Patricia Kablach Casano
Counsel, Government Affairs
Corporate Environmental Programs

GE
1299 Pennsylvania Avenue, NW
Suite 1100
Washington, DC 20004-2407
USA

T 202-637-4228
F 202-637-4017
Pat.casano@ge.com

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW.
New Executive Office Building
Room 10201
Washington, DC 20503

June 15, 2006

Re: Proposed Risk Assessment Bulletin (Notice of availability at 71 Fed. Reg. 2600 (Jan. 17, 2006)

Dear Dr. Beck:

Enclosed please find the comments of the General Electric Company on the Office of Management and Budget's Proposed Risk Assessment Bulletin.

Sincerely,

Patricia Kablach Casano

Enclosure

COMMENTS OF THE GENERAL ELECTRIC COMPANY ON THE OFFICE OF MANAGEMENT AND BUDGET'S JANUARY 9, 2006 PROPOSED RISK ASSESSMENT BULLETIN

June 15, 2006

The General Electric Company
Corporate Environmental Programs
3135 Easton Turnpike
Fairfield, CT 06431

Table of Contents

INTRODUCTION

Since at least 1983, serious attempts have been made to reduce or eliminate controversies arising from federal agency efforts to evaluate the health and environmental risks presented by chemicals. See *Risk Assessment In The Federal Government: Managing the Process* (NRC 1983). In some cases, the problem has been "the sparseness and uncertainty of the scientific knowledge of the health [and environmental] hazards addressed." Id. at 6. For those cases, agencies rely on inferences, belief and policy to fill the gaps. Id. at 48. Even where there is sufficient scientific knowledge, however, controversies arise because agencies do not always objectively consider relevant evidence that does not support the agencies' preconceptions, or the agencies employ assumptions or default factors that are not warranted given the available scientific knowledge. The recent controversies regarding EPA's draft dioxin, perchlorate, and TCE risk assessments are examples of this. See also *Comments of the General Electric Company on the USEPA Staff Report Titled "An Examination of EPA Risk Assessment Principles and Practices"* (June, 2004).

The Proposed Risk Assessment Bulletin ("Proposed Bulletin") should go a long way toward (1) increasing the science, and reducing the guessing, in risk assessments; (2) ensuring their objectivity; and (3) reserving policy determinations for risk managers. When issued in final form, the Bulletin would "define[] general risk assessment and reporting standards for [federal] agency risk assessments and . . . special standards for influential agency risk assessments," as well as establish "[s]tandards for risk assessments used in regulatory analysis." OMB Press Release, *OMB Requests Peer Review Of Proposed Risk Assessment Bulletin* (Jan. 9, 2006).[1] The standards are aimed at "improving the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public," and " enhanc[ing] the technical quality and objectivity of risk assessments prepared by federal agencies." Proposed Bulletin ("PB") at 1, 3. Representatives of key agencies expressed support for the Bulletin's goals at the recent public meetings at the National Academy of Sciences and Society for Risk Analysis,[2] with several representatives indicating that their agencies' risk assessment practices are in many ways consistent with the Bulletin.[3]

The Proposed Bulletin is a logical extension of, and complement to, Executive Order 12866, the quality standards established in the Safe Drinking Water Act,
OMB's Information Quality Guidelines, the Information Quality Bulletin on Peer Review, and OMB Circular A-4 (2003), "which was designed to enhance the technical quality of regulatory impact analyses, especially benefit-cost analysis and cost-effectiveness analysis." Id. at 3. The Proposed Bulletin clearly reflects public comments provided to OMB in response to OIRA's February 2003 request for comments on risk assessment practices across the federal government; conclusions reached by OMB in its 2003 report to Congress on regulatory policy[4]; and reports issued by the

---

[1] http://www.whitehouse.gov/omb/pubpress/2006/2006-01.pdf

[2] G. Gray (EPA)(EPA supports the broad goals of the Bulletin; many of the standards in the Bulletin are drawn from NRC reports that EPA supported); H. Dezfuli (NASA)(NASA supports general goals of Bulletin, which has good features); K. Dearfield (USDA)(the Bulletin is "laudable for all risk assessments"); C. Sofge(CDC)(for the most part, Bulletin embodies best practices for full quantitative risk assessment).

[3] N. Abbott(USDA)(the Bulletin might slow things down, but many things already are evaluated in the way the Bulletin proposes); W. Perry (OSHA)(for health risks, OSHA already does a number of the things that the Bulletin requires); K. Dearfield (USDA)(Bulletin does not add a lot to what USDA is already doing).

[4] OMB, *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2003)

National Academy of Sciences, EPA's Science Advisory Board, and other bodies over the last two decades.

The Proposed Bulletin is necessary because risk assessments performed by federal agencies ultimately can have substantial effects on public health, the environment, and private and public sector finances. Federal risk assessments also can affect how other persons and entities - such as state environmental agencies – conduct their risk assessments, regulate activities, and manage cleanups of contaminated sites. As a manufacturer and user of chemicals, and as a party with substantial experience in remediating contaminated sites, GE appreciates the opportunity to comment on this much-needed Bulletin. We agree with the many speakers at the recent public meetings who expressed the view that the Bulletin will lead to substantial improvements in agency risk assessments.[5]

I. General Comments Regarding Implementation

The Proposed Bulletin summarizes concisely many of the principles essential to accurate and unbiased risk assessment. GE's comments, which are based on our experience with chemical- and site-specific risk assessments performed by EPA, suggest further specifications and clarifications that will both help agencies apply the Bulletin's principles in risk assessments and enable stakeholders to better understand the science and reasoning behind agency risk assessments. Our overarching comments are described in this Section. Further details and comments are set forth in the "Detailed Comments" section.

