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March 2, 1995

Edward Hanlon
Project Remedial Manager
Fields Brook Superfund Site
Region 5 (HSRM-6J)
U.S. Environmental Protection Agency
77 West Jackson Boulevard
Chicago, IL 60604-3590

Re: Fields Brook Floodplain

Dear Ed:

The Fields Brook Potentially Responsible Party Organization ("FBPRPO") would like to resolve the remaining scientific differences with EPA concerning the appropriate exposure assumptions and methodology that should be used in the baseline risk assessment and the risk assessment to derive floodplain health-based soil cleanup goals ("FCUGs").

The continuing EPA-FBPRPO risk assessment differences, such as the assumptions implicit in and consequences of EPA's expansion of exposure units, proliferation of exposure scenarios directed at unlikely subpopulations, and the assumption that one hundred per cent of the dietary intake of chemicals comes both from the sediment and the Floodplain, can best be resolved using a probabilistic statistical approach (e.g., Monte Carlo analysis) to incorporate the range of exposures from the full array of subpopulations in an explicit and scientifically sound manner (see Attached Memo from Neil Shifrin to the FBPRPO, explaining the technical support for this approach).

Should EPA employ a series of extreme worst-case maximum value assumptions proposed in EPA's October 20, 1994 preliminary risk evaluation in the final Floodplain risk assessment, an exposure level that no real human could encounter would be used to assess risk and the FCUGs would be unreasonably low. The cumulative cost impact of the difference in the risk assessments is substantial, yet no meaningful increase in the protection of human health is provided. Many other Superfund sites have much higher cleanup levels in similar circumstances.

Probabilistic analysis is allowed by EPA guidance,[1] has been recommended by a recent National Academy of Science ("NAS") Committee that EPA funded to provide advice on ways to improve the scientific component of risk assessment,[2] has been recommended by EPA's own Science Advisory Board (SAB) as part of a review of EPA's risk assessment guidance,[3] has already been used in several EPA approved Superfund risk assessments,[4] and has

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1. EPA, Exposure Factors Handbook Part II, 1-2 (1989) (EPA/600/8-89/043); Risk Assessment Guidance For Superfund, Vol. I, Human Health Evaluation Manual, Part A (EPA/540/1-89/002, 1989); Guidelines on Exposure Assessment, 57 Fed. Reg. 22,888 (1992).

2. NAS, Science and Judgment in Risk Assessment (National Academy Press, Washington, D.C., 1994). The National Academy Of Sciences ("NAS") in an EPA sponsored study on how to improve EPA's risk assessment methodology also recommends strongly that probabilistic analysis be used to aid in assessing uncertainty in risk assessment.

3. Environmental Protection Agency, Science Advisory Board Report: Review of the Office of Solid Waste and Emergency Response's draft risk assessment guidance for Superfund Human Health Evaluation Manual by the Environmental Health Committee, EPA-SAB-EHC-93/007,1993. The SAB recommended that EPA adopt a full distributional approach in which distributions are developed for each of the terms in the exposure equation and a probabilistic analysis be applied to obtain the resulting distribution for exposure. The SAB promotes the use of probabilistic analysis as a method for providing a more realistic picture of exposures and risks when various exposure inputs are being combined.

4. A systematic review of recent Superfund risk assessments has not been performed. Probabilistic analysis have been used at least at the American Creosote Works Site, Escambia County, Florida (submitted to Region IV, 1989); Final Public Health Evaluation, Halby Chemical Company Site (submitted to Region III, Sept. 1990); Feasibility Study for the Sharon Steel/Midvale

(continued...)

been used by EPA in developing it hazardous waste regulations.[5] In fact, the NAS Report concludes that

> Simply to ignore the uncertainty in any process is almost sure to leave critical parts of the process incompletely examined, and hence to increase the probability of generating a risk estimate that is incorrect, incomplete, or misleading.[6]

It is precisely because each of the exposure values is a distribution in the real world that EPA guidance now recommends that the "best approach" is to "represent reasonable worst-case ... exposure level ... by using Monte Carlo techniques".[7] (emphasis added) (see also attached letter from Neil Shifrin of Gradient).

The FBPRPO offers its assistance in implementing a probabilistic analysis for this site. The FBPRPO is confident that use of a probabilistic analysis should **not** add any delay in the implementation of the Floodplain remedial action and clearly will provide a significant incentive for the FBPRPO members to agree to implement the remedy since they will have greater assurances that the remedy is consistent with the NCP.

Use of a probabilistic analysis will determine whether the existing assumptions are inconsistent with EPA risk assessment policy and allow the risk assessment to be performed in a scientifically defensible and health protective manner.

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4. (...continued)
Tailings NPL Site (submitted to EPA Region VIII, 1990); Rocky Mountain Arsenal, Preliminary Draft Risk Characterization, Integrated Endangerment Assessment Report (submitted to Region VIII, July 1992); and Draft Remedial Investigation for Tabbs Creek (prepared for the National Aeronautics and Space Administration, February 1993).

5. Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristic Revisions, 55 Fed. Reg. 11,798, 11,826-27 (1990) (final rule).

6. Id. at 162.

7. Exposure Handbook Part II at 1-2 (underlining in original, bold added).

If you or your risk assessment consultants have any technical questions, please call Neil Shifrin at (617) 576-1555. If there are legal questions , please call me at (202) 828-1452 or Neil Shifrin at (617) 576-1555.

