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November 10, 1994

Mr. Frederick N. Mac Millan (3HW22)
Remedial Project Manager
U.S. Environmental Protection Agency
Region III
841 Chestnut Building
Philadelphia, PA 19107

Subject: Response to correspondence issued September 27, 1994 requesting input on EPA Region III's upcoming risk assessment for Operable Unit #3 of the Palmerton Zinc Superfund Site.

Dear Mr. Mac Millan:

The following is our response to written correspondence from Mr. Thomas C. Voltaggio, Director of the U.S. EPA Region III Hazardous Waste Management Division, dated September 27, 1994, requesting input relevant to the upcoming risk assessment of OU-3 at the Palmerton Zinc Superfund site, in Palmerton, Pennsylvania.

First of all we would like to thank the staff and administrators of U.S. EPA Region III for your past, present and future efforts toward remediating the hazardous industrial contamination present in the vicinity of Palmerton, Pennsylvania. As technical assistants to the only civic organization in Palmerton that supports an environmental clean-up of the Palmerton Zinc Superfund Site, we would also like to thank you for your support of the Palmerton Citizens for a Clean Environment (PCCE).

As you are aware, the Palmerton valley has been subjected to unacceptable levels of environmental contamination for nearly 100 years. Consequently, a significant percentage of the population has become desensitized to the current level of environmental degradation, often reacting with ambivalence or even anger to the suggestion that an environmental clean-up is appropriate. To further compound the problem of public perception, there are the myriad misinformation campaigns designed to quell citizen concerns, promote a false sense of industrial dependence, and intimidate potential dissidents. Simply refusing to support an industry initiative, or cooperating with an EPA sponsored study or clean-up activity is sufficient for members of the community to fear retribution. We know that the EPA is aware of this extreme level of community polarization, but feel it is necessary to recapitulate these facts because the need for a risk assessment at Palmerton is more related to the need for effective risk communication than a clinical demonstration of the potential for adverse health effects from exposure to heavy metals.

The reason that we believe it is important to focus on risk communication as a key element of the risk assessment process is that previous studies to date seem to indicate that clinical health effects from chronic exposure to sub-occupational levels of heavy metal contamination are difficult to demonstrate. This is one of the key findings of the two reports written by ATSDR, and in both instances the lack of conclusive statistical correlation between environmental contamination and the biological indicators of interest was misconstrued by both special interests and the media as proof that there are no health risks from exposure to heavy metal contamination at Palmerton.

For risk to be effectively communicated at Palmerton, the study needs to be carefully designed to avoid critical flaws or questionable assumptions. For example, in retrospect the use of Jim Thorpe as a comparison community for the ATSDR Biological Indicators study was a poor choice because the study revealed that Jim Thorpe also has a lead contamination problem. Several well known features should have indicated the potential for lead contamination in Jim Thorpe, but appear to have been overlooked. These are: The Tonolli superfund site, a secondary lead smelter that operated from about 1975 to 1985, which is also an NPL Superfund site, and is located only a few miles upwind of the community of Jim Thorpe. Atmospheric deposition from the Tonolli smelter could be partly responsible for some of the soil lead detected in the Jim Thorpe area. Furthermore, the geologic strata in the Jim Thorpe area contains sub-economic deposits of uranium, which through the process of natural radioactive decay eventually becomes lead. If these factors had been identified prior to development of the ATSDR study, they could have been used to disqualify Jim Thorpe as a comparison community. This would have avoided the confusion created by common misinterpretation of the ATSDR study.

Several of the other scientific investigations conducted at Palmerton have had similar flaws. For example, the CDM Federal Programs Corp. study of environmental contamination in Jim Thorpe and Palmerton was widely criticized for the type of XRF testing used for the detection of lead-based paint. Even the excellently planned and documented NEIC Hazardous Substance Source Identification study had flaws or inadequacies that provided the opportunity for credible technical criticism. Although it is true that all scientific studies are in one way or another open to some kind of criticism, the EPA should be especially careful in the development of their work plan and study design simply because the Palmerton site is so controversial. It is absolutely essential that effective risk communication be accomplished in a risk assessment context through the application of rigorous scientific principles that are free from inadequacy, inconsistency and ambiguity. In particular, statistical methods should be carefully designed and applied, and the general application of mathematical relationships with low correlation coefficients should be avoided.

