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**VIA OVERNIGHT MAIL**

Ms. Anna Krasko
Remedial Project Manager
U.S. Environmental Protection Agency, Region 1
1 Congress Street, Suite 1100 (HBO)
Boston, MA 02114

**Re: Centredale Manor Restoration Project Superfund Site, North Providence, Rhode Island**

Dear Ms. Krasko:

On behalf of Emhart Industries, Inc. ("Emhart"), we are submitting for inclusion in the administrative record for the above-referenced site comments on the Addendum to the Interim-Final Baseline Human Health Risk Assessment: Oxbow Area (Aug. 2006) ("Oxbow BHHRA") and the Addendum to the Interim-Final Baseline Ecological Risk Assessment: Oxbow Area (Aug. 2006) ("Oxbow BERA") for the Centredale Manor Restoration Project Superfund Site ("Site"). These comments supplement the comments we submitted on Emhart's behalf by letter dated October 19, 2006. Emhart respectfully requests that EPA withdraw the Oxbow Area risk assessment documents and correct the errors set forth therein, as discussed below and in the enclosed comments.

AMEC Earth and Environmental, Inc. ("AMEC") has reviewed and prepared technical comments on EPA's Oxbow Area risk assessment reports. As with their review of the BHHRA and BERA for the other areas of the Site, AMEC has identified significant flaws in the EPA risk assessments that lead to very uncertain and overly conservative estimates of risk both to human and ecological receptors.

Of primary concern are the sampling data used in the assessments. These data are assumed to be representative of soil in the Oxbow Area. However, the data are more indicative of submerged sediment and/or saturated soil on the fringes of the Oxbow Area. Contact with the submerged sediment and saturated soil, if any, will occur at a much lower frequency than with the upland soil areas. The use of these data has significant implications for the human exposure assessment.

Moreover, the very high soil moisture in these samples result in the areas being very unsuitable habitat for earthworms, which are receptors in and of themselves as well as a food source for receptors further up the food chain. These data are used without any consideration of the suitability of the habitat. In addition, the Oxbow BERA includes an ecological receptor (American Woodcock) which, admittedly, is not likely to be present in the Oxbow Area due to a lack of suitable habitat.

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AMEC's *Comments on the Addendum to the Interim-Final Baseline Human Health Risk Assessment: Oxbow Area*, dated December 21, 2006, are enclosed as Exhibit A. AMEC's *Comments on the Addendum to the Interim-Final Baseline Ecological Risk Assessment: Oxbow Area*, dated December 21, 2006, are enclosed as Exhibit B.

* * *

Please feel free to contact us if you have any questions concerning the foregoing. We appreciate the opportunity to submit these comments.

Sincerely,

Jerome C. Muys, Jr. /LFB

Jerome C. Muys, Jr.

Enclosures

cc: Eve Vaudo, Esq.
Ms. Linda H. Biagioni
Jeffrey M. Karp, Esq.
Laura Ford Brust, Esq.

A

**COMMENTS ON THE ADDENDUM TO THE INTERIM-FINAL BASELINE HUMAN HEALTH RISK ASSESSMENT: OXBOW AREA**
**CENTREDALE MANOR RESTORATION PROJECT SUPERFUND SITE**
**NORTH PROVIDENCE, RHODE ISLAND**
**AUGUST 2006**

**December 21, 2006**

**AMEC Earth and Environmental, Inc.**
**15 Franklin Street**
**Portland, ME 04101**

## 1.0 INTRODUCTION

In August 2006, EPA Region I released the Addendum to the Interim-Final Baseline Human Health Risk Assessment: Oxbow Area (Oxbow BHHRA) for the Centredale Manor Restoration Project Superfund Site (Site) (MACTEC, 2006). The Oxbow BHHRA was prepared by MACTEC Engineering and Consulting, Inc., under contract to Battelle Corporation, and was submitted to the Department of the Army, U.S. Army Corps of Engineers, New England Division under Contract No. DACW33-01-D-0004, Delivery Order No. 1. The Oxbow BHHRA evaluated potential exposure and corresponding risks to chemicals detected in Oxbow Area sediment via direct contact. Greystone Mill Pond was designated as the upstream background area. The Oxbow BHHRA identified one exposure scenario: a receptor that uses the area for passive recreational purposes.

At the request of Emhart Industries, Inc., AMEC Earth & Environmental, Inc. prepared these comments on the Oxbow BHHRA. The comments focus on those exposure scenarios and risk assessment topics that have the greatest impact on setting target remediation goals and assessing remedial options. Accordingly, the comments do not address aspects of the report that do not appear to be influential in evaluating remedies or determining outcomes for the Site.

Section 2.0 of this document addresses concerns with the assumptions used in the Oxbow BHHRA to establish exposure point concentrations based on the available Oxbow Area sediment data. Section 3.0 discusses concerns with other exposure assumptions used in the Oxbow BHHRA to evaluate soil/sediment ingestion. Among these concerns is the selection of a realistic and reasonable rate of incidental soil ingestion from the Oxbow Area. Section 4.0 provides comments on the direct contact exposure pathways. Finally, Section 5.0 considers the limitations of EPA's discussion of dioxin toxicology.

## 2.0 SEDIMENT DATA

The Oxbow BHHRA relies on seven sediment samples collected from the Oxbow Area in June 2004. Review of the data, the work plan underlying the sample collection, and photographs and maps of the Oxbow Area indicate that the data used in the Oxbow BHHRA are not likely to be indicative of the types of exposures that could occur during contact with floodplain soils in the Oxbow Area.

The stated goal of the Oxbow BHHRA is to "evaluate current and potential future risks to human health associated with human contact with floodplain surface soil and sediment in the Oxbow Area" (MACTEC, 2006, p. ES-2). The chemical data that were used to assess the potential risks, however, were almost entirely limited to sediment data. Of the seven samples used in the assessment, only one had a solids content greater than 50% (58% in sample LPX-SD-4405-005). The remaining six samples had solids contents between 12 and 36% with an average of only 21%. Samples with such low solids content (12-36%) are indicative of sediment samples and not soil samples. As the sediment samples represent six of the seven samples, it can be concluded that the data used in this assessment are primarily sediment data and not floodplain soil data.

