of-the-art probabilistic and food chain modeling to augment site-specific studies and provide a more comprehensive picture of potential risks and uncertainties.

The following are brief summary comments regarding the evaluation of the general items specified in the Consent Decree :

1. The ecosystem of the Housatonic River, primarily the Primary Study Area (PSA), was comprehensively characterized with regard to biotic communities. Extensive, detailed field studies were conducted to delineate and quantify the type and number of terrestrial and aquatic habitats, populations and species within the varied communities existing in the Housatonic River and its floodplain. This information was appropriately applied in the Problem Formulation phase and served as the basis for identifying appropriate assessment endpoints, illustrating complete exposure pathways, providing a relational depiction of COPC and assessment endpoints and allowing for additional risk hypotheses.

2. The screening of Contaminants of Potential Concern (COPC) was comprehensive and accurate. Assessment and measurement endpoints centered around the survival, growth and reproduction of a variety of communities representative of the majority of biota present in the PSA. Measurement endpoints were traditionally focused on very detailed studies to explore the potential exposure and effects to individuals from Contaminants of Concern (COC), with subsequent extrapolation to population/community impacts. Study design for the varied and wide-ranging measurement endpoints was scientifically sound and defensible.

3.

A. The EPA studies were conducted with the utmost scrutiny and scientific rigor. This statement is based on the fact that several rounds of high-level internal and external peer review were conducted by nationally-respected researchers prior to, during and after studies were designed and implemented.

B. The GE studies were conducted without prior scrutiny from cooperating agencies and trustees. Therefore, scientific method, study design and measurement and assessment endpoints were not agreed upon by all parties before or after the initiation and completion of their studies. We believe that GE had parallel but separate interests in conducting their studies. We also believe that GE conducted their studies within the bounds of reasonable scientific and professional ethics. However, in some instances, there is insufficient information necessary to make important distinctions between their findings and the EPA study findings. The majority of this issue may have been easily avoided with consultation prior to study implementation. EPA incorporates GE's studies in the ERA in appropriate areas and provides reasonable critiques on the effects and non-effects data.

C. Exposure estimates were based on both study-specific data and literature-derived models. Study-specific exposure data were available for a number of assessment endpoints and were applied in a scientifically representative manner. Literature-derived exposure data were necessary for several assessment endpoints and were attained by thorough literature searches and were also applied in a scientifically representative manner.

D. Effects metrics were also based on study-specific data and literature-derived models and were generally representatively applied. In some cases, study-specific data were used in conjunction with literature-derived models to characterize potential risks to an indicator species/class. In some cases, modeled effects data over-estimated the effect potential when compared to site-specific data. Generally, site-specific data are preferable compared to modeled data but each dataset has important qualifiers. Environmental variables may mask or magnify site-specific COC effects whereas imperfect model assumptions and inputs can skew model outcomes. Therefore, we suggest that both inputs and outcomes of both datasets be carefully reviewed for consensus.

E. The enormous quantity of data was analyzed in a variety of manners. As is apparent throughout the ERA, statistics play a huge role in quantifying and characterizing risk. It appears that EPA did a commendable job conducting and presenting the study-specific and modeled data. However, as with all statistical analyses there is a wide range of potential statistical methods and interpretations. It is not apparent in all cases how certain studies merit inclusion or exclusion based on statistical analysis. Further description of statistical procedures may allow for a better understanding of the issues and decisions based on statistical analyses.

F. The characterization of risk was again based on site-specific data and literature-derived models. In many instances, non-site-specific species were utilized for model inputs due to a lack of literature effects data on site-specific species. This is an inherent problem in almost every risk assessment conducted.. In some cases, the risk characterization appears conservative based on effects endpoints for potentially more sensitive species. However, EPA has acknowledged this conservative approach and attempted to address it through weighting criteria in the Weight of Evidence (WOE) process.

G. Inherent in all risk assessments that conduct field studies and modeling efforts is a large array of uncertainties related to study design, uncontrollable variables, and assumptions. The ERA has attempted to identify and classify major uncertainties through each step and phase of investigation. It is impossible to identify and address all uncertainties and it is up to the reviewers of the ERA to decide whether specific uncertainties decidedly undermine study outcomes. We believe within the limits of normal site investigations and large-scale ERAs that the uncertainties outlined do not unduly compromise study findings.

H. The WOE approach was appropriately used in the ERA based on fundamentals originally authored by the MA Weight of Evidence Workgroup. However, the WOE has a certain amount of subjectivity built into its process. Therefore, a mechanism to further assign quantitative values to weighting categories may assist in making weighting seem less subjective. Generally, the ERA WOE attempts to quantify numerous aspects of multi-measurement assessment studies and does so in a relatively consistent representative manner.

I. Modeling efforts conducted for reaches that had no site-specific studies utilized the best available literature studies. Unfortunately, site-specific species data were again lacking for several species and elevated uncertainty was associated with modeled risks. These modeled risks were presented in a relatively representative manner with uncertainty identified and characterized.

J. Generally, the conclusions drawn in the ERA are supported by the preponderance of evidence and the detailed evaluation of the large and diverse dataset via the WOE approach.

4. The following is a summary or our opinions per Assessment Endpoint category:

Benthos: Chronic laboratory and in-situ toxicity tests, TIE evaluations, sediment quality benchmarks and benthic community impacts combine to indicate a community at high risk.

Amphibians: Wood frog and leopard frog multi-stage and phase tests combine to indicate a variety of impacts and elevated risk. These appear to be dependent on life stage and strategy with potentially severe implications to more sensitive species. The GE studies document reproduction but do not relate it effectively to larval survival, population effects or a range of relevant PCB concentrations across both species.

