Comments of the General Electric Company on the U.S. Environmental Protection Agency's Ecological Risk Assessment for the Housatonic River Site – Rest of River

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January 13, 2004

Introduction

- **Format of presentation:**
  - **General comments – Andy Silfer**
  - **Species-specific comments – Ken Jenkins**
  - **Comments on ERA Summary – Ken Jenkins**
  - **Overall GE conclusions – Andy Silfer**
- **ERA includes an extensive amount of data, including numerous site-specific studies, and applies a weight-of-evidence analysis.**
- **Due to time limitations, this presentation focuses on most critical areas of disagreement with ERA.**
- **Main issues relate to how the ERA has interpreted the study data, applied the weight-of-evidence analysis, and drawn conclusions from the data.**

Overview of GE Position: ERA Does Not Interpret and Weight the Study Results Objectively To Assess Impacts to Local Populations and Communities

- **In interpreting and drawing conclusions from the various studies, it is critical that the ERA:**
  - **Evaluate the study results in terms of their potential impacts to local populations and communities, not individuals.**
  - **Give appropriate weight to the results of the various studies, with emphasis on site-specific data that assess potential impacts to actual local populations.**
  - **Interpret the study results in an objective and consistent manner, avoiding conclusions that are not supported by the data.**
  - **Present the analyses in a transparent and reproducible manner.**
- **We will show in this presentation that current ERA does not meet these criteria.**

Primary Study Area Provides Appropriate Setting for Use of Field Studies

- **ERA evaluates Housatonic River ecosystem that has experienced long term exposure – PCB use began in 1932.**
- **The ERA Rest of River area is composed of 17 river reaches – from confluence of East and West branches to Long Island Sound.**
- **The Primary Study Area (PSA) is represented by Reaches 5 and 6 and covers the area to the Woods Pond Dam.**
- **Extensive sampling by EPA and GE confirm that the PSA contains approximately 90% of PCB mass in river.**
- **PSA contains the highest PCB levels. Levels decline rapidly below Woods Pond Dam (RFI Figure 4-12, BBL & QEA 2003).**
- **PSA is composed of riverine and adjacent floodplain wetland and upland habitats and provides appropriate setting for field studies evaluating site-specific risks.**

Despite Long-Term PCB Exposure, Local Wildlife Populations and Communities Are Abundant and Diverse

- **EPA's Ecological Characterization of PSA shows diverse communities with abundant wildlife – including:**
  - **12 mussel species**
  - **38 dragonfly species**
  - **41 fish species**
  - **5 reptile species**
  - **14 amphibian species**
  - **139 bird species**
  - **42 mammal species**
- **ERA attempts difficult task of determining if PCB-related effects are present in a river and floodplain setting populated with abundant populations and communities.**
- **GE's comments can be summarized in several major themes that run throughout ERA.**

ERA Fails To Adequately Evaluate Potential Impacts on Local Populations and Communities

- **Since remedial actions "should not be designed to protect organisms on an individual basis … , but to protect local populations and communities of biota," ecological risk assessments "should use site-specific assessment endpoints that address chemical specific potential adverse effects to *local populations and communities* of plants and animals" (EPA 1999, pp. 3, 5).**
- **Effects on individual organisms (even reproductive effects) do not necessarily translate into effects on local populations due to compensating factors in field populations (e.g., density-dependence).**
- **While EPA guidance allows for effects on local populations and communities to be extrapolated from effects on individuals (EPA 1999, p. 3), the assessment endpoints should remain focused on local populations or communities.**
- **However, ERA focuses almost entirely on individual-level assessment endpoints (except for one endpoint each for benthic invertebrates and amphibians), without evaluating potential impacts on local populations and communities.**
- **Recommendation: ERA should evaluate population- and community-level effects, and assess individual-level endpoints *only* in context of relevance to local populations and communities.**

ERA Underweights Site-Specific Field Studies and Overweights Hazard Quotients

- **Under EPA guidance, site-specific data should be used in ecological risk assessments wherever practicable (EPA 1999, p. 4).**
- **ERA does not adequately recognize strengths of site-specific field studies, which:**
  - **Reflect actual exposure and responses of local populations.**
  - **Address responses within the context of natural population dynamics and a full range of environmental stressors (e.g., competition, predation, climatic variation).**
  - **Provide direct linkage to appropriate assessment endpoints.**
  - **Avoid the need for uncertain extrapolations from literature.**
- **ERA overemphasizes and overweights modeled HQs, which:**
  - **Do not address population-level effects.**
  - **Reflect highly conservative literature-based exposure assumptions and often inappropriate toxicity values.**
  - **Have high uncertainty.**
  - **Are contradicted by field studies at this site.**

ERA Makes Incorrect or Unwarranted Interpretations

- **ERA incorrectly interprets the results of some studies as showing ecologically relevant PCB effects when the underlying data do not support that conclusion due to:**
  - **Study design or implementation flaws that preclude reliable conclusions;**
  - **Absence of exposure-response relationships; and/or**
  - **ERA's selective reliance on a subset of endpoints that show effects, ignoring numerous endpoints that show no effects.**
- **ERA unduly minimizes studies that show no effects by:**
  - **Giving them low weight;**
  - **Inaccurately designating their results as "undetermined"; and/or**
  - **Including unsupported speculations to explain away the results.**
- **ERA fails to present several analyses in a transparent and reproducible manner.**

Specific Receptor Group Comments

Kenneth D. Jenkins, Ph.D., BBL Sciences

- **Benthic Invertebrates**
- **Amphibians**
- **Fish**
- **Insectivorous Birds**
- **Piscivorous Birds**
- **Piscivorous Mammals**
- **Omnivorous/Carnivorous Mammals**
- **Threatened and Endangered Species**

Benthic Invertebrates

- **Lines of Evidence in ERA:**
  - **Chemical measurements (water, sediment, tissue)**
  - **Toxicity tests (laboratory, in-situ, TIE)**
  - **Benthic community field study**
- **Key Points:**
  - **ERA incorrectly interprets results of EPA's toxicity tests to set PCB effects threshold lower than supported by the test data.**
  - **Thresholds derived from EPA's toxicity tests are rebutted by EPA's benthic community study results, which show no PCB-related adverse effects.**

ERA's Sediment Effects Threshold Is Not Supported by Toxicity Test Data

- **ERA establishes sediment effects threshold of 3 mg/kg PCBs based on EPA's toxicity test results.**
- **There are four main problems with how this threshold was derived:**
  - **ERA relied primarily on sediment exposure point concentrations based on the medians from several sampling events over a 7-month period, rather than the actual sediment PCB concentrations to which test organisms were exposed in the toxicity tests (the "most synoptic" data).**
  - **ERA included a comparison of test results to laboratory controls that the ERA acknowledges did not account for important physical/chemical differences between the controls and the test samples.**
  - **ERA used multiple measures of some of the same endpoints – e.g., same endpoint at different times, two measures of same endpoint – rather than taking the average of the six lowest *distinct* effects endpoints.**
  - **ERA included 20% effects levels, which are likely too low in magnitude to be statistically distinguishable from reference site responses.**

Correction of ERA's Errors Would Raise Sediment Effects Threshold Based on Toxicity Tests by ~ 3X

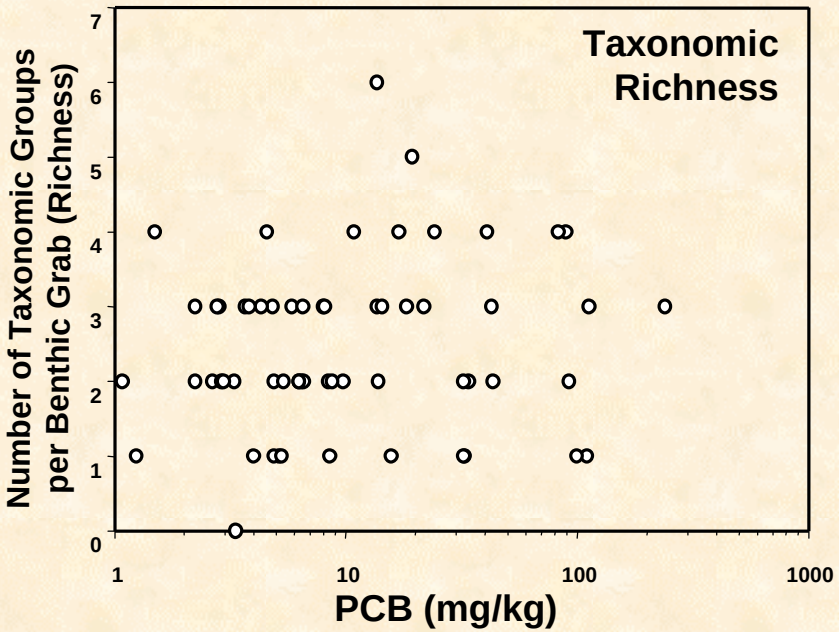
- **Correcting for the above errors, toxicity test data alone would support a sediment effects threshold of ~ 8 mg/kg PCBs. This is based on:**
  - **Use of "most synoptic" sediment data**
  - **Comparisons only to reference sites, not lab controls**
  - **Use of average of six lowest *distinct* endpoints**
  - **Use of 50% effects levels**
- **This threshold is uncertain due to reliance on comparisons to reference sites that may not be comparable to PSA sites.**
- **The benthic community field study shows that this threshold overstates effects on the actual benthic community, since that study demonstrated no PCB-related effects at higher PCB concentrations.**

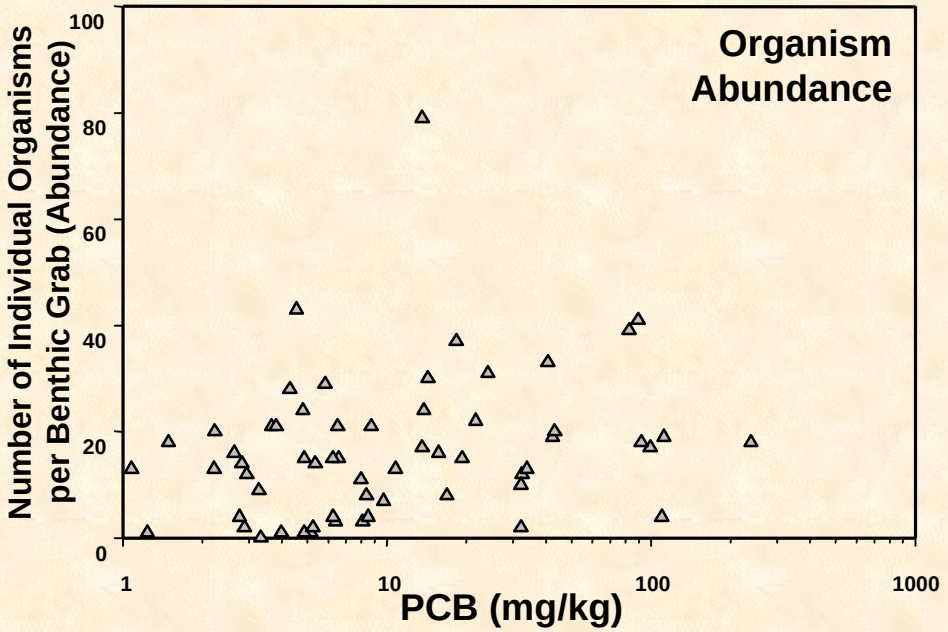
EPA's Benthic Community Field Study Results Show No PCB-Related Effects

- **EPA's benthic community field study addressed both fine-grained and coarse-grained sediment types.**
  - **Fine-grained stations had mean PCB levels of 2 to 16 mg/kg, with maximum of 50 mg/kg.**
  - **Coarse-grained stations had mean PCB levels of 8 to 24 mg/kg, with maximum of ~ 150 mg/kg.**
- **At fine-grained sediment stations, ERA correctly concludes that study showed no PCB effects:**
  - **No differences in community metrics compared to reference sites.**
  - **No exposure-response relationship with PCBs.**
- **At coarse-grained sediment stations, ERA incorrectly concludes that study showed PCB effects:**
  - **While differences were observed between target and reference sites (e.g., species abundance and richness),**
  - **Study did not account for important habitat factors and shows no exposure-response relationship with PCBs within PSA sediments.**