The fact that the samples were limited to sediment matrices is not unexpected. The document, *Final Work Plan, Sediment Sample Collection and Analysis at the Oxbow Area, Centredale Manor Restoration Project Superfund Site* (Battelle, 2004a) ("*Final Work Plan*"), which details where the Oxbow Area samples would be collected, states clearly in its title that the samples were intended to represent sediment. In fact, the term "soil" in not used in this document. The *Final Work Plan* states in the Sediment Sample Collection section that "Sample locations will be adjusted in the field to exclude areas of artificial fill or gravel, and *ensure that samples are collected from topographically low areas"* [emphasis added]. The sampling work plan goes on to describe that three specific locations would be collected from within the North Channel, which is hydraulically connected with the main stem of the Woonasquatucket River. Based on Figure ES-2 of the Oxbow BHHRA, and consistent with the *Final Work Plan*, the remaining samples were collected from low lying, wet areas.

Battelle describes the chemical and physical analysis of these data in the report entitled *Chemistry Data Report, Task RI-12 Oxbow Area Sediment Investigation* (Battelle, 2004b) ("*Chemistry Data Report*"). The *Chemistry Data Report* is replete with references to the subject samples as sediment. In fact, the term "sediment" or its shortened version "sedimen" is used *103 times* in the *Chemistry Data Report* to describe the samples.

The high moisture content of the sediment samples suggests that all but one of the samples were either submersed sediments that were in areas of pooled water in the former channel, which is hydraulically connected with the river channel, or saturated soil samples. The mean daily flow rate of the Woonasquatucket River at the time of sampling (June 21, 2004) was only

18 cubic feet per second (cfs), which is approximately one-third the monthly mean flow for June and only the 5th percentile flow for this day using data collected between 1960 through 2004. Even with such low river flow, areas were easily found during the sampling event to collect sediment samples apparently beneath standing water.

Given the fact that: 1) the *Final Work Plan* was written specifically to target the evaluation of sediments -- the term "soil" is not used once in this document; 2) the *Chemistry Data Report* describes the samples collected from the Oxbow Area as sediment 103 times; 3) the very low percent solids content of the Oxbow Area samples (29%, 14%, 38%, 12%, 13%, 23%, and 58%) indicates the samplers followed the instructions of the *Final Work Plan* and collected the samples from submerged areas or areas targeted because of their apparent hydraulic connection with the main stem of the River; and 4) the river flow at the time of sampling was only 18 cfs -- the 17th percentile for the year, one can easily conclude that the samples collected are *not* floodplain soil samples, but rather sediment samples.

Because the samples appear to have been collected in submerged areas or areas targeted because of their apparent hydraulic connection with the main stem of the River, the samples do not represent the entire flood plain. If anything, these samples are more indicative of submerged sediment or the areas on the immediate fringe of the wet areas.

## 3.0 DIRECT CONTACT PATHWAYS

The Oxbow BHHRA uses a number of direct contact assumptions that lead to overestimates of exposure and risk, as discussed in this section.

First, as mentioned above, the data collected for the Oxbow Area are indicative of submerged sediment or the areas on the immediate fringe of the wet areas. Given that the flow of the river during the time of sampling was relatively low with respect to the average daily flow during the season in which exposure is assumed to occur (May through October), it is likely that the sample locations are typically submerged. Thus, exposure to the areas sampled for this risk assessment are better defined as exposure to sediments by wading rather than exposure to bank soil from passive uses (walking, bird watching, and exploring).

Wading is not likely to occur at the same frequency as exploring and bird watching. In fact, wading will not likely occur unless the individual is prepared to swim. However, the wet areas in the Oxbow Area are not attractive swimming locations, so swimming is not a likely reason for wading in the Oxbow Area. While it is possible that the older child may wade while exploring, the frequency, however, would be less than that used in the Oxbow BHHRA. In fact, it is unlikely that most individuals would spend substantial amounts of time wading in the river or ponds that do not have beach areas. Adults may wade while exploring or doing maintenance activities (e.g., cleaning out litter or vegetation) but would not generally be expected to wade unless they planned to swim as well. Thus, it would be more reasonable to assume that adults wade two days per month, for an additional exposure frequency of six days per year. Young children would not be permitted to play along the ponds without adult supervision. Thus, their water exposure frequency would be similar to adults (15 days).

## 4.0 SELECTION OF SOIL INGESTION RATES

In assessing exposures and risks from the ingestion of Oxbow Area sediment, the Oxbow BHHRA uses the upper-bound soil ingestion rates of 200 mg/day for young children (1 to 6 years of age) and 100 mg/day for older children and adults. For the CTE exposures, the Oxbow BHHRA generally uses soil ingestion rates of 100 mg/day for young children and 50 mg/day for older children and adults.

As described in the Oxbow BHHRA, the general soil ingestion rates are based on *EPA New England's Risk Update Number 2* (EPA, 1994a). However, improved, more recent studies of soil ingestion by both children and adults have been published in the peer-reviewed literature. These studies show that the rates used in the Oxbow BHHRA are overestimated. Because of improvements in study methodologies, the results of these more recent studies are more representative of potential exposures to these receptor groups. Specifically, two recent studies (discussed below), published by the authors of the studies upon which EPA has based its upper-bound estimates, provide the most objective information for use in deriving high-end estimates of daily soil intake. Adoption of these more recent data would be consistent with EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA, 2002b). These guidelines identify information suitable for inclusion in risk assessments as "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies."

**Soil Ingestion Rates for Younger Children**

The Oxbow BHHRA uses a soil ingestion rate of 200 mg/day to evaluate RME exposures to 1- to 6-year-old children. Fifteen years ago, EPA recommended this rate in its *Risk Assessment Guidance for Superfund* (EPA, 1991), and reiterated that recommendation in its *Exposure Factors Handbook* (EPA, 1997), as a "conservative estimate of the mean." The latter recommendation was based primarily on tracer studies in children (ages 1 through 5) that were undertaken by Calabrese and his coworkers (Calabrese et al., 1989; Stanek and Calabrese, 1995a; 1995b). However, updated studies by these same authors, conducted using improved methodologies and published since that guidance was released, indicate that these previous estimates are overestimates and can be refined and improved.