Yours truly,

Stephen M. Truitt

cc: Michael Berman, EPA
Connie Puchalski, EPA
FBPRPO Negotiating Committee

Gradient Corporation

MEMORANDUM

To:	FBPRPO Technical Committee	**Date:** January 25, 1995
From:	Neil Shifrin and Terri Bowers	
Subject:	Risk Assessment for Fields Brook Floodplains	

As you know, EPA has taken a stand for what we feel are very extreme, ultra-conservative values for several of the exposure parameters in the floodplain risk assessment. For example, EPA has argued for a soil ingestion rate for children of 200 mg/day for each of the sediment and floodplain soils (totalling 400 mg/day), which is twice the typical value recommended by EPA guidance. EPA has justified this and other ultraconservative assumptions with nontechnical arguments such as the existence of separate subpopulations for which there are no supporting data. In fact, the site-specific data we do have suggest that much different, less conservative assumptions are more appropriate. Although we understand EPA's need to consider the possibility of extreme assumptions to protect public health, the concatenation of all these assumed extreme values in the quantitative risk equation will lead to unrealistically high risk estimates for the floodplain.

Fortunately, there is an approach to cross this impasse which will allow quantitative consideration to be given to EPA's extreme assumption values while resulting in a realistic assessment of risk. That approach is what is referred to as Monte Carlo risk assessment (or Monte Carlo "analysis").

Monte Carlo risk analysis is a simulation technique that is often adopted to characterize the impact of both uncertainty and variability on risk estimates. As opposed to single point values used for each assumption in a conventional risk assessment, Monte Carlo analysis uses a range of possible values to characterize each exposure parameter in the risk assessment equation, and thus yields a range of calculated risks that are appropriate to the population(s) of concern. The technique requires that parameters in the risk assessment equation be described by a distribution of values, such as a probability density function. The probability density function is a measure of variability or uncertainty in the model parameters and reflects the range of possible values and the most probable value (if there is one) for that parameter. Common functions used in Monte Carlo simulations are uniform, normal, and lognormal distributions, although numerous other functions may be used. A uniform distribution implies that there is an equal probability that the value of the parameter is between a user defined minimum and maximum value. Use of normal and lognormal distributions implies that there is a most probable value for the parameter, described by a mean and geometric mean respectively, and a range of possible values, described by a standard deviation and geometric standard deviation.

The Monte Carlo simulation is performed by first establishing probability density functions for each parameter in the risk assessment equation. Many of these distributions have been defined in the scientific literature (Gephart *et al.*, 1994; Fenley *et al.*, 1994) and even in past Region V risk assessments (The Parallel Baseline Risk Assessment, UCC Marietta Facility, Marietta, Ohio). Any correlations that might exist among parameters (*e.g.* age and body weight, or age and soil ingestion rate) must be accounted for in the model. This step is repeated several hundred to several thousand times in order to generate a distribution of possible risks based on the risk assessment equation parameters randomly selected from their probability density functions. By generating a distribution of possible risks instead of a single risk, Monte Carlo simulation provides information on the range of possible risks, the average expected risk, and the probability that any particular risk will be generated by the model.

Monte Carlo analysis can more accurately characterize and facilitate the interpretation of risks than can a traditional risk assessment approach. It is also the best way to account for uncertainty in risk assessment, required by EPA guidance but typically handled poorly in conventional risk assessments.

Monte Carlo analysis is allowed, and in fact encouraged, by EPA guidance. A discussion on the use of quantitative uncertainty analysis in risk assessment is provided in a memo issued in February in 1992 by EPA Deputy Administrator F. Henry Habicht. Habicht's memo recommends use of Monte Carlo analysis as an option for providing a more complete description of population exposures and associated risks. Monte Carlo analysis has also been recommended by a recent National Academy of Science (NAS) Committee funded by EPA to provide advice on ways to improve the scientific component of risk assessment, and it has been recommended by EPA's own Science Advisory Board as part of a review of EPA's risk assessment guidance. The NAS report concludes that:

"Simply to ignore the uncertainty in any process is almost sure to leave critical parts of the process incompletely examined, and hence to increase the probability of generating a risk estimate that is incorrect, incomplete, or misleading."

EPA and Regional acceptance of Monte Carlo analysis in risk assessment is growing. Although a systematic review of recent Superfund risk assessments has not been performed, Monte Carlo simulations have been used at the American Creosote Works Site, Escambia County Florida (submitted to Region IV, 1989); Final Public Health Evaluation, Halby Chemical Company Site (submitted to Region III, Sept. 1990); Feasibility Study for the Sharon Steel/Midvale Tailings NPL Site (submitted to EPA Region VIII, 1990); Rocky Mountain Arsenal, Preliminary Draft Risk Characterization, Integrated Endangerment Assessment Report (submitted to Region VIII, July 1992); and Draft Remedial Investigation for Tabbs Creek (prepared for the National Aeronautics and Space Administration, February 1993). These are only a few examples of Monte Carlo analysis used in risk assessment.

Additionally, attempts are being made by some Regions to provide guidance on the use of Monte Carlo analysis in risk assessment. For example, Region III has issued a Technical Guidance Manual Risk Assessment memo entitled "Use of Monte Carlo Simulation in Risk Assessments" (Feb. 1994) with guidelines for conversion from deterministic to probabilistic risk assessment. The memo suggests a phased conversion, starting with the simultaneous calculation of risks by both the single point and Monte Carlo methods, and the establishment of national default exposure parameter distributions. Once default exposure parameter distributions are established the memo suggests that the single point risk calculations will no longer be necessary except in unusual circumstances where the distributions cannot be developed. Region III has begun to accept Monte Carlo analyses for human health risks, following some of the guidelines laid out by this technical memo.

In conclusion, Monte Carlo risk assessment is technically sound, well received within the scientific and regulatory community, and an ideal way to resolve the Fields Brook floodplain risk assessment issues. We recommend the EPA and/or the FBPRPO use this tool as part of the floodplain cleanup decision process.