Benthic Community Metrics at Coarse-Grained Sites Show No PCB Exposure-Response Relationship

- **ERA's comparison of target and reference coarse-grained sites did not account for many potential habitat differences that are known to significantly affect benthic community structure (e.g., water depth, velocity, pore water ammonia).**
- **Results do not show an exposure-response relationship between benthic community metrics and PCBs at coarse-grained sites within PSA.**





Multiple Regression Analyses Show Lack of Meaningful PCB Influence on Benthic Community Structure at Coarse-Grained Sites

- **Multiple regression analyses by BBL and Drs. Scott Cooper and Erik Silldorff (UC-Santa Barbara) show that PCBs account for only a small fraction of variability in community metrics at coarse-grained sites.**
  - **Initial analysis included PCB concentration, % fine sediment, and TOC content (other physical-chemical parameters not measured).**
    - **These factors together accounted for ~ 10 to 30% of variability in community metrics.**
    - **PCBs accounted for only 1 to 6.8% of variability.**
  - **Additional analysis included sand and PCBs vs. total organism abundance. These factors together accounted for 31% of variability in abundance, with PCBs accounting for only 3%.**
- **These analyses show that over 93% of variability in community metrics at coarse-grained sites is unrelated to PCBs.**

EPA's Multiple Regression Analysis Confirms Lack of Meaningful PCB Influence on Benthic Community Structure

- **EPA conducted new multiple regression analysis in response to peer reviewers' questions. Performed for abundance of 35 taxa at all sites, considering PCBs and % fines (but not TOC).**
- **Results show strong influence of % fines, but not PCBs.**
  - **21 taxa – no significant relationship with PCBs.**
  - **12 taxa – significant relationships with both PCBs and % fines or significant interactions; relative contributions not distinguishable.**
  - **2 taxa – significant relationship with PCBs only and no interactions; but PCBs explained only ~ 2 to 9% of variability.**

Variable	Total Number of Significant Relationships	Sole Significant Variable with No Interactions	Range of R^2 Values for Sole Significant Variable
All Taxa			
PCBs	14 of 35	2 of 35	0.019 - 0.091
% Fines	28 of 35	14 of 35	0.026 - 0.517
Chironomids			
PCBs	8 of 14	2 of 14	0.019 - 0.091
% Fines	12 of 14	5 of 14	0.026 - 0.425

Benthic Invertebrates – Conclusions

- **ERA overstates magnitude of risks to benthic invertebrate community and certainty of conclusions.**
  - **ERA incorrectly interprets toxicity test results and thus sets threshold lower than supported by those data.**
  - **ERA incorrectly interprets results of benthic community field study, which showed no adverse PCB-related effects at fine- or coarse-grained stations.**
- **While toxicity test data would support sediment effects threshold of 8 mg/kg PCBs, field data indicate no PCB-related community impairment at sites with higher PCB levels (means up to 16 mg/kg at fine-grained sites and up to 24 mg/kg at coarse-grained sites).**
- **Thus, based on field community study, appropriate threshold for benthic community impairment should be > 16 mg/kg (fine-grained) or > 24 mg/kg (coarse-grained).**

Amphibians

- **Lines of Evidence in ERA:**
  - Site-specific leopard frog toxicity study (EPA)
  - Site-specific leopard frog egg mass survey (GE)
  - Site-specific wood frog toxicity study (EPA) (and use of those data in population model)
  - Site-specific wood frog study of early life-stage exposure (GE)
  - Comparison to literature-based effects thresholds (EPA)
- **Key Points:**
  - ERA misinterprets the leopard frog data, which do not provide reliable evidence of adverse effects.
  - EPA's wood frog study provides no evidence that the effects observed result in adverse impacts on local populations.
  - ERA's MATCs are overly conservative and not relevant to sustainability of local populations.

Overview of EPA's Leopard Frog Toxicity Study

- **Study design:**
  - **Collection of male and female frogs from PSA and reference locations.**
  - **Evaluation of reproductive status of the adult frogs and the growth and development of the offspring related to PCB exposure.**
- **Study implementation:**
  - **Due to lack of adult frogs at reference locations, "external reference frogs" were purchased from Carolina Biological Supply.**
  - **Most PSA adult female frogs found to have immature oocytes.**
  - **EPA subsequently collected fertilized egg masses and larval frogs from PSA for laboratory evaluation.**
- **ERA interpretation:**
  - **Relies on comparisons between PSA frogs and commercially purchased frogs to claim reproductive and developmental effects.**
  - **Relies on lack of mature oocytes in PSA frogs to claim impaired reproduction in adult frogs.**

EPA's Leopard Frog Study Is Significantly Flawed

- **Scientifically inappropriate to compare target and commercially purchased frogs to assess the presence and magnitude of effects in adults and offspring:**
  - **Commercially purchased frogs were not exposed to environmental conditions at site, thus likely at different reproductive states.**
  - **Inappropriate to compare "randomly" collected field specimens with commercially purchased frogs specifically selected for gravidity and health.**
  - **PSA frogs were subjected to greater handling stress (e.g., holding times and transportation).**
  - **Authors of underlying report (FEL 2002) recognized purchased adult frogs "were not exposed to the same environmental stressors" as PSA frogs, and thus excluded them from their statistical analyses.**
- **Conclusion that adult PSA female frogs had reproductive impacts (due to immature oocytes) most likely due to collection outside the prime breeding season.**
  - **Adults collected March 25 - April 22, 2000, when surface water temperatures in PSA are ~ 8-10°C (ERA, p. 4-34); leopard frogs do not begin breeding until water temperature reaches ~ 10°C.**

GE's Leopard Frog Egg Mass Survey Shows Significant Reproductive Activity in Local Population

- **Survey undertaken to determine if EPA finding of immature oocytes in female leopard frogs was due to timing of collections or other factors.**
  - **Initial reconnaissance identified 44 ponds in PSA with potentially suitable habitat; ponds with even marginal habitat included.**
  - **Ponds searched for egg masses on 15 days between April 21 and May 8, 2003 during peak breeding season (avg. water temp. = 15°C).**
  - **216 leopard frog egg masses identified in 17 ponds; developing larvae visible in many egg masses.**
  - **Ponds without egg masses all had habitat/environ. limitations (e.g., little vegetative cover, non-permanence of pond, water temp. < 10°C, water depth > 65 cm, pH not 6.5-8.5).**
- **No relationship between sediment PCB levels and numbers of egg masses found.**

Results rebut EPA study finding of reproductive failure in PSA leopard frogs.

Comparison of Egg Mass Density Across Studies Is Misleading

- **In 12/18/03 presentation, EPA compared egg mass density in PSA ponds with those from other studies (Hine et al. 1981; Gilbert et al. 1994).**
- **This comparison is misleading because:**
  - **Does not take account of differences in habitat (e.g., Hine et al. selected 7 ponds with best habitat out of 269 surveyed; Gilbert et al. included meadows as well as shallow marsh).**
  - **Egg masses are typically laid in small areas within the breeding pond (Merrell 1968, 1977, Hine et al., Gilbert et al.), clustering in areas with best habitat. Thus, not appropriate to look at density alone; should also consider other measures (e.g., number of egg masses/pond).**
  - **Considering both number/pond and density, performance at PSA is within range reported in literature.**

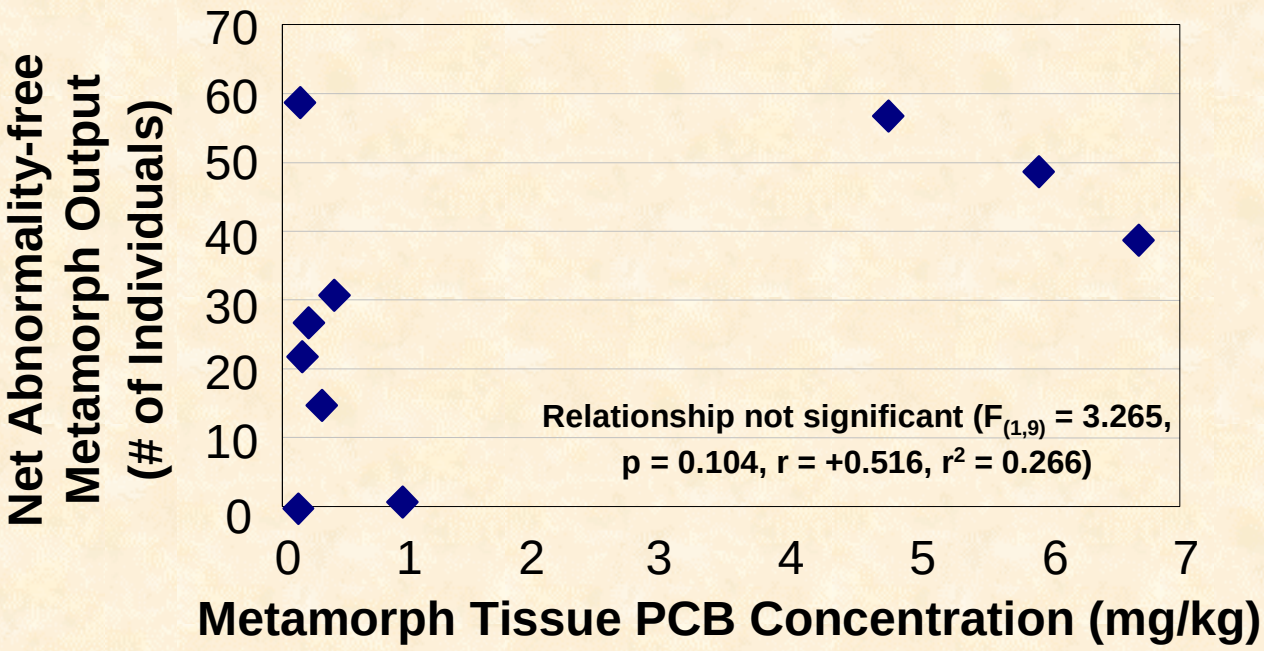
Study	Areas Included	Mean No. per Pond or Habitat	Mean Density (#/ha)
Hine et al. (1981)	7 best ponds of 269	11.5	277
Gilbert et al. (1994)	4 of 7 habitats w/in 6 ha	61	58
GE study of PSA	All ponds with egg masses	12.7	78

ERA Ignores Wood Frog Study Results That Are Directly Relevant to Sustainability of Local Populations

- Study involved collection of egg masses (Phase I), larvae (Phase II), and metamorphs (Phase III) from PSA vernal pools and reference areas.
- In total, study evaluated eleven endpoints.
- No adverse effects observed for nine endpoints, including survival, hatching success, metamorphosis, and egg mass fertilization.
- ERA focuses on two endpoints where effects were found:
  - Percent malformations
  - Sex ratio (only in Phase III metamorphs)
- These two endpoints are not directly related to sustainability of local populations.
- Endpoints showing no effects (e.g., survival, metamorphosis) are more relevant to sustainability of local populations.