1. The Proposed Bulletin Should Incorporate The Supplementary Information Section

The principles, practices and procedures that enable the development of a high quality risk assessment are discussed more fully and informatively in the Supplementary Information section of the Proposed Bulletin than in the Proposed Bulletin *per se*. The Supplementary Information Section therefore should be incorporated into the Proposed Bulletin. (Hereinafter, "Proposed Bulletin " refers to both the Supplementary Information Section and the Bulletin *per se*.)

2. The Proposed Bulletin Should Specify In Greater Detail The Essential Characteristics Of A Credible Risk Assessment

The Proposed Bulletin reflects the fact that rational risk management is possible only if the risk assessor (1) focuses on verifiable adverse effects and meaningful precursors to such effects instead of biological events of unknown significance; (2) considers all relevant positive and negative studies, weighted to reflect the strength of their findings, their power, their quality and other relevant factors; (3) provides the risk manager with an objective assessment of the full range of risks, (i.e., neither understates nor overstates the risk, but provides the high- and low-end estimates and the most likely, or expected risk); and (4) for both ecological and human health assessments, provides

[5] S. Cuniff (DOD)(cost of any additional work required by Bulletin will be outweighed by benefits of improved risk assessments); R. Krupnick (RFF)(the Bulletin "eliminates risk aversion bias"); T. Billy (the Bulletin, with some improvements, represents a major step forward); C. Hilaire (Center for Health Sciences Research)(the Bulletin "addresses the hubris of scientists" who think that they should be making the decisions, so their biases are factored into the risk assessment).

estimates of population risks, which are absolutely necessary to compare the overall costs and benefits of regulatory alternatives or remedial options . To further strengthen agency risk assessments, the Proposed Bulletin should point out that risk assessments "disseminated" by federal agencies within the meaning of the Information Quality Act *must* meet applicable OMB IQA quality standards.

The Proposed Bulletin will have little value unless it is routinely implemented by agencies in a transparent, reproducible and objective manner.[6] The Proposed Bulletin therefore should (1) emphasize that thorough weight-of-evidence assessment is the best way to ensure objectivity; (2) establish the elements of such an assessment; (3 define uniform criteria that must be used consistently to evaluate studies and data and assign them weight; and (4) require risk assessors to display the results of the weight-of-evidence evaluation in a complete, graphic, and transparent manner. In particular, agencies should be required to identify all relevant studies – positive, negative, and inconclusive – and explain why they were or were not given weight in the risk assessment. These requirements will promote reproducibility and enable the public to determine whether agency risk assessments are objective. (For further details on criteria for weight-of-evidence analyses, see Detailed Comment 7, below.)

The Proposed Bulletin states that risk assessments "should use the best available data." The Proposed Bulletin suggests, but should stress, that in human health risk assessments, "real world" human data, where available, should be used in lieu of animal data. Where relevant human data are not available, risk assessors should be directed to determine whether effects observed in animals are relevant to people, and, if so, how. Where both human and animal data are lacking or insufficient, any assumptions employed should be (1) clearly identified and scientifically justified; (2) reasonably probable and realistic; and (3) consistent with empirical data. The impacts of using alternative or multiple assumptions should be presented. Where models are employed, all of the underlying data and models, including model input and code, must be provided so that the public has an opportunity to determine whether the agency's results are based on reliable science, objective, and reproducible.

The Proposed Bulletin states that information about risk presented in risk assessments should be "presented in proper context. "Context" should include (1) the assumptions and safety factors used in the risk assessment, and (2) a comparison of the risk projected to arise from the circumstance or exposure under consideration with baseline risk. In particular, OMB should make clear that the present-use portion of the baseline risk analysis for risk assessments performed for contaminated sites must be based on the conditions that exist at the time of the risk assessment, not the conditions that might have existed previously. The future-use portion of the baseline risk analysis should be based on reasonable predictions of future conditions, not on wildly hypothetical or unlikely conditions that countervail existing trends, likely human behavior, and population demographics (e.g., the assumption used in establishing MACT for gas turbines that some individuals will remain at the point of maximum exposure 24 hours per day, 365 days per week, for 70 years)(Exh. 3 at 1).

EPA's draft risk assessments typically carry a disclaimer to the effect that the document "is a draft for review purposes only, and does not constitute Agency policy." This disclaimer is usually accompanied by the notation: "DRAFT – DO NOT CITE OR QUOTE." Both the disclaimer and the notation are routinely ignored by EPA offices and state agencies. For example, EPA's 2001 draft TCE Reassessment, which is under review by a panel of the National Academy of Sciences, has been used

[6] GE commends to OMB's attention the Comments of the Coalition for Effective Environmental Information, which focus on the steps that should be taken to ensure that the Bulletin is implemented consistent with its terms and spirit.

by some EPA regions and states to establish remedial objectives, even though it bears the disclaimer and the notation. Since draft reassessments do not necessarily reflect the best available science or the weight of the relevant evidence, and are subject to change, OMB should include in the Bulletin a provision that generally prohibits agencies from relying upon draft risk assessments unless there is compelling evidence that the draft risk assessment meets the requirements of this Bulletin and is the best available science.