1. We request that the risk assessment follow the general guidelines established by the EPA document (or a more recent update if available), "Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual" (EPA/540/1-89/002; December 1989). This was developed by a technical work group consisting of 27 members representing 17 different offices within EPA, including four different regional offices. This document is based on policies proposed for the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) which was published in the Federal Register (1988) and thus has had the benefit of review by both the public at large and the scientific community.

It should also be noted that EPA's risk assessment procedures as outlined in this manual were influenced by several outside agencies and teams of professionals in the field, including the National Academy of Sciences (e.g., NAS 1983. Risk Assessment in the Federal Government, Managing the Process). Recently (1994), another NAS report was published reviewing EPA's approach to risk assessment for air toxics and in general EPA's procedures were found to be consistent with "state of the art" methods recommended by the peer-review panel.

2. The risk assessment should address all media (air, water, soil, food) and exposure pathways (ingestion, inhalation, etc.) for all four of the elements of concern (Pb, Cd, Zn, As). We are aware that the current risk assessment is focused on OU-3, but if only contaminant sources from this unit (e.g., metals in soil and lead in house paint) are evaluated, the risk assessment will be inadequate; in other words, the assessment must address the total exposure (multimedia) of each contaminant for those people at risk who live within OU-3.

Please note that we are not suggesting that the risk assessment needs to partition risk for each specific source other than OU-3 at this time (e.g., another operational unit or some aspect of current operations); however, the data on multimedia exposure should at least reflect or integrate exposure from other sources (e.g., lead in drinking water or air) as part of both natural and anthropogenic "background" levels; all sources of these contaminants from drinking water to current operations (see below also) need to be included as part of establishing such background levels of exposure before incremental risk from OU-3 can be estimated specifically. For example, lead exposure from ingestion of house paint or soils at some locations within OU-3 could turn out to be at or just within the limits of acceptable risk but if air-borne sources are considered, the health risk to sensitive individuals (e.g., children) could be unacceptably high, even though atmospheric concentrations could be just under ambient air quality standards. Any remedial actions taken on the basis of an incomplete view of exposure assessment might not be cost-effective or may not protect the health of sensitive individuals. This issue is probably most crucial for atmospheric exposures and this pathway is addressed in more detail below.

3. The EPA risk assessment guidance manual provides extensive information on various procedures used to assess health risks; the guidance is also based on extensive experience with such assessments at a number of previous EPA Superfund sites. For the contaminants cadmium, arsenic and zinc, reference doses (RfDs) and carcinogenic potency factors (CPFs), when available, should be the starting point in the estimation of risk for each contaminant. These values should be the most recent that are available from an established data base determined by scientific consensus of an expert panel (e.g., the Integrated Risk Information System, an EPA data base, is preferred as the source of toxicity information for Superfund). "Ad hoc" RfDs or CPFs based on professional judgement should be avoided.

The August 1994 document "Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities" (EPA/540/F-94/043, OSWER directive 9355.4-12) discusses the superiority of the agency's new Integrated Exposure Uptake Biokinetic (IEUBK) model for evaluating the health risks of lead exposure for the most sensitive segments of the population such as children. Therefore, we request the use of the IEUBK Model for Lead in Children (Pub. #9285.7-15-2, PB93-963511), which was developed to: recognize the multimedia nature of lead exposures; incorporate important absorption and pharmacokinetic information; and allow the risk manager to consider the potential distributions of exposure and risk likely to occur at a site. The "Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities" manual also provides valuable advice for applying other important guidance documents such as the recent TSCA 403 guidelines for evaluating residential lead-based paint, lead contaminated dust, and lead contaminated soil. These documents provide technical support and guidance for a broad cross section of risk assessment activities, ranging from sample collection to development of an effective remedial action plan.