The most recent such study in children was published by Stanek et al. (1999) and Stanek and Calabrese (2000). As described by Stanek and Calabrese (2000), this study implemented several improvements in study design and analytical procedures that occurred since the publication of their earlier papers and that led to an improved estimate of the 95$^{th}$ percentile soil ingestion estimate for this age group. The advantages of this recent study include: (1) a relatively large study group (n = 64 children); (2) improved particle size measurements that focused attention on soil of smaller particle size; (3) a longer study duration (365 days); (4) randomized selection of participants; (5) the use of a relevant age group (1- to 4-year-old children); (6) use of a random sample of the population for that age group; and (7) better control for input/output error. The soil ingestion rates reported by Stanek and Calabrese (2000) for these children were:

- A 95$^{th}$ percentile rate of 106 mg/day (when evaluated over a 365-day period);
- An arithmetic mean ingestion rate of 31 mg/day; and
- A median (50$^{th}$ percentile) ingestion rate of 17 mg/day.

This study also calculated the best linear unbiased predictors of the 95$^{th}$ percentile of soil ingestion over different time periods and reported the following results:

- Over a 7-day exposure period, the 95$^{th}$ percentile soil ingestion rate was 133 mg/day;
- Over a 30-day exposure period, the 95$^{th}$ percentile soil ingestion rate was 112 mg/day;
- Over a 90-day exposure period, the 95$^{th}$ percentile soil ingestion rate was 108 mg/day; and

- Over a 365-day exposure period, the 95th percentile soil ingestion rate was 106 mg/day.

These data suggest that as the length of time that the children are studied increases and as the precision of the analysis improves (i.e., reduced uncertainty), the daily ingestion rate estimates decline. This result is reasonable due to the fact that daily fluctuations in soil ingestion rates will tend to average out over time. This narrowing of the distribution in the soil ingestion estimates when daily variability and uncertainty are reduced is not unexpected and is referred to as "regression to the mean" (Stanek and Calabrese, 2000). As noted by Stanek and Calabrese (2000), the use of these longer-term estimates is more appropriate when assessing risks and hazards associated with chronic exposure, as is the case in the Oxbow BHHRA.

In a presentation to EPA Region 1 in May 2002, Dr. Calabrese explained these developments and recommended, based on this more recent study, that the soil ingestion rates to be used for young children in recreational scenarios should be 100 mg/day for the upper bound and 20 mg/day (based on the median in this study) for the central tendency estimate. Dr. Calabrese has reiterated these recommendations in correspondence submitted to EPA Region 1. A copy of Dr. Calabrese's letter is attached as Exhibit 1. Based on the more recent and scientifically robust study data, the Oxbow BHHRA should be revised to use these newer rates as the general soil ingestion rates for 1- to 6-year-old children in residential and recreational exposure scenarios.

**Soil Ingestion Rates for the Older Child and Adult**

As noted in the Oxbow BHHRA, the general soil ingestion rates used to evaluate exposures to older children and adults (100 mg/day for the RME and 50 mg/day for the CTE) are based on EPA (1994a). Again, however, there is now a more recent study of adults by the same investigators (Stanek et al., 1997), which included a number of improvements to previously published studies: (1) a larger number of subjects and days of participation; (2) improved study design that considered seven consecutive days of fecal sampling; (3) improved selection of soil tracers; (4) a broader range of soil ingestion validation; and (5) enhanced capacity for additional assessments including particle size of the soil ingested. The result of the improved study is more reliable daily estimates of soil ingestion and a greater capacity for more reliable long-term modeling estimates.

The 1997 study was not without complications, however. Of the ten adults participating in the study, one had an unusually high soil ingestion estimate (2 grams) for the first day of the study week. This high estimate resulted in an inflated upper percentile estimate of the overall ingestion rates. In fact, Stanek et al. (1997) stated that "the 95th percentile soil ingestion estimate was 331 mg/day, but based on present data, it is substantially uncertain" because of the results from this one subject. Further, as described by Dr. Calabrese (a co-author of the paper) in his attached letter, this subject had four times higher freeze-dried fecal weight on the first day than on any other day of the study, thus suggesting that his excretion on that day reflected a multi-day accumulation, instead of just one day, as assumed in the calculations. This fact further substantiates the view that the 95th percentile value from this study, which is driven by the result for this one subject, is not only uncertain but substantially overestimated. Due to this aberrant result from one participant, Dr. Calabrese has recommended, in his attached letter, that the upper 75th percentile (49 mg/day, rounded to 50 mg/day) from the Stanek et al. (1997) study is the most appropriate value to use as an estimate of high-end soil ingestion by adults. He has also recommended use of a value of 10 mg/day for the central tendency estimate. This is consistent with the results of Stanek et al. (1997), who reported an adult mean daily soil ingestion estimate of 6 mg/day, and it represents 50 percent of the young children's median rate. EPA should use these soil ingestion rates in the Oxbow BHHRA.

For the reasons discussed above, EPA should revise the Oxbow BHHRA to adopt general soil ingestion rates based on the more recent and improved studies (Stanek and Calabrese, 2000, for young children; Stanek et al., 1997, for older children and adults).

If exposure parameters for the soil and sediment contact pathways were modified to reflect more reasonable exposure conditions, estimated risks would be within EPA's acceptable risk range.

## 5.0 TOXICOLOGY OF DIOXIN AND DIOXIN-LIKE COMPOUNDS

The Site-wide BHHRA's (EPA, 2005) discussion of dioxin toxicology fails to fully discuss the full range of potential dioxin cancer potency factors. EPA should include further discussion on the toxicology of dioxin, specifically identifying peer-reviewed scientific studies spanning the full range of plausible cancer slope factors for 2,3,7,8-TCDD. Moreover, the Oxbow BHHRA should state that EPA has never published a cancer slope factor (CSF) for TCDD in IRIS and that the carcinogenic potential of TCDD is a matter of much debate in the dioxin reassessment process that has been underway at EPA for 15 years.