3. Given The Consequences Of Agency Risk Assessments, Exemptions From The Bulletin Should Be Limited

The Proposed Bulletin does not take a mandatory or "one size fits all" approach, but applies only to "all publicly available risk assessments" "to the extent appropriate," with a "rule of reason" used to assess applicability. PB at 9, 23. In addition, the Proposed Bulletin authorizes agency heads to "waive or defer some or all of the requirements of this Bulletin where warranted by compelling rationale." Id. at 26. Since the Bulletin was written with chemical risk assessments in mind, there should be few, if any, circumstances in which it would be appropriate to waive or defer any of the Bulletin's requirements for such an assessment. Nonetheless, representatives of agencies such as NASA that assess risks other than those arising from chemicals have expressed concern about their ability to mesh their existing risk assessment policies and procedures with the requirements of the Proposed Bulletin. Given those concerns, OMB should employ here the approach used for the Information Quality Guidelines, i.e., finalize the Proposed Bulletin and direct the agencies to issue, through a public comment process, agency-specific guidelines that adopt the principles and procedures stated in the Proposed Bulletin, but tailor their application as needed to fit any non-chemical risk assessments that the agencies perform. This would satisfy OMB's need to provide guidance to the agencies on what constitutes a credible risk assessment, while acknowledging that the process employed to perform a risk assessment justifiably might depend upon the agency's statutory mandate, the type of risk addressed, and the circumstances in which the assessment is performed.

Because risk assessments -- public or not -- ultimately can have substantial societal effects, any generally available exemptions from the Bulletin's requirements should either be specifically identified in the Bulletin or explicitly limited to situations posing true emergencies. This is especially true for influential risk assessments, as it is difficult to conceive of a situation in which it would not be appropriate for such an assessment to comply with the entire Bulletin. If the final Bulletin permits agencies to waive requirements for influential risk assessments, all such waivers should be justified by a compelling rationale, and subject to public comment except in the case of true emergencies.

The Proposed Bulletin also should apply explicitly to CERCLA and RCRA risk assessments (including Remedial Investigations, Hazard Ranking Scoring, and risk assessments conducted during RCRA corrective action proceedings and Part B permitting), and to risk assessments performed in the context of NPDES permitting. Such risk assessments are "influential risk assessments" because they can establish significant precedents and drive multi-million dollar expenditures by both the public and private sectors.

The Proposed Bulletin applies to "final public risk assessments disseminated after 12 months following the publication of this Bulletin in final form" and to "draft risk assessments disseminated after six months following the publication of this Bulletin in final form." We note that the federal agencies were required to draft, publish and comply with their own IQA guidelines within seven months of adoption of the OMB IQA guidelines, and generally were able to meet that requirement.

Complying with the final Bulletin within six months of publication should not pose a problem for any federal agency in light of the substantial advance notice provided by the lengthy (six month) comment period on the Proposed Bulletin and the fact that the Bulletin in many respects simply summarizes good risk assessment principles and practices. We therefore recommend that the final Bulletin apply to all risk assessments that are disseminated beginning six months after publication of the Bulletin in final form.

4. The Proposed Bulletin Should Require And Facilitate Meaningful Public Involvement

The Proposed Bulletin suggests that agencies need involve the public only when a draft risk assessment is released for peer review (i.e., after the agency has formed an opinion). Public input is more likely to be considered meaningfully before agency staff have formed an opinion. As several speakers noted at the recent public meetings, the public should have an opportunity for input during the problem formulation or planning stage and throughout the conduct of the risk assessment.[7] This principle is embodied in EPA's *Guidelines for Ecological Risk Assessment* (1998)[8] and *Contaminated Sediment Remediation Guidance for Hazardous Waste Sites (Dec. 2005)*[9], but should be broadly applied and implemented.

The Bulletin states that "the purpose of an assessment (e.g., to assess exposure to a chemical at a Superfund site) should be made clear before the analytical work begins." The Proposed Bulletin also should direct agencies to consider thoroughly and state clearly the reason(s) for a risk assessment (e.g., information on exposure at the Superfund site is not already available) and the methods to be used to conduct the risk assessment before the assessment work begins. This should promote informed, early public comment. It also should help to prevent the results of a risk assessment performed for one purpose (e.g., screening) being used for another purpose (e.g., establishing clean-up standards).

---

[7] G. Omenn (need early, active engagement of stakeholders, including during problem formulation stage); J. Sass (NRDC)(NRDC has been asking for increased transparency and more public access); C. Menzie (problem formulation is the most important step in the process);K. Dearfield (USDA)(agrees with C. Menzie, and encourages OMB to expand Bulletin's discussion of scoping stage).

[8] http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460 ("A major theme of the guidelines is the interaction among risk assessors, risk managers, and interested parties at the beginning (planning and problem formulation) and end (risk characterization) of the risk assessment process. In problem formulation, the guidelines emphasize the complementary roles of each in determining the scope and boundaries of the assessment, selecting ecological entities that will be the focus of the assessment, and ensuring that the product of the assessment will support environmental decision making.")

[9] http://cfpub.epa.gov/si/osp_sciencedisplay.cfm?dirEntryID=83010&ActType=project&kwords=Superfund at 1-13 to 1-14 ("One of EPA's eleven principles for managing risk of contaminated sediment is to involve the community early and often. . . . Early involvement allows necessary input from communities and other stakeholders and facilitates more comprehensive identification of issues and concerns early in the site management process.")

II. Detailed Comments

1. All Risk Assessments Should Comply With IQA Guidelines. GE endorses the Proposed Bulletin's reference to and incorporation of the OMB Information Quality Act ("IQA") guidelines and the IQA guidelines of the respective federal agencies. The final Bulletin should state clearly that all risk assessments prepared by *or for* a federal agency and disseminated by that agency must comply with the IQA guidelines of OMB and that agency.