Analysis Shows No Relationship Between PCB Exposure and Metamorph Output

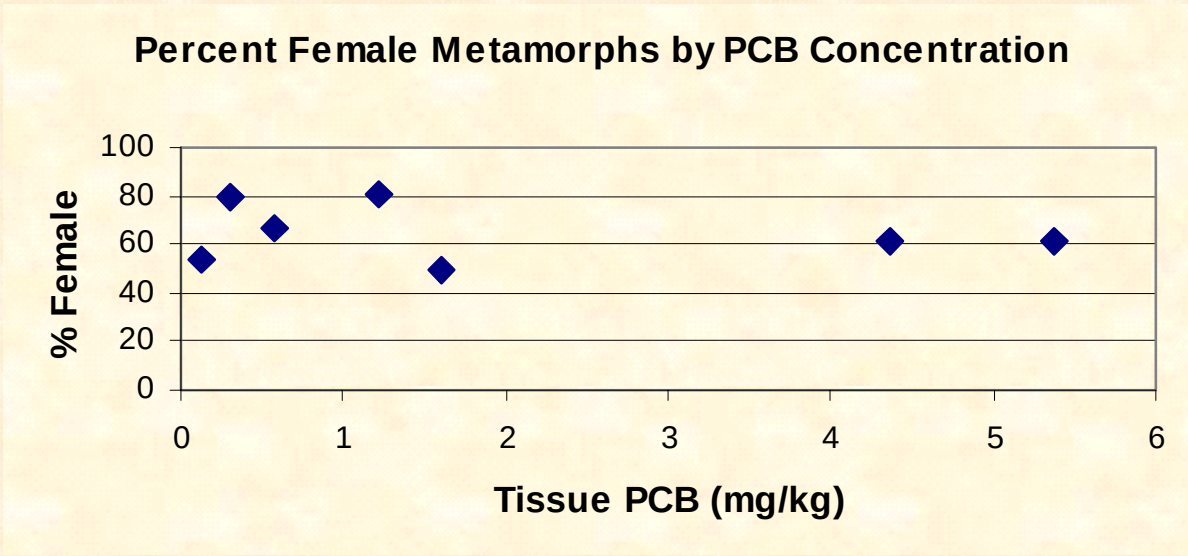
- To better understand implications of abnormalities for recruitment of metamorphs into the population, GE analyzed relationship between PCB exposure (in sediment, egg mass, and metamorph tissue) and net abnormality-free metamorph output (in Phase I).
- No relationship was found. Example:



Observed abnormality rates do not affect recruitment of viable metamorphs into local population.

Wood Frog Sex Ratio Data Do Not Provide Reliable Evidence of Adverse PCB-Related Effects

- **ERA relies on Phase III metamorph sex ratio data (more females than males).**
- **Since these metamorphs were collected from field, not possible to distinguish PCB effects from effects of other factors known to affect sex ratio (e.g., temperature, pH).**
- **However, in a separate field study, EPA found sex ratio in adult PSA frogs to be within normal range (44-52% female).**
- **In addition, there was no significant relationship between tissue PCB levels and sex ratio in Phase III metamorphs (excluding one site with only three metamorphs).**



GE's Wood Frog Study Shows Density-Dependence and No Consistent Effects of Maternally Transferred PCBs

- **Conducted by Dr. William Resetarits (Old Dominion Univ.).**
- **Wood frog egg masses collected from 5 ponds and hatched in lab.**
- **Newly hatched larvae analyzed for PCBs and divided into three groups: High (11.2 mg/kg); Low (3.28 mg/kg), and Very Low (0.89 mg/kg).**
- **Larvae placed in enclosures in 2 ponds with very low sediment PCB levels at varying initial densities.**
  - **Original design was to place enclosures in ponds with varying sediment PCB levels, but could not be done because drought conditions reduced water levels in most ponds.**
- **Measured survival and size of metamorphs and surviving tadpoles.**
- **Results showed:**
  - **Expected density-dependence – i.e., negative relationship between initial density and % survival, proportion metamorphs, and size of metamorphs and surviving tadpoles.**
  - **No consistent exposure-response relationship between hatchling PCB levels (from maternal transfer) and survival or growth.**

ERA's Wood Frog Population Model Is Flawed

- **Model does not take adequate account of density-dependence – a key mechanism in frog population dynamics.**
  - **EPA admits, and GE's wood frog study and other studies in literature show, that frogs exhibit strong density-dependence.**
  - **ERA claims that it incorporated density-dependence in model by assuming a maximum size (ceiling) for frog population at each pond.**
  - **But this has no effect on population growth below ceiling. Below ceiling, all parameters in ERA model are density-independent.**
  - **If base population is assumed to be stable or declining (as in ERA), a density-independent model will inevitably predict rapid population extinction.**
- **Due to inappropriate assumptions, ERA model overpredicts risk of extinction.**
- **For example, model predicts that PSA wood frog population has 50% probability of extinction in:**
  - **32 years in absence of PCB exposure,**
  - **17-30 years with PCB exposure, and**
  - **Even faster (< 6 years for both cases) if population assumed to be already declining.**

Presence of Wood Frogs in PSA Rebuts ERA Model Predictions

- **Given PCB presence in PSA over 70 years, documented presence of wood frogs in PSA rebuts model conclusions.**
- **In December 18 presentation, EPA advanced various speculations to explain presence of frogs at the site despite model predictions:**
  - **Local populations may be en route to extinction.**
  - **Site may be a population sink with immigration from uncontaminated populations.**
  - **Population may be stable due to density-dependence.**
- **No support for first two speculations. Most obvious explanation is that population is stable due to density-dependence and thus model is fundamentally flawed.**

Conclusion: Model is unreliable for assessing PCB impacts to local frog population.

ERA's MATCs Are Overly Conservative

- **ERA establishes site-specific effects levels of 3 mg/kg PCBs in pond sediments and 1 mg/kg PCBs in frog tissue, based on the sex ratio and malformation results from EPA's wood frog toxicity study.**
- **The data do not support these thresholds:**
  - **There is no relationship between tissue PCB concentrations and skewed sex ratios in Phase III metamorphs, and there is no evidence that adult wood frogs have skewed sex ratios.**
  - **The malformation rates observed in this study did not affect survival, metamorphosis, or net output of viable metamorphs, and thus would not affect recruitment into local populations.**

Amphibians – Conclusions

- **ERA overstates magnitude of risks to frogs.**
  - **EPA's leopard frog toxicity study does not provide scientifically sound evidence of adverse effects.**
  - **GE's leopard frog egg mass survey rebuts ERA's conclusion of reproductive failure in PSA.**
  - **EPA's wood frog study provides some evidence of increased abnormalities in individual frogs, but they do not affect the local populations.**
  - **Wood frog toxicity study's sex ratio data are inconsistent with EPA's field data and do not provide reliable evidence of adverse PCB-related effects.**
  - **ERA's population model is fundamentally flawed and rebutted by EPA field data on presence of wood frogs in PSA.**
  - **ERA's MATCs are not supported by the data.**

Fish

- **Lines of Evidence in ERA:**
  - Two-phase fish toxicity studies (EPA)
    - Phase I: Lab study of largemouth bass from field. Evaluated reproduction and development of offspring.
    - Phase II: Eggs of non-native species injected with extracts from Phase I fish. Eggs and fry evaluated for survival and developmental effects.
  - Field study of largemouth bass habitat, reproduction, and population (GE)
  - Field studies of fish community (EPA and GE)
  - Comparison of fish tissue concentrations to literature-based effects metrics (EPA)
- **Key Points:**
  - EPA's toxicity study data do not show consistent PCB exposure-response relationships.
  - Field studies show a self-sustaining population of largemouth bass and a diverse fish community in PSA.

Phase I Toxicity Study Data Do Not Show Consistent Exposure-Related PCB Effects

- **Phase I study: Collected largemouth bass from 3 locations in River (Reach 5BC, Woods Pond, Rising Pond) and 1 reference site (Three-Mile Pond).**
- **Data show inconsistent incidence and magnitude of effects among sites and developmental stages; no PCB exposure-response relationships.**
- **Examples for survival and some abnormalities (from Tillitt et al. 2003a):**

Observation	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
(mg/kg PCB whole body composite)	0.106	43	108	149
Mean Survival to Swim-up (%)	68	45	57	**28***
Mean Survival to 15 Days Post Swim-up (%)	19	5	25	20
Median Survival to 15 Days Post Swim-up (%)	28	**2***	26	13
Craniofacial Deformities (# per 1000)	0	1	1	3
Pericardial Edema (# per 1000)	36	33	**7***	40
Vertebral/Spinal Deformity (# per 1000)	46	42	**17***	54

* Significantly different from Three-Mile Pond reference site.

Lack of exposure-response relationships indicates that PCBs are unlikely to be responsible for effects.

Phase I Data on Swim Bladder Abnormalities Show No PCB Exposure-Response

- **Abnormalities do not show PCB exposure-response.**
- **Most occurred in only one spawn per location.**

Phase I Gross Pathologies (per 1000) at 15d Post Swim-up

Observation	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
(mg/kg PCB whole body composite)	0.106	43	108	149
Uninflated Swim Bladder	0	333	9	24
Partially Inflated Swim Bladder	0	120	429	88
Partially External Swim Bladder	0	67	27	24

Phase I Number of Affected Spawns at 15d Post Swim-up

Observation	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
(mg/kg PCB whole body composite)	0.106	43	108	149
Uninflated Swim Bladder	0 of 3	1 of 5	1 of 6	1 of 8
Partially Inflated Swim Bladder	0 of 3	1 of 5	1 of 6	2 of 8
Partially External Swim Bladder	0 of 3	1 of 5	3 of 6	1 of 8

- **Results not consistent with Phase II swim bladder data (discussed below).**

Phase II Toxicity Study Does Not Support ERA Conclusion of PCB Toxicity to Fish

- **Phase II study: Eggs of non-native fish (largemouth bass, rainbow trout, medaka) injected with extracts from Phase I fish (at various doses), as well as with TCDD and PCB-126; lab controls also used.**
- **Study showed no significant effects on survival of bass and trout injected with Housatonic River extracts.**
- **ERA incorrectly pools all abnormality data.**
- **However, individual abnormality endpoints show no consistent evidence of effects relative to reference site, lab controls, or PCB dose level.**
  - **For example, for numerous abnormalities, there were as many or more abnormalities in lab controls or fish exposed to reference site extracts as in the individual dose groups exposed to site extracts.**
  - **Among dose groups exposed to site extracts, data on individual abnormalities do not show consistent dose-response relationship.**

Phase II Data on Individual Abnormalities Do Not Show Dose-Related PCB Effects

Selected Abnormalities in Injected Largemouth Bass (# per 1000 at Swim-up)

Examples selected based on greatest number of abnormalities (other than swim bladder abnormalities) - Tillitt et al. 2003b

Craniofacial Abnormalities

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	17	0
Solvent Injected	0	0	17	0
1	0	34	22	0
2	0	0	52	0
3	0	0	17	0
4	0	80	52	0
5	190	0	0	0

Vertebral/Spinal Deformities

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	50	0	51	59
1	48	0	43	0
2	0	0	86	50
3	0	0	102	48
4	77	0	52	50
5	95	0	19	56

Eye Deformities

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	50	0	0	0
1	48	0	43	0
2	0	0	0	0
3	0	0	17	0
4	0	0	0	0
5	95	0	0	0

Pericardial Edema

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	17	0
Solvent Injected	50	0	0	0
1	0	0	43	0
2	0	0	34	0
3	0	0	0	0
4	0	40	34	0
5	48	0	19	0

Number of abnormalities varies independently of dose and location.