Fish: Fish tissue concentrations, early life stage studies and adult reproductive effects indicate substantial risk to the fish community. The GE single species study on LMB documents reproduction but does not fully substantiate nest success and reproductive fitness or overall fish community health.

Insectivorous Birds: Tree swallow and robin studies indicate that low levels of PCBs do not affect their reproductive success. However, the tree swallow study indicated that high tissue levels may reduce hatching success. This potential effect and modeling results have ramifications for these and other more sensitive species linked to areas of higher contamination and high risk feeding strategies. The GE robin study did document unimpaired reproduction and a variety of no-effect variables but did not study birds with consistently high PCB levels or conduct multi-year studies.

Piscivorous Birds: The two species profiled indicate mixed results relative to risk. The GE kingfisher study documents reproduction within the PSA but the study is potentially flawed due to sample size, sample location and a lack of correlation between PCBs in prey, eggs and nestlings.

Osprey modeling predicts high potential risk but is based on conservative assumptions. Area use factors would provide less conservative inputs for average use scenarios. Literature values indicate significant potential risk to avifauna in general based on prey item concentrations documented in the PSA. Therefore, we assume that sensitive avifauna utilizing high risk feeding strategies will incur sublethal and/or reproductive effects.

Piscivorous Mammals: The mink feeding study with kit mortality and significant adult mandibular squamous cell proliferation at low PCB concentrations indicates a high degree of risk. Additionally, literature values underscore the high likelihood of mustelid impacts based on PSA prey concentrations. The GE study does document the presence of mustelids in the PSA, specifically during winter months, but does not document a viable breeding population.

Omnivorous and Carnivorous Mammals: The modeling data and findings for the red fox appear to be reasonable. However, modeling and site-specific data as presented for the small mammal component, are conflicting and could benefit from additional scrutiny.

Threatened and Endangered Species: The literature species profiles suffer from a lack of species-specific effects data and the potential sensitivity of the species to manmade perturbations. Therefore, conservative assumptions have been made with regards to exposure and effects at the individual level. We feel that these assumptions are warranted based on the documented historic presence and potential for breeding individuals in the future. Area use factors may also be appropriate for predicting average use scenarios.

PCB heterogeneity, congener distribution and weathering processes in abiotic and biotic media in the Housatonic River system inherently complicate the evaluation of the potential exposure and effects of PCBs. Consistent with many risk assessments, not all of the studies conducted supported a finding of significant risk from PCBs. Additionally, some studies evidenced effects that were not completely aligned with effects produced in other studies, relative to PCB concentrations. However, the number and scope of investigations conducted in support of the ERA provide a relatively comprehensive picture of potential risk. Individual studies, with a wide range of taxonomic representation, involved multi-level assessments. The literature-based deterministic and probabilistic modeling generated hazard quotients and probability distributions that allowed for comparison to or incorporation of site-specific data. The NOAEL/LOAEL effects benchmarks generated from these studies and models demonstrate pronounced effects or potential for effects in several taxonomic groups while other taxa appear to be less impacted based on gross measures such as survival or reproductive success. Evaluation of the magnitude and consistency of PCB concentrations throughout the Primary Study Area (PSA), relative to literature and site-specific studies, infer that numerous acute and chronic impacts are probably occurring to a variety of biota, including and in addition to indicator species.

While it was not possible for EPA to investigate the effects of PCBs on every species or potential mode of biological action, numerous studies were conducted on select indicator organisms that were appropriate and representative of species assemblages found within the Housatonic River PSA. As stated in the ERA, individual species, even within similar taxa, may exhibit different toxic responses to PCBs based on their Ah-mediating mechanisms and cytochrome P450 capacity. EPA addressed the potential for impacts to species assemblages similar to indicator species through comparison of foraging behavior, dietary composition, home ranges and body weights. In most cases, associated species were also found to be at potential risk though species-specific physiologic

mechanisms for PCB disposition are unknown for most species. Based on literature studies of surrogate species, we believe that the risk potential is high and may be even more pronounced in species other the indicator species selected for the ERA.

EPA conducted numerous traditional and non-traditional assessment studies to evaluate grosschanges in community structure, specific toxic responses and survival/reproductive success. However, genetic, immunological, histological, endocrinological and behavioral impact studies across taxa were not consistently included in the ERA. Literature-based studies infer that numerous mammalian, avian and aquatic species may be exhibiting PCB-induced toxic responses in these more basic physiological functions within the Housatonic PSA. In many cases, these potentially chronic impacts would not be discernible in relatively short-term survival and reproduction studies. DNA adduct formation and oxidative DNA damage, compromised immune systems, cellular dysfunction, endocrine disruption, and courtship/parental disruption are a few of the potential effects expected to impact site-specific species. These chronic impacts could potentially alter the gene pool, cause population shifts, promote carcinogenicity, allow for reduced plasticity of individuals and populations, and impact reproductive success. We realize that evaluation of many of these potential effects would have added greatly to assessment costs, required more involved long-term studies and been challenging to interpret, relative to assessment endpoints.

In summary, EPA's Weight of Evidence approach incorporates a wide variety of studies and modeling in a representative and comprehensive manner. The findings of the ERA, in conjunction with the issues mentioned above, clearly show that substantial and extensive impacts are occurring to a variety of species within portions of the PSA.

Paraphrasing a statement made by colleagues in a SETAC journal Learned Discourse. The underlying fundamental endpoints of any ERA are: clean air, clean water, clean soil, and clean sediment. We believe that healthy biota, not just reproducing populations, would be the result. Based on these tenets all else follows. The devil is in the details as is apparent from the comments and testimonies presented today. In the final analysis it comes down to how clean and how healthy we and the public we represent want things to be and find to be acceptable. That's our real charge.

Thank you for your time, consideration and participation on the Peer Review Panel.

Sincerely,

Kenneth C. Carr
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