2. The Bulletin Should Apply To Individual Steps In Risk Assessment. A chemical risk assessment comprises four steps: (1) hazard identification, which defines the risks posed by a chemical; (2) dose-response assessment, which typically includes development of a numerical risk estimate (whether a NOAEL, LOAEL, cancer slope factor ("CSF"), Benchmark Dose ("BMD") or Reference Dose ("RfD")); (3) exposure assessment; and (4) risk characterization, which develops and places in context an assessment of the risks posed by a particular chemical exposure. These four steps of the risk assessment process, in the words of the Proposed Bulletin, "determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment." PB at 1.

The Proposed Bulletin should apply to each of these steps. It should, however, recognize their differences, especially the differences between the steps that focus on toxicology (steps 1 and 2) and those that focus on the effects of a given exposure (steps 3 and 4). Some of the principles established by the Proposed Bulletin apply differently in these areas. For example, in "Standards Related to Regulatory Analysis," PB at 15-16, the discussion of characterizing the central estimate of risk should differentiate between (1) the central, or expected, "unit risk" (i.e., predicted risk arising from exposure to a given dose of a chemical[10]) and (2) the central estimate of risk to some defined population which is exposed to the chemical. See Comment 18, below.

3. The Distinction Between Risk Assessment And Risk Management Should Be Clarified. The Proposed Bulletin applies only to risk assessment, not risk management. PB at 3 ("Although this Bulletin addresses certain technical aspects of risk assessment, it does not address in any detail the important processes of risk management and risk communication. The Proposed Bulletin nevertheless should discuss the distinction between risk assessment and risk management. In particular, the Proposed Bulletin should address the ease with which risk management can be injected, intentionally or inadvertently, into risk assessment. The most common instance of this occurs in the process of exposure assessment. Typically, risk assessors evaluate a variety of parameters that will be used in equations to calculate potential exposure and risk. The risk assessor must appreciate that in many cases where there is significant doubt about the appropriate value for a parameter – e.g., how many days per year a child plays out of doors in a particular area – choosing a single value for that parameter might be *risk management*, not *risk assessment*.

For example, it is possible that a child might never play in an area where contaminated soils are proximate to a residence or known recreational area. It is also possible, however, that a child

[10] For example, EPA Reference Doses ("RFDs") express EPA's estimate of the unit risk arising from exposure to a particular chemical. EPA defines RfD as follows: "The RfD is a numerical estimate of a daily oral exposure to the human population, including sensitive subgroups such as children, that is not likely to cause harmful effects during a lifetime. http://www.epa.gov/OCEPAterms/rterms.html. Thus, an RfD essentially establishes a zero risk level for exposure to a given chemical. As an example, the RfD, or "safe level of exposure," for chloroform is 0.01 (mg/kg/d) (i.e., milligrams of chloroform per kilogram of human body weight per day). http://www.epa.gov/iris/subst/0025.htm#reforal.

could play in that area regularly. Without site-specific information, it is not possible for the risk assessor to determine with any certainty whether the most appropriate choice is to assume infrequent usage (e.g., 1 day/month) or regular usage (e.g., 3 days/week). Thus the risk assessor makes a judgment as to the most appropriate value. To ensure that risks are not underestimated, the risk assessor typically assumes the highest conceivable frequency of use, despite the fact that it is equally likely that no use occurs. This is a risk management decision that defines the exposed population as those individuals who use the area with a higher frequency, even though such individuals might not actually exist.

While we agree that deterministic risk assessments should discuss the degree of uncertainty associated with each key parameter, often the end result is little confidence that the resulting risk estimates reflect likely exposures.[11] To avoid this, the Proposed Bulletin should require that, in cases where reasonable estimates of parameters bearing on risk differ significantly, the full range of potential assessments of risk be presented to the risk manager. This can be accomplished through the use of probabilistic risk assessment techniques. Probabilistic risk assessment, also known as Monte Carlo analysis, provides an estimate of the likelihood or probability of risk associated with the entire range of exposure. Whereas in a deterministic approach, the risk assessor assigns point estimates to each of the parameters in a dose rate equation, in probabilistic risk assessment, the same basic exposure equation is used, but the point estimate for each parameter is replaced by a distribution of values. Each distribution expresses the probability that the value for a specific parameter will occur for an individual in the exposed population. Distributions reflect either empirical or site-specific modeled data, thus providing the basis for an objective analysis. The end results of a Monte Carlo analysis are then used to estimate potential risks for the typical person[12] and for the high-end exposed individual[13], who might not even exist.[14] In addition, probabilistic risk assessment can effectively identify and quantify the sources of uncertainty. As discussed in EPA guidance, "there

---

[11] As discussed in EPA's Probabilistic Risk Assessment Guidance, "[a]s additional sources of uncertainty are quantified and included in the risk assessment, uncertainty in risk estimates may appear to increase, suggesting there may be little confidence in a risk management decision." EPA, *Risk Assessment Guidance for Superfund: Volume 3* (*Part A, Process for Conducting Probabilistic Risk Assessment*) (EPA 540-R-02-002, December 2001).

[12] This "typical" exposure meets the definition of the regulatory policy-based CTE or *Central Tendency Exposure* as described in EPA policy and guidance. See in particular: EPA (1992). *Final Guidelines for Exposure Assessment*. U.S. Environmental Protection Agency, Washington, D.C. 57 FR 104. (May 29); EPA. (1995). *Guidance for Risk Characterization.* U.S. Environmental Protection Agency, Science Policy Council, Washington, DC. February; and EPA.(2001). *Risk Assessment Guidance for Superfund: Volume 3 - (Part A, Process for Conducting Probabilistic Risk Assessment).* Final. United States Environmental Protection Agency, Solid Waste and Emergency Response. EPA 540-R-02-002. December.

[13] Likewise, this "high-end" exposure is in accordance with the definition of the RME or *Reasonable Maximum Exposure* as described in EPA policy and guidance.