Phase II Data on Swim Bladder Abnormalities Show No PCB Dose-Response

- **Phase II data on swim bladder abnormalities are inconsistent with Phase I results.**
  - **External swim bladders found only rarely, with no dose-response.**
    - **For largemouth bass, found only in 2 of 28 treatments at swim-up (Doses 3 & 5 for Reach 5BC) and in 1 of 28 treatments at 15 days post swim-up (Dose 1 for Woods Pond).**
    - **None found in medaka or rainbow trout.**
  - **Uninflated or partially inflated swim bladders found in various treatments, with no dose-response.**
    - **Found frequently at swim-up in all treatments, including laboratory controls and fish exposed to reference site extracts, and showed no dose-response relationships.**
    - **Found only sporadically at 15 days post swim-up – e.g., for LMB, in only 4 of 28 treatments (2 lab controls and one dose each for Reach 5BC and Rising Pond).**
    - **These may reflect developmental stage, not abnormality.**
- **Inconsistencies in swim bladder abnormalities within and between Phases and lack of dose-response indicate that effects are likely associated with factors other than PCBs.**

Phase II Delayed Development Observed Mainly in Rainbow Trout, with No Consistent Dose-Response

Delayed Development

Largemouth Bass (Swim-up)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	**50**	0	0	0
1	0	0	0	0
2	0	0	0	0
3	0	0	0	**0**
4	0	0	0	0
5	0	0	0	**0**

Medaka (100h Post Hatch)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	0	0	0	0
1	0	0	0	0
2	0	0	0	0
3	0	**17**	0	0
4	0	0	0	0
5	0	0	0	0

Rainbow Trout (600 DTU)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	**24**	**40**	**45**	**38**
Solvent Injected	**8**	**32**	**89**	**29**
1	**8**	**25**	**84**	**52**
2	**32**	**66**	**86**	**12**
3	0	**54**	**619**	**29**
4	**54**	**40**	**266**	**86**
5	**25**	**87**	**620**	**212**

ERA's Tissue-Based Effects Metrics Derived from Toxicity Test Data Are Unsupported and Too Low

- **Effects level derived from Phase I for warmwater fish is unwarranted because Phase I did not show consistent dose-related effects.**
- **Effects levels derived from Phase II for warmwater fish are unsupported:**
  - **Based on pooling of all abnormalities and mortality when individual endpoints did not show consistent PCB dose-response relationships.**
  - **When expressed on TEQ basis, effects levels imply that the Housatonic PCB extracts are more toxic to fish than TCDD.**
    - **This contradicts numerous studies showing that TCDD is most potent dioxin-like chemical (e.g., Van den Berg et al. 1998, Wright and Tillitt 1999)**
    - **Result likely an artifact of pooling procedure; no basis for ERA's speculation that this finding is due to synergy of PCB mixtures or other PCB compounds not quantified in TEQ model.**
- **Effects level for coldwater fish downstream of PSA is based on dividing warmwater fish threshold by factor of 4, with no quantitative basis.**

Field Studies Show Self-Sustaining Bass Population and Diverse Fish Community in PSA

- **GE largemouth bass (LMB) reproduction study by Dr. Dudley Reiser et al. demonstrates widespread reproduction in PSA.**
  - **71 separate active nests observed, broods of fry observed in all sites monitored.**
  - **Young-of-year abundance and growth rate within ranges reported in literature for (uncontaminated) LMB systems.**
  - **Growth rate of adults in 90th percentile of all LMB populations evaluated for this parameter (246 populations in North America).**
  - **Mean relative weight of adults above "standard range" and within the upper 80th to 95th percentile of all LMB populations evaluated for this parameter (115 populations in North America).**
  - **Results not due to tributary recruitment – minimal bass habitat except in river.**
- **Both EPA and GE field studies indicate presence of a diverse fish community in PSA.**
- **ERA mischaracterizes these studies as providing "undetermined" evidence of harm, when they in fact showed no evidence of harm.**

Fish – Conclusions

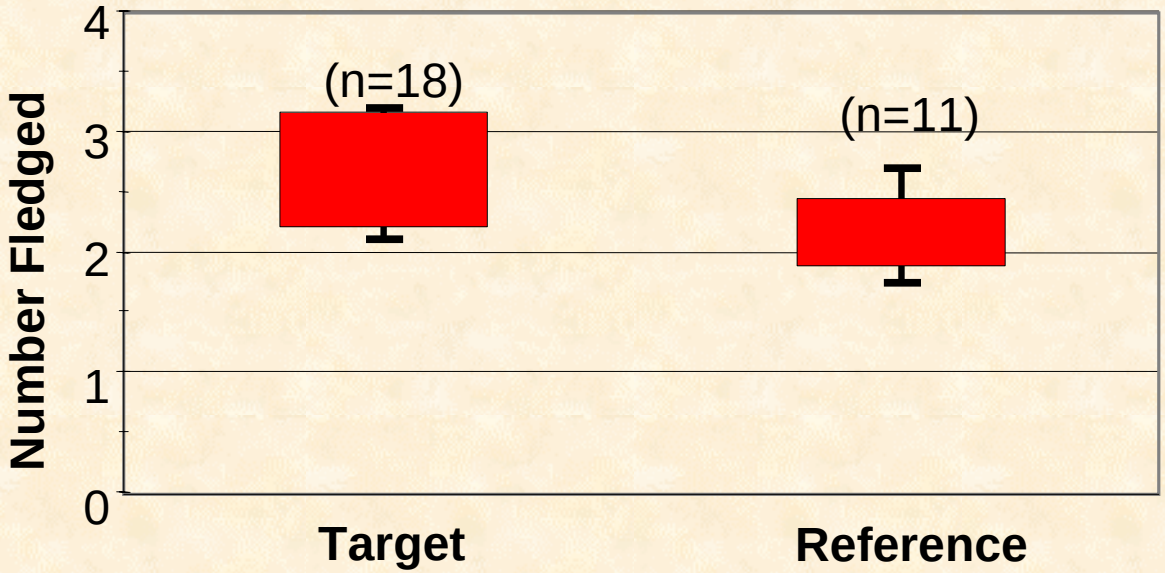
- **ERA misinterprets results of Phase I and Phase II toxicity studies, which provide no evidence of consistent dose-related PCB effects.**
- **The overall data do not show any impairment to local fish populations in the PSA.**
  - **The toxicity test data show ambiguous and inconsistent evidence of abnormalities in individual fish at early life stages.**
  - **EPA and GE field studies indicate that any such effects are not adversely affecting the sustainability or condition of local fish populations.**

Insectivorous Birds

- **Lines of Evidence in ERA:**
  - **Site-specific field study on tree swallow productivity (EPA)**
  - **Site-specific field study on American robin productivity (GE)**
  - **Hazard Quotients (HQs) for tree swallows and robins based on modeled exposures and effects (EPA)**
- **Key Points:**
  - **Field studies of tree swallows and robins show no evidence of harm.**
  - **ERA's HQs rely on inappropriate exposure and effects inputs, resulting in overestimates of risks.**

Field Studies Show No Evidence of Harm

- **GE concurs with ERA's interpretation of EPA's tree swallow study – no evidence of significant harm.**
- **GE's American robin field study found no evidence that PCBs had adverse effects on productivity, compared to robins in reference areas.**
  - **For example, number of robins fledged per nest from PSA were similar to or greater than those from reference areas:**



  - **Published in *Environmental Toxicology and Chemistry* (Nov. 2003).**
  - **ERA inappropriately weights this study lower than EPA's tree swallow study; study should be assigned same weight (high).**

ERA's HQs Substantially Overpredict Risks

- **Tree Swallows:**
  - **PCB exposure estimated from modeled concentrations in 12-day nestlings (median = 215 mg/kg), when effects were based on different age class (pippers). Should use EPA's measured site-specific PCB exposure data for pippers (median = 45 mg/kg).**
  - **Effects metrics used study from a different site. Should only use site-specific tree swallow study.**
- **American Robins:**
  - **Exposure based on modeled food intake rate. Should use measured rates for free-living robins from EPA's *Wildlife Exposure Factors Handbook* (EPA 1993).**
  - **Effects metrics based on chickens and kestrels. Should use site-specific robin study.**
- **Over-conservatism in HQs demonstrated by fact that predicted risks are contradicted by site-specific field data for both species.**
- **Above corrections would reduce HQ values below 1, making HQ results consistent with field study results.**

Insectivorous Birds – Conclusions

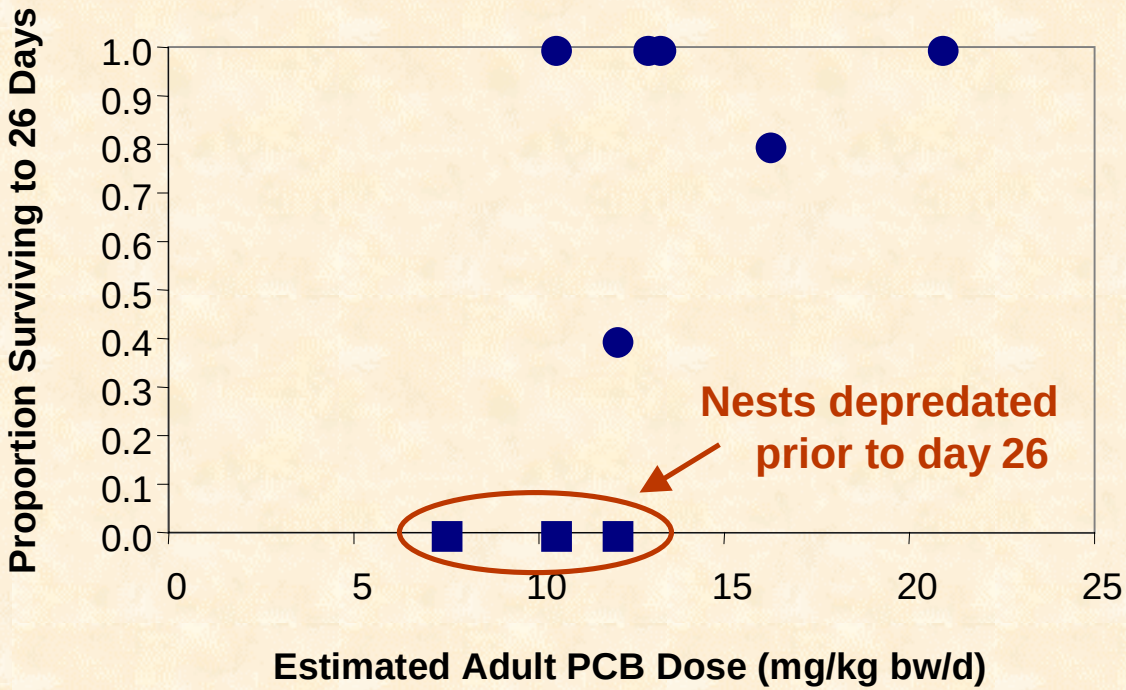
- **Site-specific field studies show no PCB effects on tree swallows or American robins.**
- **While recognizing this, ERA qualifies conclusion of low risks as "uncertain" due to conflict between field study results and HQs.**
- **BUT: ERA's HQs overestimate risks due to flawed and unnecessary exposure modeling and use of non-site-specific effects data.**
- **Corrections to the HQs would make HQ results concordant with field study results, supporting conclusion that insectivorous birds are at negligible risk from PCBs.**

Piscivorous Birds

- **Lines of Evidence in ERA:**
  - **Site-specific field study on productivity of kingfishers (GE)**
  - **HQs for kingfishers and ospreys based on modeled exposures and effects (EPA)**
- **Key Points:**
  - **GE's kingfisher study found no evidence of impaired reproduction.**
  - **ERA's selection of ospreys as representative receptor species is unwarranted.**
  - **Great blue herons would be better second species than ospreys.**
  - **ERA's HQs substantially overstate risks due to overly conservative exposure assumptions and inappropriate effects metrics.**

GE's Belted Kingfisher Study Found No Evidence of Impaired Reproduction

- **Primary conclusions of study:**
  - **Population is breeding and fledging successfully.**
  - **Population density is consistent with habitat quality.**
  - **No relationship between estimated dose and breeding success.**
- **ERA correctly recognizes that this study showed no evidence of harm.**