Several other important and relevant documents warrant review and careful consideration. Toxicological data provided by agencies or the consensus of expert panels (e.g., Centers for Disease control, 1991, Preventing lead poisoning in young children) should be used. For lead, an intervention level of 10 ug/dL is recommended by CDC based on their evaluation of the scientific data. Another source of relevant information on lead is from the panel of the Society for Environmental Geochemistry and Health (Wixson and Davis, 1994, Env. Sci. and Techn.).

4. In several of our previous reviews of environmental reports on the Palmerton site, we had indicated that sufficient data were not presented for contaminant concentrations in the atmosphere. In one instance, some historic data were summarized and in another report, passing reference was made to ongoing monitoring of ambient air quality relative to current operations and facilities. Our expectation had been that the issue of atmospheric concentrations and exposure by inhalation would be adequately dealt with in the risk assessment currently being developed. Therefore we recommend that the risk assessment for OU-3 explicitly address this pathway.

In particular, the adequacy of historic and current (ongoing) air monitoring data needs to be evaluated and documented. For example, we were recently informed by Mr. Tom Dilazaro, from the Pennsylvania Department of Environmental Resources, Bureau of Air Quality, that the air monitoring program at Palmerton is part of a regional ambient air quality monitoring system, and is not adequate for evaluating facility compliance. Similarly, the authors of the U.S. EPA NEIC Hazardous Substances Source Identification study suggested that although the Palmerton air monitoring stations demonstrate that air quality in the valley is within the National Ambient Air Quality Standards (based upon a three month average of predictable periodic sampling), continuous 24 hour sampling would probably indicate that the standard is exceeded on a regular basis.

This raises several questions that need to be addressed for the inhalation pathway of the risk assessment to be adequately evaluated: Is there a sufficient number of sampling sites in the valley (compared to the literature and/or studies conducted at other similar Superfund sites, e.g. Bunker Hill, Idaho)? Is the sampling frequency appropriate and adequate for detecting short-term events when concentrations may be quite high (e.g. see Gilbert 1989, Environmental Statistics)? Is the existing monitoring program and resulting data suitable for a risk assessment of the Palmerton valley? Is the air monitoring QA/QC documented and appropriate?

We are concerned about this component of the risk assessment for several reasons. First, as noted above, we have yet to see much air quality data actually presented in previous reports oriented towards quantifying the level of environmental contamination at Palmerton. Second, inhalation is expected to be an important pathway for these metals. Third, the NEIC report (see above and below) presented data that indicates that current industrial operations are of concern relative to these contaminants, and the atmospheric pathway could be a primary route of exposure. And fourth, at the July 29, 1994 Palmerton Scientific Symposium, Dr. Michael Ketterer (one of the NEIC study authors) expressed the opinion that there were not enough air quality monitoring sites in the Palmerton valley (only 2 vs. 8-10 at other similar sites he was familiar with) to sufficiently measure atmospheric concentrations of metals. If there is inadequate air quality sampling and data, how will EPA quantify the risk associated with this important exposure pathway?

The EPA may currently have the answers to some of the questions we raised above. In any event, we respectfully request that these issues be dealt with (documented, explained, and evaluated) in the risk assessment study. In particular, if there is some concern about air quality data, will new data be collected (in what fashion, etc.) or will "best professional judgement" and uncertainty factors be applied (to maintain a "conservative" assessment, sufficient to protect the most sensitive segments of the population)?

5. The ATSDR health consultation memorandum was only an overview of summary data for metals in soil at OU-3 in Palmerton. As such, it was not intended as a multi-media risk assessment study that documents incremental risk of heavy metals above natural and anthropogenic (including current sources and operations) background levels. Nevertheless, there are findings and data in the health consultation memorandum that are relevant to the larger risk assessment document being planned for OU-3. Therefore, the final risk assessment should cite and address, where relevant, the major findings of the health consultation document. Where results between the two studies are inconsistent, the more extensive multimedia risk assessment should discuss and account for these differences.