[14] According to the EPA's guiding principles for probabilistic analysis, a Monte Carlo analysis is useful "when it is necessary to disclose the degree of bias associated with point estimates of exposure; when it is necessary to rank exposures, exposure pathways, sites or contaminants; when the cost of regulatory or remedial action is high and the exposures are marginal; or when the consequences of simplistic exposure estimates are unacceptable." EPA, *Policy for Use of Probabilistic Analysis in Risk Assessments at the U.S. Environmental Protection Agency* (May 15, 1997).

are a variety of methods that can be used to effectively quantify uncertainty as well as communicate confidence in risk estimates."[15]

4. Risk Assessments Should Only Be Used For Their Stated Purpose. GE agrees that "the purpose of an assessment should be made clear before the analytical work begins." PB at 3. As OMB notes, risk assessments can be performed for a variety of purposes, including priority setting, screening, risk reduction, rulemaking, and risk communication. PB at 3-5. OMB also should recognize that the results of a risk assessment performed for one purpose (e.g., screening) should not be used for another purpose (e.g., establishing clean-up standards).

Unfortunately, screening level assessments are often used by default as the basis for preliminary remediation goals or remedial action objectives. EPA has, at times, even applied ecological screening values as final site cleanup standards. An example is the so-called Baseline Ecological Risk Assessment that EPA conducted for the Hudson River PCB Superfund Site, as documented in Exhibit 1. In this case, the Agency failed to follow its own guidance, which provides that screening analyses are to be used only to separate sites that pose no threat, and therefore require no additional consideration, from sites that might pose a threat and require additional investigation. [16]

Several state agencies, including New York DEC and New Jersey DEP, have used screening level procedures adopted by EPA to calculate uniform cleanup objectives that are imposed without site-specific risk assessment. Such objectives are, by definition, screening levels that are applied as final remediation standards – inconsistent with EPA guidance but, unfortunately, consistent with EPA's actions at some sites.

---

[15] EPA, *Risk Assessment Guidance for Superfund: Volume 3 - (Part A, Process for Conducting Probabilistic Risk Assessment)* (EPA, December 2001, p. 1-18).

[16] A number of EPA guidance documents confirm that screening level assessments are only to be used to identify areas needing additional evaluation and to eliminate chemicals, exposure pathways, and receptors that are of no concern. *See, e.g.*, EPA, *Ecological Risk Assessment Guidance for Superfund. Process for Designing and Conducting Ecological Risk Assessments.* (EPA 540-R-97-006, June 1997) and EPA, *EcoUpdate. The Role of Screening-Level Risk Assessment and Refining Contaminants of Concern in Baseline Ecological Risk Assessments* (EPA 540/F-01/014, June 2001). It is expected that if the screening analysis indicates that a site warrants additional investigation and/or evaluation, the screening level will be refined to incorporate site-specific characteristics and more realistic science.

For example in its guidance for ecological soil screening levels (SSL), EPA clearly states that the SSLs are to be used during the screening level risk assessment only and are "not designed to be cleanup goals." EPA, Guidance for Developing Ecological Soil Screening Levels, (March 2003) (www.epa.gov/ecotox/ecossl). *See also* EPA's soil screening guidance for human receptors. EPA, Soil Screening Guidance Technical Background Document (EPA/540/R-95/128, July 1996) (http://www.epa.gov/superfund/resources/soil/index.htm). This is because SSLs are derived based on worst-case default assumptions, including the use of conservative Toxicity Reference Values (TRVs), defined as the "[d]ose above which ecologically relevant effects might occur to wildlife species following chronic dietary exposure and below which it is reasonable to expect that such effects will not occur." These TRVs are combined with highly conservative estimates of food and/or soil ingestion rates, dietary composition, seasonal use, habitat use areas, and bioavailability. Thus, they do no reflect site-specific conditions where available habitats, food sources, and soil chemistry may have a marked impact on the actual exposure. In addition, the TRVs are often based on surrogate species that may or may not have the same sensitivity as the species being evaluated in an ecological risk assessment. This is why field studies should be undertaken to corroborate or refute the results of screening analyses.

New York DEC has used EPA's screening levels approach to develop generic soil cleanup objectives which are set forth in DEC's Technical and Guidance Memorandum (TAGM) 4046[17]. TAGM 4046 does not include provisions that allow site-specific adjustments to the generic objectives to reflect actual exposure conditions. The resultant TAGM 4046 values represent the initial goals for a remedial action. Any variances from the TAGM 4046 values must be approved by New York DEC prior to the implementation of a remediation program.

In New Jersey, highly conservative exposure assumptions and a target risk level of 1×10^{-6} have been used to develop numerical remediation standards for soil based on worst-case residential exposures. Mimicking EPA's screening level approach, NJDEP derived these standards by assuming that exposure will occur 350 days per year for a period of 30 years, and that upper bound levels of soil ingestion and dermal contact will occur on each of those days. If any soil concentration of any constituent exceed these standards by more than a factor of 10, corrective action must be taken. The standards, although based on worst case assumptions about hypothetical residential exposures, are applied widely, even in non-residential areas, provided there is no restriction on land use. In addition, the standards are applied to all soil depths, giving no consideration to lack of regular access to subsurface soils. Finally, evaluation of compliance with these standards is to be made on a point-by-point basis so that averaging of soil concentration data is not allowed to more closely replicate likely levels of exposure.