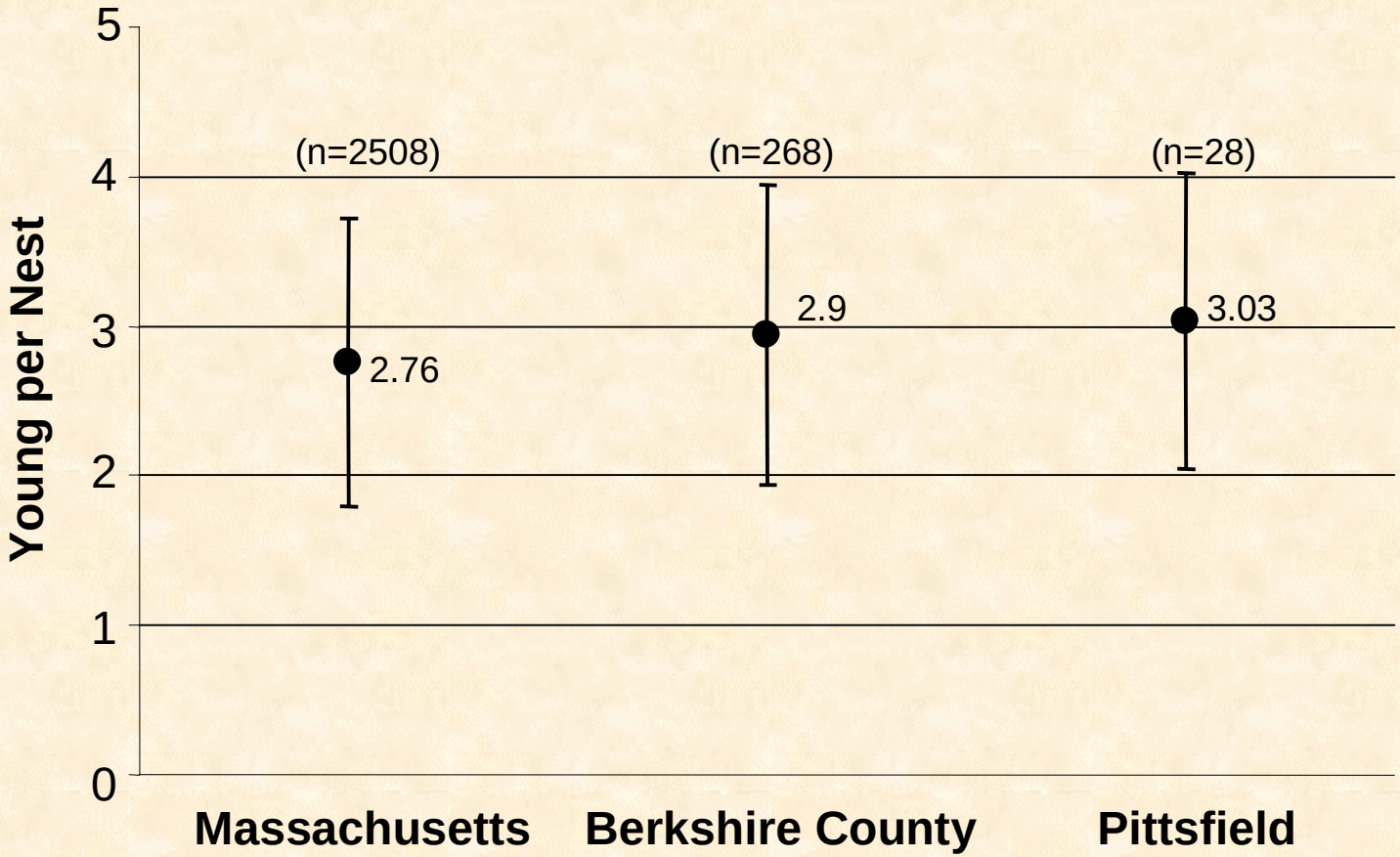


ERA's Selection of Osprey as Representative Species Is Unsupported

- **Western MA is outside of breeding range of ospreys:**
  - **Only ospreys seen in PSA during EPA's Eco-Characterization were observed during fall migration.**
  - **MDFW, MA Audubon, Breeding Bird Survey, MA Breeding Bird Atlas all agree that ospreys do not breed in Western MA, but only along coast within MA.**
  - **No nesting attempts (either successful or failed) anywhere in region.**
- **As a result, ERA's suggestion that absence of breeding pairs in PSA was caused by PCBs is unsupported speculation.**
- **Kingfishers are the most highly exposed piscivorous birds breeding within PSA (smallest feeding range, highest normalized ingestion rate). Hence, they should be used as single representative receptor.**

Great Blue Herons Are More Appropriate Second Species

- **If a second piscivorous bird species is necessary, great blue herons are a better choice than ospreys since great blue herons do breed within foraging distance of PSA and field data are available for them.**
- **Based on 1980-1999 data collected by MDFW and GE, heron productivity within foraging distance of the river is consistent with state-wide performance (mean ± 1 SE).**



ERA's HQs Substantially Overpredict Risks

- **ERA uses overly conservative exposure assumptions:**
  - **Uses modeled food intake rates. Should use measured species-specific data for free-living living kingfishers and ospreys from EPA's *Wildlife Exposure Factors Handbook*.**
  - **Incorrectly assumes that ospreys derive 100% of prey from PSA even though they are only in area during migration. Should adjust for realistic foraging time in PSA (e.g., assume 1-3 days per year in area).**
- **ERA uses inappropriate effects metrics for range based on "most sensitive" to "most tolerant" avian species:**
  - **For "most sensitive" species, ERA relies on studies of chickens (domesticated birds). Should use effects metric for wild bird species (e.g., mallards).**
  - **For "most tolerant" species, ERA excludes site-specific tree swallow data. Should use effects metric from that study.**
- **As a result of above problems, HQs substantially overestimate risks.**

Piscivorous Birds – Conclusions

- **ERA overestimates risks to piscivorous birds due to:**
  - **Selection of breeding ospreys, despite fact that the site is beyond the species' breeding range; and**
  - **Overly conservative HQs.**
- **Piscivorous bird populations in PSA are at low or negligible risk from PCBs, based on field data showing no effects on belted kingfishers and great blue herons.**
- **Although ospreys should not be used as representative species, correction of HQs for this species (to reflect limited time in PSA) would likewise show negligible risks.**

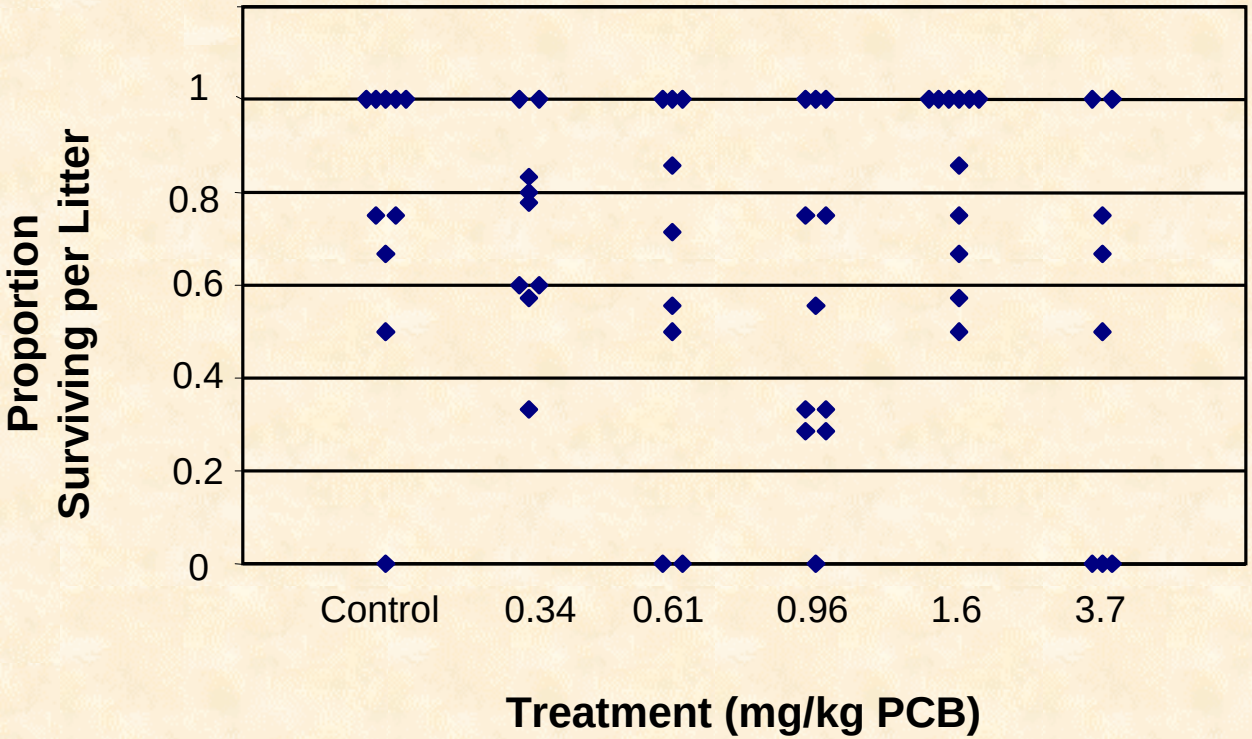
Piscivorous Mammals

- **Lines of Evidence in ERA:**
  - **Laboratory mink feeding study (using site-specific fish in diet) (EPA)**
  - **Field surveys of mink and otter signs (EPA and GE)**
  - **HQs for mink and otter (EPA)**
- **Key Points:**
  - **EPA's mink feeding study does not provide reliable evidence of adverse effects.**
  - **Effects threshold for mink and otter should be based upon the NOAEL from site-specific study, not literature.**
  - **Field survey data show substantial utilization of PSA by mink and otter.**

EPA's Mink Feeding Study Does Not Provide Evidence of PCB-Related Effects

- **Study evaluated 13 endpoints.**
- **Study found no PCB-related effects on most endpoints (e.g., adult survival, breeding success, whelping success, litter size, organ histopathology).**
- **ERA concludes study showed significant decrease in kit survival at 6 weeks of age at highest dose utilized (3.7 mg/kg PCBs in feed).**
- **Data do not support relationship between reduced kit survival at 6 weeks and PCB exposure:**
  - **Proportion of kit survival per litter ranged from 0 to 100%.**
  - **No necropsies were conducted on the 6 week old kits that died to determine cause of death.**
  - **Necropsies of other kits that died confirmed death due to infections common in captive mink.**
  - **ERA does not provide sufficient details to replicate statistical analyses.**

Independent Analysis Finds No Significant Effect on Kit Survival at Six Weeks



- **Kit survival variable at all doses.**
- **Independent statistical analysis (ANOVA) shows no significant effect upon kit survivability at six weeks due to dietary treatment ($F_{(5,52)} = 1.49$; $p = 0.21$).**

EPA's Jaw Lesion Study Does Not Provide Reliable Evidence of Adverse Effects

- **Study found no measurable effects in the form of gross abnormalities.**
- **At the three highest doses of PCB-126, a proliferation of maxillary and mandibular squamous cells were noted, but implications of this finding are unclear.**
- **Earlier study by Render et al. (2001) reported loose and displaced incisor teeth, but at doses 58X greater than those used in EPA's study.**
- **ERA's speculation that effects observed during the mink feeding study could lead to starvation is not supported by either the results or the literature.**

EPA's results did not find any evidence of loose teeth, wasting or similar effects in mink kits.