6. At the Palmerton Scientific Symposium, Dr, Reginald Harris reviewed a number of problems with the R.E. Wright Risk Assessment. In many cases, the problems identified were due to deficiencies and/or omissions. The work plan for the proposed EPA risk assessment should be designed to be free of these problems. In particular, the following issues should be considered: Soil samples should be collected so as to include the litter layer, which has been shown to contain the highest levels of heavy metal contamination, and is the most available media in terms of exposure pathways. Arsenic levels are high enough that they should be included as one of the contaminants of concern (note that the ATSDR Health Consultation memorandum supports this view). As appropriate, EPA risk assessment guidelines need to be followed. When applied, Reasonable Maximum Exposure (RME's) levels should be based upon conservative estimates, so as to be protective of the most sensitive segments of the population such as the elderly and young children. Finally, it should be stated that a risk assessment does not have to demonstrate clinical health effects, but only indicate a potential for health risks from potential exposure.

7. The NEIC report has been mentioned above in a few places, especially in regard to atmospheric exposures. In our review of the NEIC document, we identified a number of issues (e.g., sufficient sample size and the representativeness of sampling, sensitivity of indices vs. sample size, and the robustness of assumptions for some indices like indium), that could be answered with further data analyses and documentation. If these are answered adequately, then there are a number of important issues concerning contaminant exposures from ongoing, current operations. While these are not explicitly the focus of the risk assessment for OU-3, they do need to be addressed directly as part of anthropogenic background exposure for the population of Palmerton. Without this background data, incremental risk from the other exposures at OU-3 cannot be adequately determined. The atmospheric exposure pathway, as noted above, is one of critical concern here and the adequacy (number and placement of air monitors) of sampling stations needs to be addressed (as per Dr. Ketterer's comments and observations at the Palmerton Scientific Symposium last summer).

8. Because it was suggested by an EPA representative at the Palmerton Scientific Symposium that a separate ecological risk assessment would be conducted at some future date, as part of the remedial investigation for OU-4, we did not feel it was appropriate to dwell on ecological risk assessment issues at this time. However, it cannot be said that a comprehensive risk assessment was conducted for OU-3, until the risks to ecological endpoints within the populated sections of the Palmerton valley are adequately evaluated. As the number and size of natural areas in eastern Pennsylvania has diminished, the suitability of residential areas for plant and wildlife habitat has become increasingly important. This is especially true of Palmerton, since the more intensively managed environment of the Palmerton community may be more ecologically productive than the adjacent tracts of unpopulated land on Blue Mountain and Stony Ridge.

9. We presume that one of the primary purposes for conducting a risk assessment on OU-3 at Palmerton, besides meeting the need for more effective risk communication as discussed above, is to establish remediation levels and to develop an effective risk management program. Two important issues need to be addressed in this regard: First of all the Pennsylvania Department of Environmental Resources has recently published their Final Lead Policy as part of their Greenfields Implementation Plan (enclosed). They have set their soil lead clean up standards at 600 mg/kg for industrial sites, and 200 mg/kg for non-industrial properties. According to the Greenfields Implementation Plan Final Lead Policy document: "...the numerical values of these cleanup levels are based exclusively on protecting human health to a blood lead level of 10ug/dl." We recommend that EPA set similar goals and standards. Also, in the interest of effective risk management, and to avoid the potential for recontamination of previously remediated properties, it is essential that all contaminated soil on residential properties be contained. To achieve this goal we recommend the establishment of a continuous protective barrier of healthy vegetation, specifically turf grasses. Not only do turf grasses provide an effective barrier for minimizing contaminant migration, but they also provide the additional benefits of generating oxygen and assimilating atmospheric contamination.

10. As requested in the September 27, 1994, letter from Mr. Thomas C. Voltaggio, we have included copies of some of the documents that we believe should be reviewed and considered during development of the work plan for the proposed risk assessment. Please note that we did not think it appropriate to include all the documents that need to be considered (for example: "Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual" EPA/540/1-89/002; December 1989), because some of these are voluminous documents, and since many of them are published by EPA we expect that you have your own copies on file. We believe that all of the documents we have enclosed are important and require serious consideration. Since it may not be possible to give equal attention to all of the enclosed documents, we have tried to list them in some order of importance, and included comments identifying the most important elements of each.