A wide range of CSFs based on animal studies, ranging from 9,000 to 156,000 $(mg/kg\text{-}day)^{-1}$, have been proposed by various groups under the linear, non-threshold cancer model, with differences resulting from the selection of tumor classification scheme and interspecies scaling factor used (EPA, 1994b, 2000; FDA, 1993, 1994; Keenan et al., 1991). Recently, in two subsequent revisions of the draft Dioxin Reassessment, EPA proposed the use of a CSF of 1,000,000 $(mg/kg\text{-}day)^{-1}$ based on its evaluation of human epidemiological data (EPA, 2000; 2003). However, there is substantial disagreement concerning the appropriate CSF for TCDD. In fact, in its review of EPA's draft final Dioxin Reassessment, the Agency's Science Advisory Board discussed the uncertainties associated with the available dose-response data and the extrapolation methods used, and stated that they could not "reach consensus on a single value for a dioxin potency factor" (EPA, 2001; p. 6). Subsequently, Congress directed EPA to undertake an agreement with the National Academy of Sciences (NAS) to review the draft Dioxin Reassessment (House of Representatives, 2003). Among other key issues, Congress asked NAS to evaluate: 1) the validity of the non-threshold linear dose-response model in light of epidemiological studies; 2) the corresponding cancer slope factor calculated by the Agency through use of this model; and 3) the appropriateness of including dioxin-like chemicals in the risk assessment without independent empirical review of their effects. (House of Representatives, 2003, pp. 1445-46). Thus, there is substantial uncertainty associated with any selected CSF, and, depending upon the CSF selected, the resulting regulatory standards and remedial decisions can vary by orders of magnitude.

NAS recently completed its review of the draft Dioxin Reassessment (NAS, 2006). Among its conclusions, the NAS committee determined that the available data support a nonlinear relationship rather than defaulting to a non-threshold linear model as EPA has in the past. NAS concluded,

> "The committee unanimously agrees that the current weight of evidence on TCDD, other dioxins, and DLCs [dioxin-like compounds] carcinogenicity favors the use of nonlinear methods for extrapolation below the point of departure (POD) of mathematically modeled human or animal data." [p. 135]

NAS further commented that,

> "a risk assessment can be conducted without resorting to default assumptions. To the extent that EPA favors using default assumptions for regulating dioxin as

though it were a linear carcinogen, such a conclusion should be supported with scientific evidence." [p. 100]

Summarizing this issue, NAS stated that,

> "The selection of the default linear extrapolation approach was one of the most critical decisions in the Reassessment, but the decision to use this approach was not supported by a scientifically rigorous argument, nor was there a balanced presentation of arguments that would support the calculation and interpretation of a MOE [margin of exposure] with the same data. The committee determined that a balanced presentation of available data could support the use of a threshold model with subsequent calculations and interpretation of MOE. (For cancer risk assessment, the threshold approach should be used in addition to the linear approach.)" [p. 140]

While NAS (2006) commended EPA on its use of the benchmark dose (BMD) method as a replacement of the traditional approach of using the no-observed-adverse-effect level (NOAEL) and lowest-observed-adverse-effect level (LOAEL), NAS criticized EPA for using an effective dose (ED) at a 1% response level (ED01) for characterizing cancer and noncancer risks. NAS stated,

> "In its evaluation of ED01 used for cancer risk assessment, the committee concluded that EPA had not adequately justified use of the 1% response level as the POD for the analysis of either the epidemiological or the animal bioassay data...
>
> For the various noncancer end points, EPA should describe more clearly how and why the ED01 values were determined in animals and transferred to human equivalents. At the least, the risk assessment should provide more apparent and parallel calculations using a 5% response level as the POD to demonstrate the impact that this assumption might have on both the point estimates of risk at low doses and the range of uncertainty surrounding that point estimate. This recommendation applies to extrapolation for cancer risk estimates, as well as for noncancer risk estimates. " [pp. 135-136]

The NAS committee recommended that EPA consider the full range of animal bioassay data, "including the new NTP animal bioassay studies on TCDD, other dioxins, and DLCs for quantitative dose-response assessment." [p. 136]

While NAS agreed that use of body burden as the dose metric is a reasonable approach, the committee raised a number of uncertainties associated with using body burden to develop risk estimates. NAS (2006) concluded,

> "The magnitudes of the various uncertainties are not clearly defined. The most significant impact is the species differences in percentage body fat on the relationship between body burden and the concentrations present in nonadipose

tissues. An analysis of the impact of possible uncertainties in the dose metric on the final risk estimates would be informative.

It remains to be determined whether the current WHO TEFs, which were developed to assess the relative toxic potency of a mixture to which an organism is directly exposed by dietary intake, are appropriate for body burden toxic equivalent quotient (TEQ) determinations, which are derived from the concentrations of different congeners measured in BF. If body burdens are to be used as the dose metric, a separate set of body burden TEFs should be developed and applied for this evaluation. Without these corrected values, the overall TEQs estimated by use of intake TEFs might be substantially in error." [p. 138]

Furthermore, the high level of uncertainty associated with the application of the CSF for TCDD to dioxin-like PCBs is unnecessary, due to the fact that EPA (1996) has already established a CSF for PCBs that is based on empirical bioassay data. In addition, depending upon how this is done, the approach may substantially overestimate the carcinogenic potential of PCBs as it may double-count the carcinogenic potential of the entire mixture. This is because the approach that is often used evaluates the "dioxin-like" PCBs using the CSF for TCDD but then evaluates the carcinogenic potential of the remaining "non-dioxin-like" PCBs using the CSF that EPA has established for PCBs. However, the CSF that has been derived for PCBs includes the carcinogenic activity of the entire PCB mixture tested, including both the "dioxin-like" and the "non-dioxin-like" congeners. Thus, the carcinogenic potential of the "dioxin-like" congeners is counted twice and added together when this approach is used.

## 6.0 CONCLUSION

This review has identified, documented, and discussed the technical shortcomings of the analyses that comprise EPA's Oxbow BHHRA report. We have focused on those exposure scenarios and risk assessment topics that have the greatest implications for setting target remediation goals and assessing remedial options. Our review does not comment on those aspects of the Oxbow BHHRA that do not appear to be influential in evaluating remedies or determining outcomes for the Site. Instead, we have discussed the substantial shortcomings and biases inherent in EPA's assessment of potential risks via incidental soil and sediment ingestion, which is the exposure pathway that poses the greatest theoretical risk for the Oxbow BHHRA.

Because these exposure pathways will be used by EPA to develop PRGs in a separate document, the flaws in the Oxbow Area risk assessments will result in flawed and inappropriate

PRGs, if left uncorrected. The development of PRGs requires a much more robust and unbiased risk assessment in which state-of-the-art methods of risk analysis are coupled with competent interpretation and analyses of available data. The Oxbow BHHRA does not meet this standard in its present form, and anything short of a complete overhaul and revision is unlikely to approach the level of sophistication required to serve as the basis for establishing technically defensible remedial cleanup goals for the Centredale Manor Restoration Project Superfund Site.