5. <u>The Reasons And Method For Performing A Risk Assessment Should Be Stated At The Outset.</u> In addition to requiring agencies to specify "the purpose of an assessment . . . before the analytical work begins, "the Bulletin also should require agencies to state clearly the *reason for*, and the *proposed methodology of,* a risk assessment before the analytical work begins:

- *Reason for the risk assessment*: There is an important distinction between the purpose of a risk assessment and the reason for doing it. For example, in the context of a waste disposal site, EPA could easily satisfy the *purpose* requirement by stating that it intends to perform a human health risk assessment to determine whether there is an unacceptable risk to residents in the vicinity of the site. However, if ATSDR or a state environmental agency had already performed such an assessment, there would not be a valid *reason for* performing a duplicative assessment.

- *Proposed methodology of the risk assessment*: The proposed methodology should further the purpose of the risk assessment and be consistent with the reason for doing the risk assessment. This has not always been the case. As an example, the U.S. Fish and Wildlife Service is performing studies as part of the Hudson River NRDA in which wild-collected eggs obtained from tree swallows are injected with various amounts (up to six different unidentified doses) of PCBs and multiple measurement endpoints[18] are evaluated in the

[17] NYSDEC. 1994. Technical and Administrative Guidance Memorandum #4046: Determination of Soil Cleanup Objectives and Cleanup Levels. Division of Environmental Remediation. [http://www.dec.state.ny.us/website/der/tagms/prtg4046.html] TAGM 4046 was designed as guidance for the determination of cleanup levels at Inactive Hazardous Waste Sites, but is also applied to petroleum waste sites.

[18] These endpoints include hatchling viability (hatching/pipping success, embryomortality), presence of gross abnormalities, gonadal and thryroid gland morphology, endocrine hormone levels, neural status indicators, cytochrome P-450 activity, and other abnormalities. These are discussed in the *Study Plan for the Avian Injection Study, Hudson River Natural Resource DamageAssessmen*"

hatchlings. This study will do little to advance understanding of the effects of PCB exposures, given that: (1) EPA has performed a baseline ecological risk assessment of the Hudson River Valley, which included investigations of tree swallows, and concluded that their sustainability is not impaired; (2) the results of egg injection studies using PCBs have already been reported in the literature[19]; and (3) this route of exposure does not occur in nature, and studies based on "unnatural" routes of exposure are not an appropriate basis for ecological risk assessment.[20]

6. Human And Field Data Should Be Preferred. The Proposed Bulletin suggests, but does not clearly state, that "real world" human data, where available, should be used in lieu of animal data. PB at 5-6. The Proposed Bulletin should be revised to stress the primacy of human data in human health risk assessment. As more and more chemicals are studied, and techniques for hazard identification and dose-response assessment improve, the limitations of animal data in predicting human risk are becoming increasingly apparent. Exhibit 2 summarizes a recent example of EPA over-reliance on animal data.

Similarly, the Bulletin should stress the primacy of field data over laboratory data in ecological risk assessment. In many cases, laboratory toxicity studies substantially over-predict the potential for adverse effects when compared with actual field observations. For example, in its ecological risk assessment for the Housatonic River, EPA modeled dietary intakes for American robins based on site-specific information about PCB concentrations in prey items. EPA combined this information with literature values for dietary PCB concentrations that resulted in adverse effects, and predicted that the exposures of American robins in the study area posed a high threat of adverse reproductive effects (EPA, 2004)[21]. However, EPA also reported that, despite the fact that the American robins studied were exposed to these levels of PCBs, a field study of this population (Henning et al. 2002)[22] indicated that their reproductive success was not being impaired. A similar discrepancy between modeled effects and observed effects in field studies were reported for belted kingfishers. EPA (2005). Other examples are that laboratory sediment toxicity studies using laboratory-reared test organisms show greater sensitivity to sediment contaminants compared to

---

(http://www.fws.gov/contaminants/restorationplans/HudsonRiver/HudsonRiverAvianEggInjectionDraftStudyPlan021406.pdf)

[19] Many of these studies were identified in the *Study Plan for the Avian Injection Study, Hudson River Natural Resource Damage Assessment*.

[20] *E.g., Guidance for Developing Ecological Soil Screening Levels (Eco-SSLs). Attachment 4-3: Eco-SSL Standard Operating Procedure (SOP) #4: Wildlife Toxicity Reference Value Literature Review, Data Extraction and Coding*. OSWER Directive 92857-55 (June 2005) [http://mountain.epa.gov/ecotox//ecossl/pdf/ecossl_attachment_4-3.pdf]

[21] EPA. 2004. Ecological Risk Assessment for General Electric (GE)/Housatonic River Site, Rest of River. Prepared by Weston Solutions, Inc., West Chester, PA, for the U.S. Army Corps of Engineers, New England District, and the U.S. Environmental Protection Agency, New England Region. November 12.

[22] Henning, M.H., S. Robinson, and K. Jenkins. 2002. Robin Productivity in the Housatonic River Watershed. Prepared by ARCADIS G&M, Inc. Prepared for General Electric Company.

field-collected organisms of the same genus,[23] and that the same test organism has different sensitivity to laboratory or field exposures using the same sediments[24]. Thus, rather than stating merely that "real world" data should be used in lieu of animal data when the former are available, the Proposed Bulletin should compel risk assessors to seek out and assess "real world" data that might serve to confirm or refute laboratory predictions.

7. The Criteria For Weight-Of-Evidence Assessments Should Be Specified. OMB is to be commended for its suggestion that risk assessors should look at all the available data relating to the risks posed by a chemical, including studies that "support, are directly relevant to, or fail to support any estimate" of risk. PB at 13. However, the Proposed Bulletin should also provide guidance on how all of the available data should be synthesized in a risk assessment. While the Proposed Bulletin suggests that such synthesis should be achieved through "weight-of-evidence" techniques, PB at 14, OMB does not define this term. In fact, there are clear differences among various individuals' and entities' conceptions of what a weight-of-evidence analysis entails.