1. U.S. Environmental Protection Agency. Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities, OSWER Directive #9355.4-12, August 1994.

This document provides the most recent guidance for establishing soil lead cleanup standards at Superfund sites. Since the development of soil lead cleanup standards is oriented towards risk reduction, we recommend that EPA apply the principles outlined in this document towards development of the proposed risk assessment work plan. One important element of this document is provided in Appendix A-1: Suggested Decision Logic for Residential Scenarios for CERCLA and RCRA Corrective Action. This section provides a logical framework for proceeding with establishing cleanup levels in residential settings.

2. Raymond E. Grissom, Ph.D. and Steven Haness, Ph.D. (concurrence) Health Consultation: Palmerton Zinc Superfund Site (3026) Palmerton Pennsylvania. A memorandum to Charles Walters. April 12, 1993.

This is the Health Consultation Memorandum referred to in several places in the preceding pages. Although we understand that the Health Consultation Memorandum was not intended to serve as a comprehensive multi-media risk assessment, we feel that it takes the general approach to risk assessment and risk communication that is necessary for the proposed risk assessment to be effective.

3. Pennsylvania Department of Environmental Resources. Greenfields Implementation Plan Final Lead Policy. August 31, 1994.

Not only does this document provide important information related to evaluating the extent of contamination, it provides a legal framework for requiring the remediation of residential properties with soil lead levels in excess of 200 mg/kg. An especially important element of this document is the attached Technical Background Document titled: **Lead Levels In Soil**, which provides a technical justification for the cleanup standards set for the Greenfields Implementation Plan. Please note that much of the Technical Background Document is based on the peer-reviewed work of B.G. Wixson, one of the most prominent scientific specialists currently working in this field.

4. Wixson, B.G. and Brian E. Davies. 1994. Guidelines for Lead in Soil, Environmental Science and Technology. Vol. 28., No. 1.

This is an excellent peer-reviewed document by a team of prominent scientific specialists on issues related to establishing soil lead clean up standards. It provides essential insight, including mathematical models, for predicting blood lead levels from exposure to lead contaminated soil.

5. U.S. Environmental Protection Agency. Policy Towards Owners of Residential Property at Superfund Sites. OSWER Directive 9834.6. July 3, 1991.

Because of the controversy that has historically faced the residents of Palmerton, this document can be applied to assure that EPA is voluntarily provided the access and cooperation they need from the residents of Palmerton to conduct a thorough and effective risk assessment.

Once again we would like to thank you and your staff for the opportunity to provide input into the development of the work plan for the proposed Palmerton Zinc Site Operable Unit 3 risk assessment study. In keeping with the intended purpose of the U.S. EPA Technical Assistance Grant (TAG), the MKA project team has always strived to provide the most thorough and objective technical review of reports and activities related to the Palmerton Superfund Site in a format that the average citizen can comprehend. This has not been an easy task. As you are well aware, one of the problems with dealing with the public in Palmerton is that even the most visibly obvious facts are commonly refuted by that small group of individuals who put their own economic interests before the health and welfare of the community. This is the reason why effective risk communication needs to be such an important element of the risk assessment report. Having observed the events that have transpired in Palmerton in the recent past, it is clear that the risk assessment document will most likely be received by some interests with cautious scrutiny at best. Therefore, it is of the utmost importance that every effort is taken to provide the most comprehensive and conclusive risk assessment report possible. This is understandably a difficult task, but if it is successfully accomplished, it may be possible to bring the community together in cooperative support of the environmental clean up that is so necessary to the social, mental and physiological health of the entire area.

Prepared with the assistance and direction of Dr. Dale Bruns, Ph.D, Environmental Toxicologist.

Respectfully submitted,
**McTISH, KUNKEL & ASSOCIATES**

Robert H. Hosking, Jr.
Environmental Project Manager

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