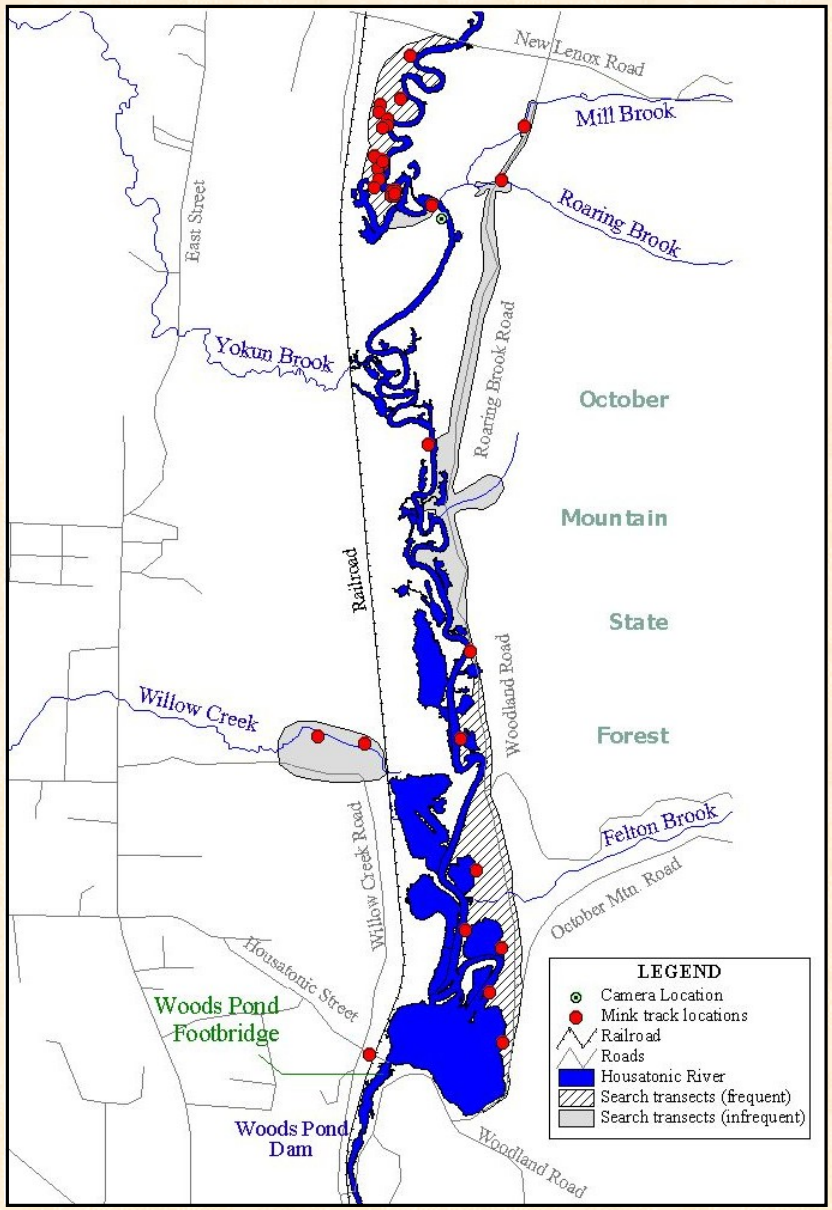
ERA's HQs Inappropriately Use Non-Site-Specific Data

- **ERA bases HQs for mink and otter not only on site-specific feeding study, but also on effects metrics derived from non-site-specific literature studies.**
- **However, EPA mink feeding study clearly demonstrates that mink are less sensitive to PCBs in Housatonic River fish than those used in studies at other sites. Therefore, other studies are not applicable to this site.**
- **EPA's feeding study provides a site-specific effects threshold – unbounded NOAEL of 3.7 mg/kg PCBs in diet.**
- **ERA should use that site-specific effects metric (> 3.7 mg/kg PCBs) to assess risks and should not use effects metrics from studies at other sites.**

Field Surveys Show Frequent PSA Usage by Mink/Otter

- **EPA conducted snow tracking in winter of 1998-99 and 1999-2000 on two or three events at PSA and reference sites. Also monitored scent-post stations on four events.**
- **ERA conclusion that fewer mink and otter were observed in PSA than at reference locations does not take into account:**
  - **Habitat differences between PSA (river) and reference sites (small ponds/lakes).**
  - **Although EPA spent 260 hours in PSA and 108 hours in reference areas, effort was focused on a few limited events.**
- **GE conducted snow tracking on 33 days in the winters of 2001-02 and 2002-03, as well as monitoring scent posts in summer/fall 2001 (total of 944 person hours); PI was Dr. Michael Chamberlain (LSU).**
  - **Numerous tracks observed in snow at various locations.**
  - **Review of tracks and photos showed substantial utilization of PSA by mink and otter as part of home range:**
    - **Dr. Chamberlain estimates ~ 6-10 mink in 2002, ~ 4-7 mink in 2003, ~ 2-3 river otter in 2003 using PSA as part of home range.**
    - **Estimated density consistent with that reported in literature based on similar habitat.**

GE Survey Mink Track Locations (Winter 03)



- **Mink tracks show widespread utilization of PSA.**

<u>Note</u>: Roaring Brook/Woodland Road is closed in winter due to snow pack and is not accessible by car.

ERA Inappropriately Discounts GE Survey Results

- **ERA criticizes GE survey and weights its results lower than EPA survey results without justification.**
  - **ERA notes that most tracks were observed in winter and argues that this means mink present were transients. But:**
    - **Most tracks were observed in winter because snow provides much more extensive area for tracking than artificial scent-post stations; thus, majority of effort was spent in winter.**
    - **No basis for claim that mink were transients. Survey provided information to estimate number of animals with home ranges that *include* the PSA; these animals cannot be confirmed as residents or simply users of the area.**
  - **ERA claims that GE field personnel lacked tracking expertise. But GE team was led by Paul Bernstein, former New York Conservation Officer with decades of tracking experience.**
  - **ERA claims information insufficient to confirm track identification. But more than half the tracks observed in 2002 and all observed in 2003 were photographed.**

Piscivorous Mammals – Conclusions

- **ERA inappropriately interprets and weights data:**
  - **ERA conclusion of reduced kit survival at one time period at highest PCB dose, 3.7 mg/kg in diet, is not supported by underlying data.**
  - **ERA inappropriately uses literature-based effects metrics when EPA feeding study shows that PCBs at this site are less harmful to mink than those from other sites.**
  - **ERA inappropriately discounts GE field survey, which shows frequent usage of PSA by mink and otter.**
- **Based on literature, there may be risks to mink and otter due to consumption of PCB-containing fish at some level. However, threshold for this site must be > 3.7 mg/kg in diet.**

Conclusions of risk to mink/otter are uncertain given lack of site-specific data showing harm.

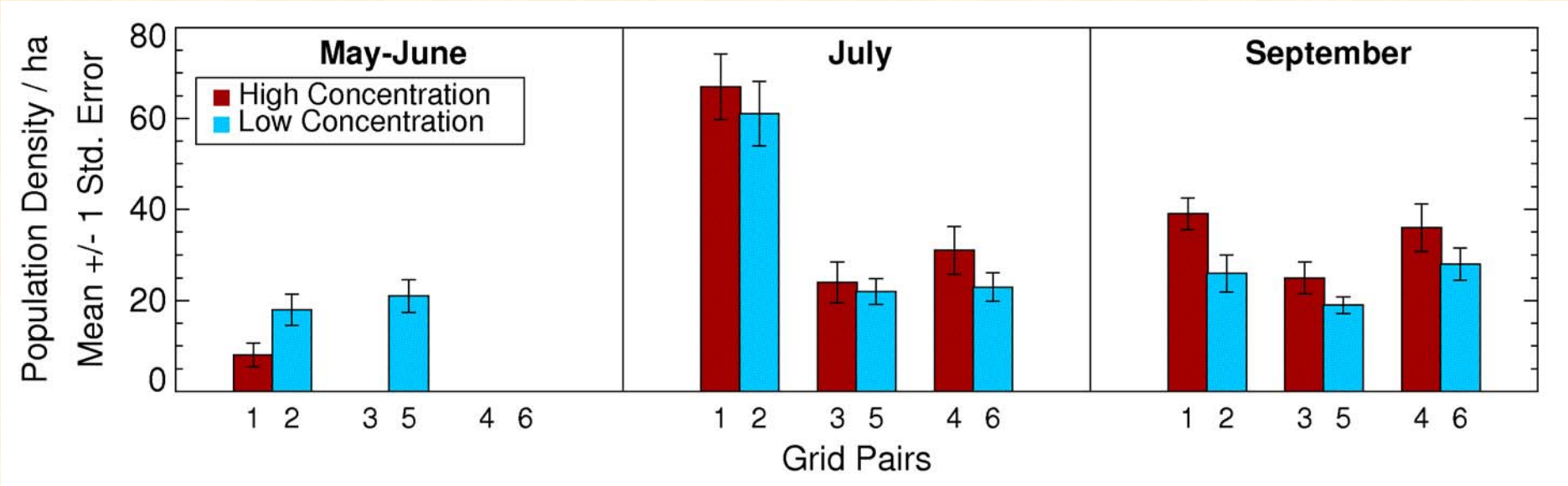
Omnivorous/Carnivorous Mammals

- **Lines of Evidence in ERA:**
  - **Small mammal field survey (EPA)**
  - **Site-specific population demography field study of short-tailed shrews (GE)**
  - **HQs for shrews and red fox based on modeled exposures and effects (EPA)**
- **Key Points:**
  - **GE's site-specific shrew study shows no evidence of adverse effects.**
  - **HQs for shrews are overstated and those for red fox are highly uncertain and not supported by any site-specific data.**

GE's Shrew Demography Study Shows No Evidence of Adverse Effects on Shrews in PSA

- **Conducted by Dr. Rudy Boonstra (U. Toronto).**
- **6 sampling grids sampled in spring to fall 2001:**
  - **3 with "low" soil PCB concentrations (1-3 mg/kg)**
  - **3 with "high" soil PCB concentrations (17-38 mg/kg)**
  - **2-3 sampling events per grid**
- **No relationship between PCBs in soils and any demographic parameters:**
  - **Density**
  - **Survival**
  - **Sex ratio**
  - **Reproduction**
  - **Growth**
  - **Body mass**
- **All values within ranges reported in literature for uncontaminated sites.**
- **Published in *Environmental Toxicology and Chemistry* (June 2003).**

Study Results: Shrew Population Densities



No PCB-Related Effects on Shrew Population Densities

Reanalyses of Shrew Study Do Not Show Effect on Survival

- **EPA reanalyzed data using different soil PCB concentrations for the grids and found a weak but significant negative relationship with shrew survival.**
  - **EPA derived spatially weighted average soil PCB concentrations using different method from Boonstra and some different assumptions and data points.**
  - **Did not change low/high designation of grids.**
  - **ERA does not provide all data needed to verify EPA's statistical analysis (i.e., not transparent).**
- **Dr. Boonstra reanalyzed data using EPA's soil PCB concentrations and EPA's statistical technique, but found no significant relationship with survival.**
  - **Details in Boonstra comments (Attach. R to GE Comments)**
- **ERA erroneously concludes that this study showed "undetermined" evidence of harm. In fact, it showed no evidence of harm.**

ERA's HQs for Shrews Overpredict Risks and HQs for Fox Are Too Uncertain to be Reliable

- **ERA's HQs for shrews and red fox are based on unnecessarily conservative exposure estimates and on highly uncertain literature-derived toxicity estimates.**
  - **ERA uses generic, modeled food intake rates, even though measured intake rates are available for both species (in EPA's *Wildlife Exposure Factors Handbook*).**
  - **ERA derives effects thresholds for both species from studies on rats and mice, resulting in high uncertainty.**
- **PCB HQ for shrews, which predicts high risk, is inconsistent with site-specific study, which showed no evidence of harm.**
- **Thus, the ERA HQs overpredict risks to shrews and do not provide reliable evidence regarding risks to red fox.**

Omni/Carnivorous Mammals – Conclusions

- **ERA overestimates risks to shrews because:**
  - **Site-specific field study showed no effects on shrews.**
  - **Model-based HQs are uncertain and unnecessarily conservative.**
  - **These facts support conclusion of low or negligible risks to shrews.**
- **For red fox, the risks are undetermined, because the only evidence of harm (the HQs) is highly uncertain and there are thus insufficient data to support any risk conclusions.**