Several weight-of-evidence approaches are available in the chemical risk assessment literature, including (1) the risk ranking approach used by the FDA (2003)[25], (2) a weight-of-evidence scoring approach summarized by Menzie et al. (1996)[26], and (3) an inference method proposed by Suter et al. (2002)[27]. All three methods share a ranking system approach but use somewhat different criteria. For example, the approach by FDA (2003) consists of the following six elements: (1) define the substance/disease relationship; (2) collect and submit all relevant studies; (3) classify and rate each study as to type of study; (4) rate each study for quality; (5) rate the strength of the total body of evidence; and (6) report the rank. The approach by Menzie et al (1996) is the most complex of the three approaches listed above. It involves the evaluation of each of the measurement and assessment endpoints in an ecological risk assessment against ten attributes, with each attribute having different scoring values. For example, the attribute "degree of association" has a value of 1, while the attribute "temporal representativeness" has a value of 0.2, indicating that the former is more heavily weighted than the latter when the endpoint is assessed. The scores are summed, divided by five, and then compared to develop a relative ranking of the different endpoints.

Although weight-of-evidence methods that use ranking or similar objective criteria may differ in their details, they all share the IQA attribute of transparency, and they all foster the IQA objectives of objectivity and reproducibility. Truly, a key goal of any weight-of-evidence approach must be reproducibility of results – if a weight-of-evidence method is to be useful, it should increase the

---

[23] Meyer, J. and R. Di Giulio. 2002. Patterns of heritability of decreased EROD activity and resistance to PCB 126-induced teratogenesis in laboratory-reared offspring of killifish (*Fundulus heteroclitus*) from a creosote-contaminated site in the Elizabeth River, VA, USA. *Marine Environmental Research*. 54(3-5): 621-626.

[24] DeWitt, T.H., C.W. Hickey, D.J. Morrisey, M.G. Nipper, D.S. Roper, R.B. Williamson, L. Van Dam and E.K. Williams. 1999. Do amphipods have the same concentration-response to contaminated sediment *in situ* as *in vitro*?. *Environmental Toxicology and Chemistry*. 18(5): 1026–1037.

[25] FDA. 2003. Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data. Center for Food Safety and Applied Nutrition. July.[http://www.cfsan.fda.gov/~dms/hclmgui4.html]

[26] Menzie, C., M.H. Henning, J. Cura, K. Finkelstein, J. Gentile, J. Maughan, D. Mitchel, S. Petron, B. Potocki, S. Svirsky, and P. Tyler. 1996. A weight-of-evidence approach for evaluating ecological risks: report of the Massachusetts Weight-of-Evidence Work Group. *Human and Ecological Risk Assessment*. 2(2): 277-304.

[27] Suter II, G.W., S.B. Norton, and S.M. Cormier. 2002. A methodology for inferring the causes of observed impairments in aquatic ecosystems. *Environmental Toxicology and Chemistry*. 21(6): 1101-1111.

probability that two scientists, reviewing the same data, will come to the same conclusion *or, at least, make it obvious why the scientists did not reach the same conclusion*. Although EPA has published several documents that discuss weight-of-evidence analysis, e.g., EPA's final *Guidelines for Carcinogen Risk Assessment* (EPA /630/P-03/001F, March 2005), none of those discussions provide rules or criteria that encourage objectivity and suppress bias.

It is informative to compare sophisticated weight-of-evidence approaches, such as those published by FDA, Menzie and Suter, with what in our experience is a typical EPA "weight-of-evidence" assessment, such as that used by the Agency to assess the cancer risks of PCBs. EPA's "weight-of-evidence" assessment for the cancer risks of PCBs set forth in IRIS consists of a single paragraph, as follows:

> II.A.1. Weight-of-Evidence Characterization
>
> *Classification -- B2; probable human carcinogen*
>
> Basis -- A 1996 study found liver tumors in female rats exposed to Aroclors 1260, 1254, 1242, and 1016, and in male rats exposed to 1260. These mixtures contain overlapping groups of congeners that, together, span the range of congeners most often found in environmental mixtures. Earlier studies found high, statistically significant incidences of liver tumors in rats ingesting Aroclor 1260 or Clophen A 60 (Kimbrough et al., 1975; Norback and Weltman, 1985; Schaeffer et al., 1984). Mechanistic studies are beginning to identify several congeners that have dioxin-like activity and may promote tumors by different modes of action. PCBs are absorbed through ingestion, inhalation, and dermal exposure, after which they are transported similarly through the circulation. This provides a reasonable basis for expecting similar internal effects from different routes of environmental exposure. Information on relative absorption rates suggests that differences in toxicity across exposure routes are small. The human studies are being updated; currently available evidence is inadequate, but suggestive.

http://www.epa.gov/iris/subst/0294.htm#carc.

This purported "weight-of evidence characterization" is, admittedly, followed by additional discussion of the human data bearing on the potential cancer risks of PCBs. That discussion, however, does little to bolster EPA's claimed "weight-of-evidence assessment" for at least three reasons: (1) it refers to, and very briefly at that, only 6 of the over 40 human epidemiological studies bearing on the cancer risks of PCBs; (2) all of the human studies that are referenced are older studies, the results of which have generally not been confirmed by more recent studies (including more recent studies of the same cohorts); and (3) the assessment does not even mention the large human studies, including those conducted by NIOSH, that have found no association between PCB exposure and an increase in mortality from any type of cancer.