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Exhibit 1

July 23, 2003

Kevin W. Holtzclaw
Manager – PCB Issues
General Electric Company
3135 Easton Turnpike
Fairfield, CT 06431

**Re: Soil Ingestion Rates**

Dear Mr. Holtzclaw:

The General Electric Company (GE) has asked for my opinion on the soil ingestion rates used by the U.S. Environmental Protection Agency (EPA) for general residential and recreational exposures in its June 2003 draft of the Human Health Risk Assessment (HHRA) for the Housatonic River. For upper bound exposures, those rates are 200 mg/day for young children and 100 mg/day for older children and adults. The central tendency estimates are 100 mg/day for young children and 50 mg/day for older children and adults. These rates are based on prior studies by our group – Calabrese et al. (1989) and Stanek and Calabrese (1995a, b) for young children, and Calabrese et al. (1990) for adults.

As explained in a presentation that I made on this subject to EPA Region 1 in May 2002, I believe that these rates are overstated and can be significantly improved by reliance on newer soil ingestion studies from our group, which used improved methodologies. I have reviewed the discussion of this topic in the document entitled "Attachment E: Selection of Soil Ingestion Rates," which GE sent me and which I understand will be part of GE's comments on the HHRA. I entirely agree with that discussion. To summarize:

1. Soil Ingestion Rates for Young Children. Our most recent study of soil ingestion rates in young children (Stanek and Calabrese, 2000) included several improvements over our prior studies. These included: 1) a relatively large study group (64 children); 2) improved particle size measurements that focused attention on soil of smaller particle size; 3) a longer study duration (365 days); 4) the use of a relevant age group (1 to 4 year old children); 5) use of a random sample of the population for that age group; and 6) better control for input/output error. The results of this study showed a 95$^{th}$ percentile soil ingestion rate of 106 mg/day (when evaluated over a year), a median (50$^{th}$ percentile) ingestion rate of 17 mg/day, and an arithmetic average ingestion rate of 31 mg/day. Based on these results, I recommend that the most appropriate soil ingestion rates to use for chronic exposures to young children would be an upper bound rate of 100 mg/day (based on the year-long 95$^{th}$ percentile value from our study) and a central tendency estimate of 20 mg/day (based on the median value from our study).

2. Soil Ingestion Rates for Adults and Older Children. Our most recent study of soil ingestion rates in adults (Stanek et al., 1997) likewise included a number of improvements over our prior (1990) study. These included: 1) a larger number of subjects (10) and days (28) of participation; 2) an improved study design that considered seven consecutive days of fecal sampling; 3) improved selection of soil tracers; 4) a broader range of soil ingestion validation; and 5) an enhanced capacity for additional assessments including particle size of the soil ingested. In this study, one of the participating adults had an unusually high soil ingestion estimate (2 grams) on the first day of the study week. In fact, on that day, this subject had 4 times higher freeze-dried fecal weight than on any other day of the study, suggesting that his excretion on that day reflected a 3-4 day accumulation, instead of just one day, as assumed in the calculations. In consequence, the 95$^{th}$ percentile ingestion rate from this study (331 mg/day), which is driven by that result for one subject, is uncertain, unstable, and artificially inflated. In these circumstances, I recommend that EPA use the upper 75$^{th}$ percentile value from this study, which was 49 mg/day, as the basis for an upper bound soil ingestion rate of 50 mg/day for adults and older children. For the central tendency estimate, I recommend use of an ingestion rate of 10 mg/day. This is consistent with the

mean soil ingestion rate observed in our 1997 study (6 mg/day) and would represent half of the central tendency rate that I have recommended for young children.

I appreciate the opportunity to review these materials. Please do not hesitate to contact me if you have any further questions.

Sincerely,

Ed Calabrese

Edward J. Calabrese, Ph.D.
Professor of Toxicology
Director of the Northeast Regional
Environmental Public Health Center

EJC/ps

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# COMMENTS ON THE ADDENDUM TO THE INTERIM-FINAL BASELINE ECOLOGICAL RISK ASSESSMENT: OXBOW AREA
CENTREDALE MANOR RESTORATION PROJECT SUPERFUND SITE
NORTH PROVIDENCE, RHODE ISLAND
AUGUST 2006

December 21, 2006

AMEC Earth and Environmental, Inc.
15 Franklin Street
Portland, ME 04101

## 1.0 INTRODUCTION

In August 2006, EPA Region I released the Addendum to the Interim-Final Baseline Ecological Risk Assessment: Oxbow Area (Oxbow BERA) for the Centredale Manor Restoration Project Superfund Site (Site) (Battelle, 2006). The Oxbow BERA was prepared by Batelle Corporation, and was submitted to the Department of the Army, U.S. Army Corps of Engineers, New England Division. The Oxbow BERA presents an assessment of potential hazards for a number of sensitive receptor communities reportedly exposed to Oxbow Area soil and sediment. Receptor communities include floodplain invertebrates and vermivorous (American woodcock and short-tailed shrew) and omnivorous wildlife. Media evaluated include soil and sediment. Weight of evidence hazards were estimated for receptors that may reside in the Oxbow Area. Greystone Mill Pond was designated as the background area for this assessment.

At the request of Emhart Industries, Inc., AMEC Earth & Environmental, Inc. prepared these comments on the Oxbow BERA. The comments focus on those calculations, exposure scenarios and risk assessment topics that have the greatest impact on setting target remediation goals and assessing remedial options. Accordingly, the comments do not address aspects of the report that do not appear to be influential in evaluating remedies or determining outcomes for the site.

There are three primary overriding concerns with the Oxbow BERA. First, the chemical data used for the Oxbow BERA are limited to seven sampling stations. By and large, these samples are indicative of wetland sediment or at least saturated soils. However, the Oxbow Area consists of both wetland features and upland features. In fact, the terrestrial receptors evaluated for the Oxbow BERA are more likely to reside and forage in the upland areas, and not in the areas represented by the saturated soil/sediment samples used for this assessment.