Threatened & Endangered Species

- **Lines of Evidence in ERA:**
  - **HQs for bald eagles, American bitterns, and small-footed myotis – based on modeled exposures and effects.**
  - **No site-specific studies.**
- **Key Points:**
  - **The HQs for bald eagles and American bitterns overstate risks, while those for myotis are highly uncertain.**
  - **ERA's extrapolation of risks to bald eagles downstream of PSA is unjustified.**

ERA's HQs Substantially Overpredict Risks or Are Too Uncertain To Be Reliable

- **ERA's HQs for bald eagles unnecessarily rely on modeled food intake rates and on effects metrics for kestrels. Should use bald eagle-specific information from the literature for both parameters. This would reduce HQs by 20-fold to below 1.**
- **ERA's HQs for American bitterns rely on inappropriate effects metrics (for same reasons as for piscivorous birds):**
  - **For "most sensitive" species, ERA relies on studies of chickens. Should use effects metrics for wild bird species (e.g., mallards).**
  - **For "most tolerant" species, ERA excludes site-specific tree swallow data. Should use effects metric from that study.**
  - **These corrections would reduce HQs by 12-fold.**
- **ERA's HQs for myotis are highly uncertain due to use of exposure and effects assumptions based on other species (tree swallows for exposure, rats for effects).**

ERA's Downstream Extrapolation of Risks to Bald Eagles Is Unjustified

- **ERA's extrapolation of risks to bald eagles wintering downstream of PSA concludes that there are risks to wintering bald eagles at Rising Pond.**
- **That conclusion is unwarranted:**
  - **ERA assumes that eagles would obtain 100% of their winter diet from Rising Pond, which typically freezes.**
  - **In fact, area of Rising Pond (18 hectares) is 1% of the bald eagle's winter foraging range (1,880 hectares of surface water).**
  - **Therefore, risks overestimated by 100-fold.**

T&E Species – Conclusions

- **ERA overstates risks to T&E species because it:**
  - **Fails to recognize uncertainties of relying only on HQs without site-specific studies.**
  - **Uses overly conservative and/or highly uncertain assumptions in the HQs.**
  - **Gives too high weight to the HQ results.**
  - **Erroneously extrapolates risks to downstream bald eagles based on an unrealistic assumption (100% of diet from Rising Pond).**
- **Based on corrections to the HQs, risks to bald eagles would be negligible and risks to American bitterns would be low. (Risks to myotis should be undetermined.)**
- **But any conclusions regarding risks to T&E species are uncertain due to lack of site-specific data on these species.**

Comments on ERA Summary

Kenneth D. Jenkins, Ph.D., BBL Sciences

ERA Summary Contains Unsupported Conclusions That Overstate Risks

- **In addition to repeating the conclusions on specific receptor groups discussed above, the ERA Summary (Section 12) contains a number of additional unsupported conclusions.**
- **ERA Summary overemphasizes and misinterprets HQs:**
  - **Makes comparisons across receptors based solely on HQs, without taking account of other lines of evidence or differences in quality or certainty among the HQs.**
  - **Mischaracterizes HQs as "not conservative" because they did not use safety factors (except for T&E species), and thus concludes that HQs > 1 are "cause for concern" indicative of expected harm (rather than potential harm).**
    - **This fails to recognize the numerous other sources of conservatism built into the HQs (apart from safety factors).**
    - **HQs > 1 are not indicative of harm, but only potential harm, and reveal nothing about severity of effect.**

ERA Summary Contains Unsupported Conclusions That Overstate Risks (cont'd)

- **ERA Summary makes overstated extrapolations of risks to reaches downstream of PSA due to:**
  - **Use of overly conservative MATCs for benthic invertebrates, amphibians, fish, mink and otter, and bald eagles (as shown above).**
  - **In some cases (e.g., bald eagles), failure to take account of habitat limitations in downstream areas.**
- **ERA Summary makes unsupported and highly uncertain extrapolations of risks from the studied species to many other species within same feeding guild:**
  - **Not supported by evidence on those other species.**
  - **Focuses on exposure, ignoring differences in toxicological sensitivity.**
  - **Based on endpoints that predict highest risks (HQs), rather than weight-of-evidence conclusions.**

ERA Summary Contains Unsupported Conclusions That Overstate Risks (cont'd)

- **ERA Summary includes unsupported speculations as to why site-specific data showing abundant populations do not show absence of effects:**
  - **ERA states:**
    - **Removal of predators could allow prey populations to remain abundant despite PCB effects.**
    - **Immigration could be compensating for losses due to PCBs.**
    - **PCB exposure may increase populations' vulnerability to future stressors, reduce their genetic diversity, or have immune system effects without affecting population abundance.**
  - **Application of these theories to PSA is entirely speculative and unsupported by any evidence.**
- **ERA Summary contains unbalanced uncertainty analysis:**
  - **For field studies, mischaracterizes integration of exposure over large areas and long time scales as uncertainty, rather than strength.**
  - **Understates uncertainties in HQs.**
  - **Provides no uncertainty analysis for extrapolations downstream and to other species.**

Overall GE Conclusions

Andrew T. Silfer, P.E., General Electric

Overall Conclusions Regarding ERA

ERA OVERESTIMATES ECOLOGICAL RISKS OF PCBs TO LOCAL POPULATIONS AND COMMUNITIES:

- **ERA overemphasizes individual-level effects without properly evaluating impacts on local populations and communities.**
- **ERA underweights many site-specific field studies and overweights modeled HQs.**
- **ERA incorrectly interprets results of several studies as showing effects when the results do not support that conclusion.**
- **ERA gives low weight to results that show no effects or inaccurately designates such results as "undetermined."**
- **ERA makes unsupported extrapolations or speculations to suggest widespread effects and to explain away results showing abundant populations.**
- **In several instances, ERA fails to provide sufficiently transparent analyses to allow reader to reproduce the analyses.**

If these flaws are not corrected, ERA cannot serve as supportable basis for risk management decisions.

Overall Conclusions: The Overall Weight of Evidence from the Available Data, Properly Interpreted, Show . . .

- **While toxicity tests on benthic invertebrates would support a sediment effects level of 8 mg/kg, the field data indicate no PCB-related impairment of the benthic community at sites with mean sediment PCB levels up to 16 mg/kg (fine-grained) and 24 mg/kg (coarse-grained).**
- **Although there is some evidence that PCB exposure in PSA could result in increased abnormalities in individual frogs and fish, there is no evidence that such abnormalities are adversely affecting the local frog and fish populations.**
- **There is no reliable evidence of harm to insectivorous birds, piscivorous birds, or omnivorous/carnivorous mammals due to PCB exposure in PSA.**
- **Based on the literature, there may be risks to mink and otter due to consumption of PCB-containing fish at some level, but the threshold for this site must be > 3.7 mg/kg in the fish.**
- **Based on corrections to the HQs, risks to T&E species in PSA are likely low or negligible, but any conclusions are uncertain given the absence of any site-specific data on those species.**

Overall, the evidence does not show adverse impacts on local populations and communities of ecological receptors despite 70 years of PCB exposure.

Table of Cross-References to GE Comments for Points in This Presentation

Page of GE Presentation*	Subject	Discussion in GE's Written Comments
p. 4	Description of Primary Study Area as appropriate setting for field studies	pp. 2-2 – 2-3
p. 5	Abundance and diversity of local wildlife populations and communities	p. 2-3
p. 6	ERA's failure to adequately evaluate potential impacts on local populations and communities	pp. 3-2 – 3-4
p. 7	ERA's underweighting of site-specific field studies and overweighting of hazard quotients	pp. 4-2 – 4-6
p. 8	ERA's incorrect or unwarranted interpretations of studies (general)	pp. 3-4, 4-6 – 4-7 for general discussion; specifics listed below.
pp. 11-12	Lack of support for ERA's sediment effects threshold based on toxicity test results	pp. 5-4 – 5-7, Attach. D
pp. 13-15	Lack of PCB-related effects in EPA's benthic community field study	pp. 5-2 – 5-4, Attach. C
p. 16	EPA's supplemental multiple regression analysis of benthic community data	GE's 12/24/03 comments on EPA's supplemental analysis

* Excludes summary pages and pages added via electronic links.

Table of Cross-References to GE Comments for Points in This Presentation (cont'd)

Page of GE Presentation	Subject	Discussion in GE's Written Comments
pp. 19-20	Flaws in EPA's leopard frog study	pp. 6-2 – 6-5, Attach. E
p. 21	GE's leopard frog egg mass survey	pp. 6-5 – 6-6, Attach. F
p. 22	Comparison of egg mass density across studies	N/A
pp. 23-25	Flaws in ERA's interpretation of EPA's wood frog study	pp. 6-7 – 6-10, Attach. G
p. 26	GE's wood frog study	p. 6-10, Attach. H
pp. 27-28	Flaws in ERA's wood frog population model	pp. 6-10 – 6-11, Attach. G
p. 29	Overly conservative MATCs for amphibians	pp. 6-12 – 6-13
pp. 32-37	Lack of consistent exposure- or dose-response relationships in EPA's fish toxicity test data for Phase I and Phase II	pp. 7-3 – 7-5, Attach. I (Sec. 3 - 5)
p. 38	Lack of support for ERA's tissue-based effects metrics for fish	pp. 7-7 – 7-9, Attach. I (Sec. 6)
p. 39	Field studies showing self-sustaining bass population and diverse fish community in PSA	pp. 7-5 – 7-7, Attach. J

Table of Cross-References to GE Comments for Points in This Presentation (cont'd)

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p. 42	Site-specific field studies on insectivorous birds (showing no evidence of harm)	pp. 8-2 – 8-4, Attach. K
p. 43	Flaws in ERA's HQs for insectivorous birds	pp. 8-4 – 8-7
p. 46	GE's site-specific belted kingfisher field study (showing no evidence of harm)	pp. 9-2 – 9-3, Attach. L
p. 47	ERA's unsupported selection of osprey as representative species	pp. 9-4 – 9-5
p. 48	Use of great blue heron data	pp. 9-5 – 9-6, Attach. M
p. 49	Flaws in ERA's HQs for piscivorous birds	pp. 9-7 – 9-9
pp. 52-53	Flaws in ERA's interpretation of EPA's mink feeding study	pp. 10-2 – 10-5, Attach. N
p. 54	EPA's jaw lesion study – lack of reliable evidence of adverse effects	pp. 10-5 – 10-6
p. 55	ERA's inappropriate reliance on non-site-specific data for mink and otter HQs	pp. 10-5, 10-11 – 10-13

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Page of GE Presentation	Subject	Discussion in GE's Written Comments
pp. 56-57	Field surveys of mink and otter	pp. 10-6 – 10-9, Attach. O & P
p. 58	ERA's inappropriate discounting of GE's mink/otter survey	pp. 10-10 – 10-11, Attach. P
pp. 61-62	GE's shrew demography study (showing no evidence of adverse effects)	pp. 11-3 – 11-4, Attach. Q
p. 63	Reanalyses of shrew study results (no effect on survival	pp. 11-4 – 11-5, Attach. R
p. 64	Flaws in ERA's HQs for shrews and red fox	pp. 11-5 – 11-6
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p. 68	ERA's unjustified downstream extrapolation of risks to bald eagles	p. 12-8
pp. 71-73	Unsupported conclusions in ERA Summary	pp. 13-2 – 13-9
pp. 75-76	Overall GE conclusions regarding ERA	pp. 13-9 – 13-10, Table ES-1