Second, the conclusion reached by the Oxbow BERA for floodplain soil macroinvertebrates is inconsistent with the conclusion for the same receptor in the BERA for the rest of the Site (Battelle, 2004a). Because the Oxbow BERA does not use the semi-quantitative weight of evidence approach used in the Site-wide BERA, it fails to conclude that there is not a substantial risk of harm to invertebrates in the Oxbow Area due to contaminants from the Site, even though the computed hazard indices for soil invertebrates in the Oxbow Area were either comparable to or less than those computed for other areas assessed in the BERA (i.e., Lyman Mill and Allendale Pond flood plain soils).

Third, use of an incremental risk assessment approach fails to fully emphasize the overall comparability of the potential risks to the evaluated receptors in the Oxbow Area and those in the background area (Greystone Mill). The merits of a chosen remedy must take into consideration the efficacy of that remedy on the overall risk to an ecological receptor with respect to background. The incremental risk assessment approach used in the Oxbow BERA has been used as an accounting tool to ascertain relative contributions of risks from different sources, but the receptors cannot and do not differentiate between source contributions (site-related vs. background). Therefore, to exclude the risks from background sources from consideration in the assessment conclusions could lead a reader to conclude that if a remedy is instituted to mitigate site-related chemicals, the receptor will no longer be at risk. However, background chemicals that may not be addressed as part of the remedy could still pose a significant risk to the receptors.

Section 2.0 of this document presents general comments regarding the Oxbow BERA. Section 3.0 provides detailed comments on the problem formulation component. Detailed comments on the floodplain invertebrate community risk analysis are presented in Section 4.0. Section 5.0 presents comments on the ecological risk assessment uncertainty assessment. Finally, Section 6.0 provides a discussion of the comments and presents conclusions about the Oxbow BERA.

## 2.0 GENERAL COMMENTS

**The samples used as the basis for the Oxbow BERA are not likely representative of the habitats needed to support earthworms and vermivores.**

As mentioned above, EPA collected samples from seven locations within the Oxbow Area. Review of the data, the work plan underlying the sample collection, and photographs and maps of the Oxbow Area indicate that the data that have been used in the Oxbow BERA are not likely to be indicative of the types of habitats in which the receptors would reside.

The data that were used to assess the potential risks were almost entirely limited to sediment data. Of the seven samples used in the assessment, only one had solids content greater than 50% (58% in sample LPX-SD-4405-005). The remaining 6 samples had solids contents between 12 and 36% with an average of only 21%. Samples with such low solids content (12-36%) are indicative of sediment samples or saturated soil samples.

The fact that the samples were limited to sediment matrices is not unexpected. The document, *Final Work Plan, Sediment Sample Collection and Analysis at the Oxbow Area, Centredale Manor Restoration Project Superfund Site* (Battelle, 2004b) ("*Final Work Plan*"), which details where the Oxbow Area samples would be collected, states clearly in its title that the samples were intended to represent sediment. In fact, the term "soil" in not used in this document. The *Final Work Plan* states in the Sediment Sample Collection section that "Sample locations will be adjusted in the field to exclude areas of artificial fill or gravel, and *ensure that samples are collected from topographically low areas"* [emphasis added]. The sampling work plan goes on to describe that three specific locations would be collected from within the North Channel, which is hydraulically connected with the main stem of the Woonasquatucket River. Based on Figure ES-2 of the Oxbow BHHRA, and consistent with the *Final Work Plan*, the remaining samples were collected from low lying, wet areas.

Battelle describes the chemical and physical analysis of these data in the report entitled *Chemistry Data Report, Task RI-12 Oxbow Area Sediment Investigation* (Battelle, 2004c) ("*Chemistry Data Report*"). The *Chemistry Data Report* is replete with references to the subject samples as sediment. In fact, the term "sediment" or its shortened version "sedimen" is used *103 times* in the *Chemistry Data Report* to describe the samples.

The high moisture content of the sediment samples suggests that all but one of the samples were either submersed sediments that were in areas of pooled water in the former channel, which is hydraulically connected with the river channel, or saturated soil samples. The mean daily flow rate of the Woonasquatucket River at the time of sampling (June 21, 2004) was only 18 cubic feet per second (cfs), which is approximately one-third the monthly mean flow for June and only the 5$^{th}$ percentile flow for this day using data collected between 1960 and 2004. Even with such low river flow, areas were easily found during the sampling event to collect sediment samples apparently beneath standing water.

Given the fact that: 1) the *Final Work Plan* was written specifically to target the evaluation of sediments -- the term "soil" is not used once in this document; 2) the *Chemistry Data Report* describes the samples collected from the Oxbow Area as sediment 103 times; 3) the very low percent solids content of the Oxbow Area samples (29%, 14%, 38%, 12%, 13%, 23%, and 58%) indicates the samplers followed the instructions of the *Final Work Plan* and collected the samples from submerged areas or areas targeted because of their apparent hydraulic connection with the main stem of the River; and 4) the river flow at the time of sampling was only 18 cfs -- the 17th percentile for the year, one can easily conclude that the samples collected are *not* flood plain soil samples, but rather sediment samples.

## 3.0 PROBLEM FORMULATION

**The identification of the American woodcock as a vermivorous receptor should be reconsidered given the urban nature of the area and the lack of adequate habitat.**

The American woodcock should not be used as a receptor in the Oxbow BERA because the habitat of the Oxbow Area is not conducive to the presence of woodcock. The lack of suitable habitat has nothing to do with the Site or the contamination present in the river sediments. Rather, the lack of habitat is due to the fact that the Oxbow Area consists primarily of a mature red maple forested wetland fringed by palustrine emergent and scrub shrub wetlands. The Oxbow Area does not have adequate open spaces that are used by woodcock. Woodcock require four different habitat types. Clearings are used by males for courtship display. Moist, fertile soils with alder or dense second growth hardwood offer feeding areas. Young, second growth hardwood stands provide nesting and brood rearing habitat. Large fields are needed as night roosting sites. It is important for woodcock to have all four habitat elements in close proximity. The Oxbow Area lacks several of these critical habitat components.

Indeed, the lack of suitable habitat is discussed in the Oxbow BERA on page 2-3 where it states, "The woodcock is selected as a receptor of concern to provide consistency with the BERA; however, it should be noted that woodcock are not likely to heavily utilize the mature red maple forested floodplain that occupies a majority of the Oxbow Area". Providing consistency with the BERA should not be a reason for selecting the woodcock as a receptor. The decision about receptors should be made based on the ability of the habitat to support a population of the receptors. If the habitat of the Oxbow Area is not conducive to woodcock, it should not be a receptor in the Oxbow BERA because the exposure pathway would not be complete.

**The data used in the Oxbow BERA are not from areas that are suitable habitat for the floodplain macroinvertebrate and vermivorous receptors evaluated.**

Battelle states that earthworms, woodcock and short-tailed shrews are some of the receptors of interest for the Oxbow BERA. However, the data that are used are collected from areas that are not representative of suitable habitat for these receptors. The presence of the latter two receptors will, in large part, be dictated by the availability of prey items. Earthworms are the prey item that comprise the base food source for the woodcock and the shrew. Therefore, if earthworms are not present, or not present at a sufficient density, vermivores such as the woodcock and shrew would not be present.

As stated above, the solids content of the samples collected from the Oxbow Area were 29%, 14%, 38%, 12%, 13%, 23%, and 58% (Battelle, 2004c) which translate to moisture contents of 71%, 86%, 62%, 88%, 87%, 77%, and 42%, respectively. Appendix E of the BERA (Battelle, 2004a) contains the results of the earthworm sampling effort conducted on the floodplain soils of Greystone Mill, Allendale, and Lyman Mill Ponds. As part of this effort, a total of eleven locations were sampled for earthworms. Battelle (2002) contains the corresponding soils chemistry data, including percent moisture, for the locations sampled for earthworms. The following table summarizes the moisture content and earthworm sampling success at each of the eleven locations.

| Soil & Earthworm Sample Locations | Soil Percent Moisture | Catch per Unit Effort (sampling hrs/120 g of tissue) |
|---|---|---|
| RWR-5001 [a] | 66.93 | 17.5 |
| RWR-5002 | 48.08 | 6.0 |
| RWR-5003 | 41.63 | 3.0 |
| RWR-5004 | 54.12 | 0.9 |
| CMS-4001 | 43.36 | 3.0 |
| CMS-4002 | 51.38 | 6.0 |
| CMS-4003 | 44.69 | 2.9 |
| CMS-4005 | 44.69 | 1.8 |
| LPX-4004 | 35.45 | 3.3 |
| LPX-4006 | 49.3 | 3.5 |
| LPX-4007 | 44.98 | 1.0 |

Notes:

a – This was the least productive sampling station. Digging and electro-shocking occurred beyond the limits of the 10' x 10' quadrat, which was the standard sampling size for all other locations.

The earthworm productivity at the location with a soil moisture content in excess of 65% is approximately 35% of the next lowest productive areas, 25% of the average productivity, and less than 6% of the highest productive sites. These percent productivity values are actually inflated because, for sample RWR-5001, the samplers had to excavate an area larger than the standard 10' x 10' area that was used for the remaining samples. Therefore on a standard area basis, the productivity is lower at RWR-5001 than shown here (i.e., >17.5 hrs/120g of tissue).

These site-specific data describe what is intuitive -- that soil with a high moisture content (e.g., >65%) will not provide a suitable earthworm habitat when compared to areas having lower moisture contents. Five of the seven samples collected for the Oxbow Area have soil moisture contents of 71% or greater. One of the remaining two Oxbow Area samples has a moisture content of 62%, marginally below the level at location RWR-5001. Only one Oxbow Area sample contains soil moisture levels in the range of the earthworm sampling locations that exhibited a higher productivity.

The Oxbow Area sampling data provide only a short-term view of soil moisture content. However, these data can be supplemented with historic river flow data to put the soil moisture contents into context with the rest of the year. According to USGS, the mean daily river flow for 82% of the days in 2004 was greater than that experienced during the time of sampling. In addition, historic USGS data indicate that the mean daily river flow during the months of May through October is far greater than the flow on the day of sampling (73 cfs vs. 18 cfs). The river flow data supports the idea that the areas where the Oxbow Area samples were collected are likely saturated for a majority of the year. As pointed out in the Oxbow BERA, if the soils are hydric saturated soils, they would not be representative of areas that could support earthworms or vermivorous receptors (such as the short-tailed shrew and woodcock). Therefore, the use of these data to evaluate the potential risks to earthworms, short-tailed shrews, and woodcock is inappropriate. As a result, the conclusions of the Oxbow BERA regarding these receptor groups are not supportable because the receptors' habitats are not collocated with the sample locations.

**EPA fails to adequately incorporate important and relevant site-specific information in the life history summaries.**

In the Oxbow BERA, EPA fails to incorporate relevant and significantly important information in the potential receptor life history discussions. Additional discussion concerning the presence or absence of the receptors evaluated at the Site should be added to the life history summaries as a means of ground-truthing the conceptual site exposure model used in the Oxbow BERA. EPA should augment the existing discussion with the relevant site-specific habitat information.

## 4.0 FLOODPLAIN INVERTEBRATE COMMUNITY RISK EVALUATION

**There is insufficient discussion of the representativeness of using several of the benchmarks in the uncertainty assessment.**

The risk characterization (Section 3.1.3) and uncertainty (Section 4.2) discussions should contain a more detailed examination of the benchmarks used to assess the floodplain invertebrates. In particular, the benchmarks based on either EPA's EcoSAR software or the equilibrium partitioning (EqP) approaches, which are based on estimated surface water toxicity, may not be fully extrapolated to floodplain invertebrates without much uncertainty. This uncertainty may explain, in part, the high hazard quotient (HQ) values that were calculated, which did not support the results of the community assessments that showed no adverse effects on the floodplain invertebrates.

**EPA should provide additional discussion concerning the uncertainty in the Critical Body Residue (CBR) values.**

Although the uncertainty in the CBR values used to evaluate earthworm concentrations is discussed to a limited extent in the uncertainty section (Section 4.2), EPA should discuss other sources of uncertainty for using CBR data for earthworms. Lanno et al. (2004) summarizes several of the key issues related to chemical bioavailability for earthworm uptake. This may become especially important when extrapolating CBR estimates of unrelated invertebrates to earthworms. For example, the 2,3,7,8-TCDD CBR benchmark for earthworms is based on crayfish following aqueous exposure.