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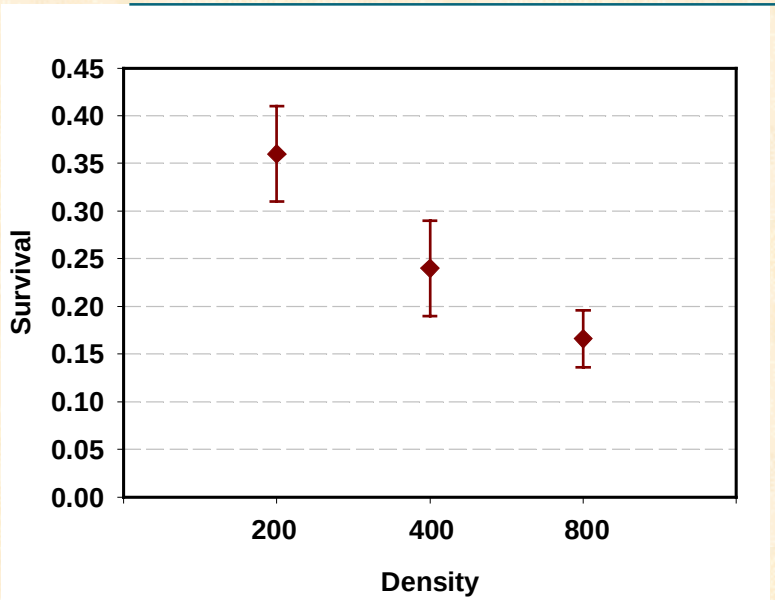
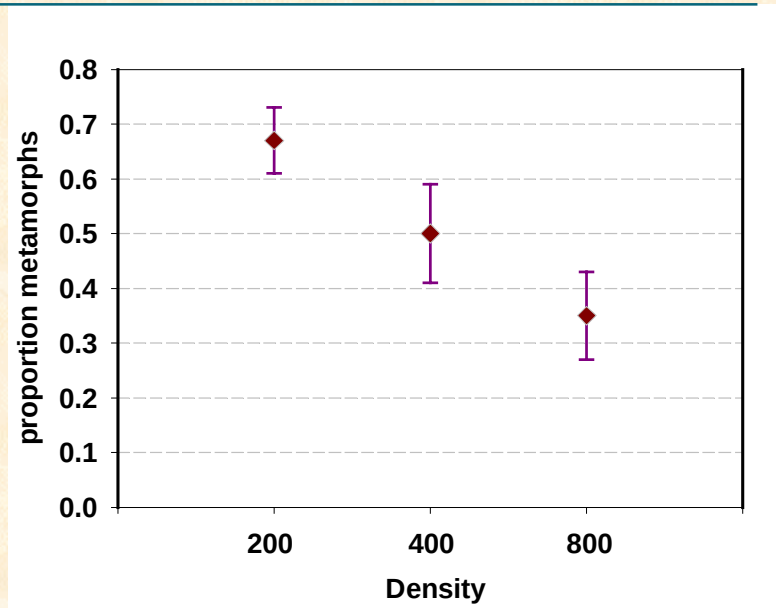
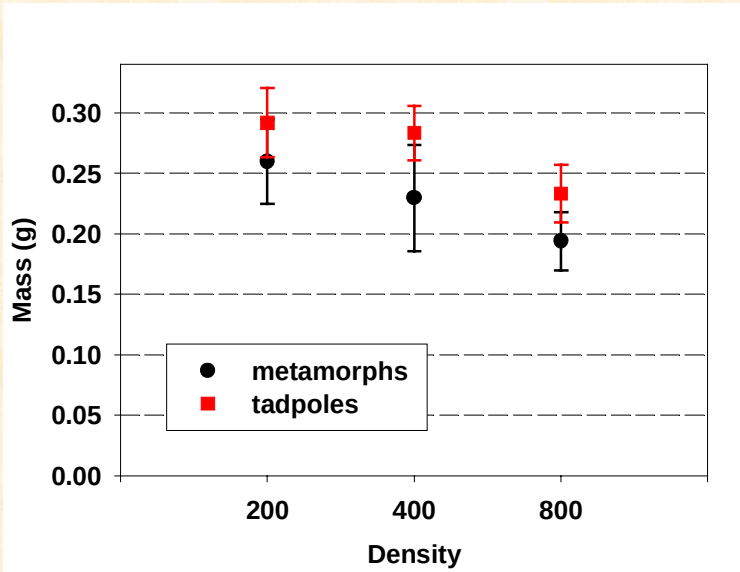
GE Wood Frog Study: Density Effects



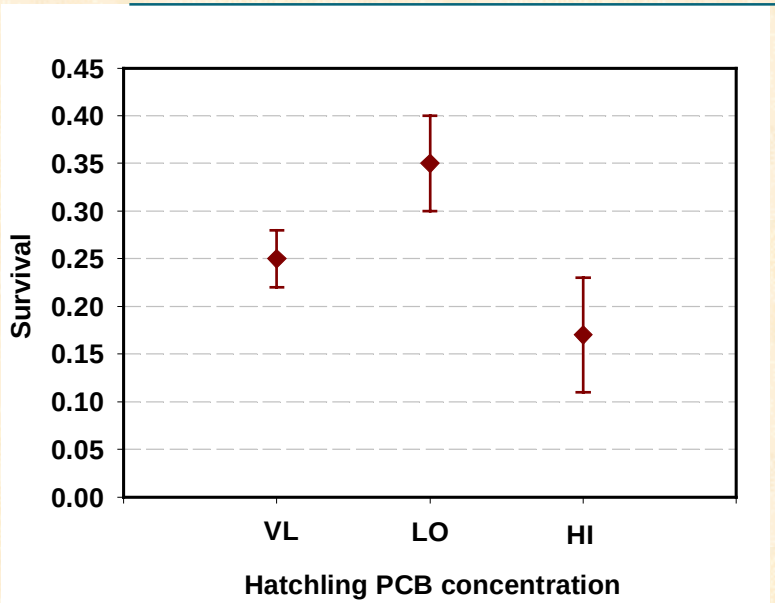


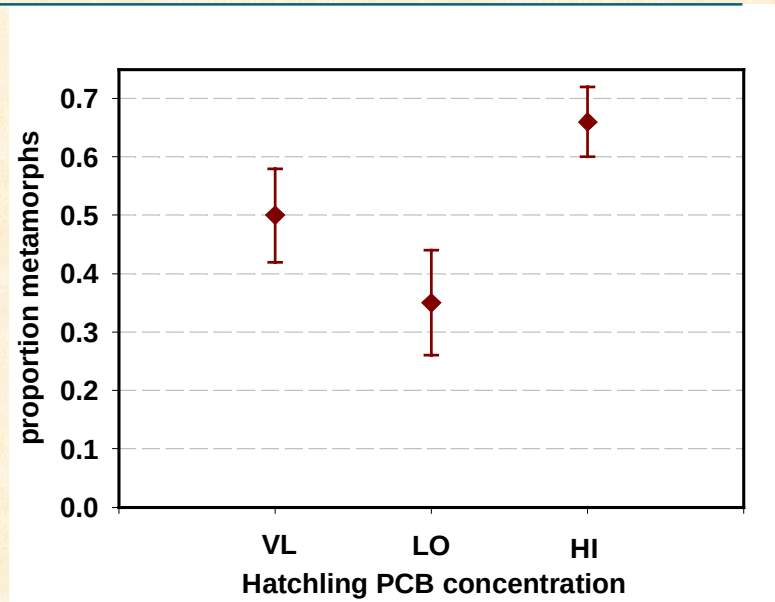


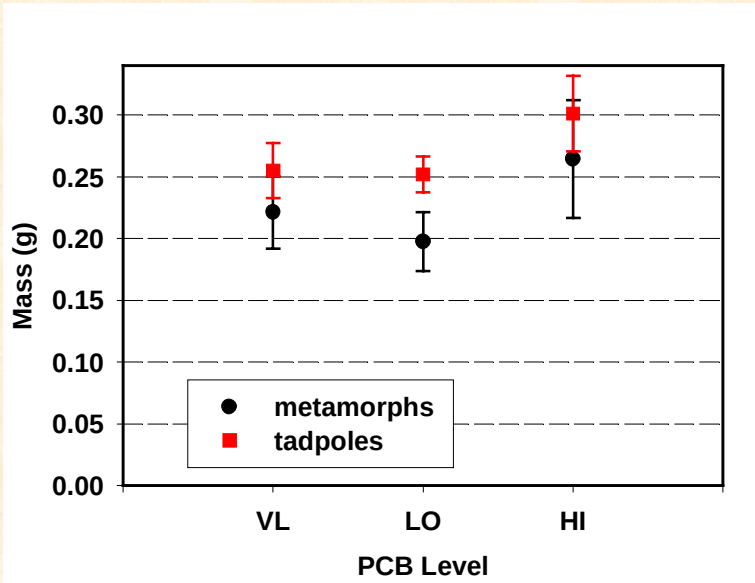
- **Classic density dependence and linear density-response relationship**

Slide from "*In situ* effects of early life-stage PCB exposure on *Rana sylvatica*" presentation made by W.J. Resetarits at SETAC Conference, November 2002.

GE Wood Frog Study: PCB Effects







- **Inconsistent effects on endpoints (variation in survival generates density compensation)**
- **No linear dose-response relationship**

Slide from "*In situ* effects of early life-stage PCB exposure on *Rana sylvatica*" presentation made by W.J. Resetarits at SETAC Conference, November 2002.

GE Shrew Study: Survival-PCB Statistics

Relationship between shrew survival on six live-trapping grids from summer to fall 2001 and PCB concentrations recalculated for these grids in the ERA (Table J.4-5).

	r	F	P
Males			
Mean Concentrations	-0.739	3.603	0.15
Spatially Weighted Arithmetic Mean	-0.721	3.247	0.17
Females			
Mean Concentrations	-0.659	3.052	0.16
Spatially Weighted Arithmetic Mean	-0.53	1.572	0.28
Combined (males + females)			
Mean Concentrations	-0.681	3.451	0.14
Spatially Weighted Arithmetic Mean	-0.52	1.481	0.29

Note: Survival for each grid was calculated as the probit value. In males, grid 3 was deleted from the analysis because only one male was captured in summer. In the combined analysis, all grids were included and each animal contributed equally to the analysis.

Table R2 in Attachment R to GE's Comments on ERA (Sept. 2003), prepared by Dr. Rudy Boonstra.

Phase II Data on Swim Bladder Abnormalities at Swim-up

External Swim Bladder (# per 1000 in Largemouth Bass at Swim-up)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	0	0	0	0
1	0	0	0	0
2	0	0	0	0
3	0	0	0	**100**
4	0	0	0	0
5	0	0	0	**278**

Uninflated Swim Bladder (# per 1000 in LMB at Swim-up)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	**59**	**421**	**400**	0
Solvent Injected	**500**	**455**	**356**	**118**
1	**95**	**483**	**500**	**59**
2	**105**	**550**	**345**	**150**
3	**83**	**583**	**407**	**48**
4	**154**	**800**	**483**	**100**
5	**238**	**571**	**547**	0

Partially-Inflated Swim Bladder (# per 1000 in LMB at Swim-up)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	**294**	0	**33**	**111**
Solvent Injected	0	**91**	**17**	0
1	**190**	**69**	**22**	**118**
2	**53**	0	0	0
3	**83**	**42**	**51**	0
4	0	0	**52**	0
5	**95**	0	**94**	0

Phase II Data on Swim Bladder Abnormalities at 15 Days Post Swim-up

External Swim Bladder (# per 1000 in Largemouth Bass at 15 d)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	0	0	0	0
1	0	0	**67**	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0

Uninflated Swim Bladder (# per 1000 in LMB at 15 d)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	0	**59**	**37**	0
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	0	**111**	0	0
5	0	0	0	**67**

Partially-Inflated Swim Bladder (# per 1000 in LMB at 15 d)

Dose	Three-Mile Pond	Rising Pond	Woods Pond	Reach 5BC
Uninjected	0	0	0	0
Solvent Injected	0	0	0	0
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0

Phase I Spawn Success Data

Site	Females (#)	Successful Spawns (#)	Spawns Evaluated for Abnormalities (#)
Three-Mile Pond	11	3	3
Rising Pond	11	7	5
Woods Pond	11	7	6
Reach 5BC	18	10	8

Smaller proportion of spawns from reference sites available for subsequent analyses.