**EPA should not use the minimum soil Total Organic Carbon (TOC) content to estimate earthworm body burdens.**

EPA used a TOC concentration of 8.9% as a representative TOC content for the Oxbow Area soil. This value is the average TOC of sample LPX-SD-4402 and its field duplicate, LPX-DU-062104B. These samples had TOC levels of 13.03 and 4.73 percent, respectively. The relative percent difference between these two samples is 93.5%, indicating that the field sampling technique did not allow for adequate soil homogenization. The other two Oxbow Area samples having TOC analysis contained 15.73 and 36.14 percent TOC. Clearly the field duplicate sample was biased low, likely having been comprised of deeper soils. The remaining samples are more in line with the TOC levels one would expect for the Oxbow Area. This is particularly true for these samples, which, as explained above, are sediment samples. The higher TOC levels detected in the Oxbow Area samples are similar to the TOC contents found in other

Lyman Mill Pond sediments. EPA should not have used the duplicate sample data because it is an outlier and not representative of the Oxbow Area sediment samples.

**The Oxbow BERA conclusion regarding the potential risks to earthworms is inconsistent with the finding of no significant risk in the BERA.**

In Section 3.0 of these comments, we discuss why the Oxbow BERA sampling locations are not indicative of a habitat suitable for supporting a significant earthworm population and, accordingly, why these data should not be used as a starting point for the earthworm assessment. Nevertheless, even if one uses EPA's current analysis, the conclusion of the Oxbow BERA for the earthworm is ambiguous as currently written. In contrast, the BERA for the rest of the Site, which had similar HQs for the earthworm, concluded that the soil invertebrate community is not likely to be at a substantial risk to harm from site-related compounds. The same statement should be made for the Oxbow BERA because it is the same system and, by extension, the results of the earthworm community study conducted for the BERA are also likely representative of the areas of the Oxbow that could support an earthworm population (i.e., areas that are upland from the current Oxbow Area sediment sampling locations). Applying this reasonable and appropriate assumption should lead EPA to conclude that the soil invertebrate community in the Oxbow Area is not likely to be at substantial risk to harm from site-related compounds.

**EPA should have used Oxbow Area-specific biota data for the Insectivorous Mammal and Bird Populations Evaluation.**

EPA relied on a food web model to predict potential exposures to the woodcock and short-tailed shrew. However, as discussed above, the samples that were used as the basis for this analysis were neither representative of the Oxbow Area nor did they represent soils that would be suitable habitat for earthworms, the primary prey item for the selected receptors. At a minimum, EPA should have collected earthworm samples from several areas within the Oxbow Area to better assess the potential exposure for higher trophic level species. The modeling that is currently used to estimate exposure to the vermivores is flawed because the data used to determine the intakes are insufficient for the assessment and likely significantly overestimate potential exposure.

## 5.0 ECOLOGICAL RISK UNCERTAINTY ANALYSIS

**The uncertainty discussion is qualitative and no quantitative discussion of the relative importance of the different uncertainty components is provided.**

The uncertainty discussion is general and qualitative, and only a minimal effort was made to estimate the potential biases in the input parameters and their impacts on the calculated risks. The use of a more quantitative assessment would provide bounding estimates for the risks, and therefore provide better supporting information for any risk management decisions.

**There is no discussion of the cumulative impact on the final risk estimates of combining a number of conservatively biased assumptions and modeling approaches.**

The lack of site-specific data for portions of many of the exposure pathways and receptors that were evaluated in the Oxbow BERA resulted in the need to model uptake values and potential exposures to the receptors of concern. Generally, very conservative assumptions and parameters have been used to ensure that potential exposures and risks are not underestimated. While any one of these assumptions may be a reasonable upper-bound estimate for a given parameter, when multiple assumptions and parameters are combined and conservative Toxicity Reference Values (TRVs) are used as points of comparison, the resulting calculated HQs may not be reasonable or realistic. It is important to address this issue and the potential magnitude of the potential biases introduced by the approach in order to provide risk managers with all of the information that will be needed to make risk management decisions.

**There are no tissue data available for any of the wildlife receptors evaluated.** Unfortunately, because tissue samples were not collected for many of the receptors, EPA found it necessary to calculate hazard quotients and model uptake for predators of those receptors using assumptions about what tissue concentrations were likely to be. Given the large amount of uncertainty associated with many of the values used to parameterize those uptake models, and the tendency to make conservative assumptions in deriving estimated values, it is likely that these exposures and HQs have been overestimated. EPA should specifically acknowledge the fact that the lack of tissue data has greatly increased the uncertainty of the risk analysis.

## 6.0 CONCLUSION

This review has identified, documented, and discussed the technical shortcomings of the analyses that comprise EPA's Oxbow BERA report. We have focused on those exposure scenarios and risk assessment topics that have the greatest implications for setting target remediation goals and assessing remedial options. Our review does not comment on those aspects of the Oxbow BERA that do not appear to be influential in evaluating remedies or determining outcomes for the Site.

The chemical data used for the Oxbow BERA are limited to seven sampling stations that, generally, are indicative of wetland sediment or at least saturated soils. However, the Oxbow Area consists of both wetland features and upland features and the terrestrial receptors evaluated for the Oxbow BERA are more likely to reside and forage in the upland areas, not in the areas represented by the saturated soil/sediment samples used for this assessment. Further, the conclusion reached by the Oxbow BERA for floodplain soil macroinvertebrates is inconsistent with the conclusion for the same receptor in the Site-wide BERA, which found no substantial risk of harm. Finally, use of an incremental risk assessment approach fails to fully emphasize the overall comparability of the potential risks to the evaluated receptors in the Oxbow Area and those in the background area.

Because these exposure pathways will be used by EPA to develop PRGs in a separate document, the flaws in the Oxbow Area risk assessments will result in flawed and inappropriate PRGs, if left uncorrected. The development of PRGs requires a much more robust and unbiased risk assessment in which state-of-the-art methods of risk analysis are coupled with competent interpretation and analyses of available data. The Oxbow BERA does not meet this standard in its present form, and anything short of a complete overhaul and revision is unlikely to approach the level of sophistication required to serve as the basis for establishing technically defensible remedial cleanup goals for the Centredale Manor Restoration Project Superfund Site.

## 7.0. REFERENCES

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