EPA is not the only federal agency to use the term "weight-of-evidence" loosely. Golden et al. (2003)[28] present a fascinating review of the circumstances surrounding the ATSDR's swift and radical modification of its opinion regarding the potential human carcinogenicity of PCBs. To summarize briefly, in 1999 ATSDR concluded that "[t]he weight of evidence does not support a causal association for PCBs and human cancer at this time." Just one year later, ATSDR's conclusion had changed

[28] Golden, R., Doull, J., Waddell, W. and Mandel, J. 2003. *Potential Human Cancer Risks from Exposure to PCBs: A Tale of Two Evaluations*. Crit. Rev. Toxicol. 33(5): 543–580.

dramatically to "[o]verall, the human studies provide some evidence that PCBs are carcinogenic" and "some of these studies provide meaningful evidence that PCBs are carcinogenic in humans." As Golden et al. (2003) demonstrate, nothing approaching a weight-of-evidence assessment influenced ATSDR's change in position, and the only relevant study published between 1999 and 2000 supported ATSDR's original opinion.

We strongly recommend that the Proposed Bulletin be expanded to include the criteria for a credible weight-of-evidence assessment. We also recommend that OMB rely heavily on the principles enunciated by Menzie et al. (1996) in developing those criteria.

8. Latency Should Not Be Regarded As A General Limitation On Use Of Human Data. The Proposed Bulletin recognizes that "[r]eal world data on adverse effects in humans or wildlife may not be available for several reasons." PB at 6. The last reason cited by the Proposed Bulletin is that "adverse effects may occur only after a long period (e.g., several decades) of exposure." Although this reason might be valid in some cases, it is not valid in others, and there is no reason for OMB to stress it as a limitation on the use of human data.[29] There might be more or equally valid reasons for rejecting the use of animal data, two of which OMB mentions: whether animal data are relevant to humans and the difficulty of extrapolation from high dose animal studies to low dose human exposures. PB at 6. As discussed above, these sorts of issues can only be resolved in a scientific manner through unbiased weight-of-evidence assessment, not through hurried –and unexplained -- rejection of negative human studies based on claims of insufficient latency.

9. Animal Data Is Not Always Relevant To Humans. In discussing extrapolation of animal data to humans, the Proposed Bulletin states that the risk assessor usually faces the critical issue of "how effects observed in rodents are relevant to people . . . ." This sentence should be reworded to state "*whether* effects observed in rodents are relevant to people and, if so, *how* such effects are relevant to people." In several cases it has been well established that animal toxicity data have no relevance to people. A good example is bis(2-ethylhexyl)phthalate, which causes liver tumors in rats at high doses by a mechanism that is not relevant to humans[30]. Despite this evidence, EPA still evaluates bis(2-ethylhexyl)phthalate as a potential carcinogen in human health risk assessments.

10. CERCLA And RCRA Risk Assessments Are Influential. On page 9, the Proposed Bulletin discusses and provides examples of "influential risk assessments." Surprisingly, the Bulletin does not provide as an example risk assessments performed under CERCLA or RCRA for the purpose of making remediation or corrective action decisions. Given both the high costs of typical CERCLA and RCRA clean-ups (including the costs of remedial investigations, which themselves can run into the millions of dollars), risk assessments under these statutes should generally be considered "influential risk assessments." This conclusion is strengthened in the case of CERCLA by the lack of opportunity for pre-enforcement judicial review under that statute.[31]

---

[29] Supposed concerns regarding lack of sufficient latency can – and have -- been used to reject valid and powerful data, including the Kimbrough et al. 1999 and 2003 epidemiological studies of human high-dose exposure to PCBs. *See* Exhibit 3, item 1, to Comments of the General Electric Company on the USEPA Staff Report Titled "An Examination of EPA Risk Assessment Principles and Practices" (June 22, 2004). The mean follow-up period of those studies was 37 years.

[30] National Toxicology Program (NTP). 2005. 12th Report on Carcinogens. Background Documents & Public Comments: bis(2-ethylhexyl)phthalate.

[31] Under Section 113(h) of CERCLA, a person potentially responsible for payment of CERCLA response costs at a site may not seek judicial review of EPA's selection of a remedy for the site prior to the EPA's initiation of judicial

11. Risk Assessments Performed In Connection With Adjudications Or Permit Proceedings Should Be Subject To The Bulletin. The second paragraph of Section II, "Applicability", states that the Proposed Bulletin generally "does not apply to risk assessments that arise in the course of individual agency adjudications or permit proceedings." On its face, this language means, among other things, that the Bulletin would not apply to important risk assessments conducted pursuant to RCRA corrective action proceedings (in the course of RCRA permitting on in the context of RCRA interim status corrective action orders), during RCRA Part B permitting, and in the context of NPDES permitting. Risk assessment is an essential part of RCRA corrective action, being used to establish clean-up objectives just as it is under CERCLA. Risk assessment is also important to some RCRA Part B permits, since risk assessments are generally required for hazardous waste incinerator permits and for permitting of so-called "miscellaneous units" (Subpart X of 40 CFR Part 264). Risk assessment for these types of units is addressed at 40 CFR §270.23(c). In NPDES permitting, risk assessment is essential to establishing Whole Effluent Toxicity ("WET") standards and in defining and applying effluent limitations based on Total Maximum Daily Loads ("TMDLs").

One possible reason for the Proposed Bulletin's approach is consistency with the OMB IQA guidelines. The IQA guidelines do not apply to adjudicatory decisions because "[t]here are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions." 67 Fed. Reg. 8454. The fact that parties can seek corrections after the fact should not mean that agencies do not have an obligation to get the science right the first time. There simply is no compelling reason for either the IQA guidelines or the Proposed Bulletin *not* to apply to risk assessments that arise in the context of adjudicatory or permit proceedings – regardless of the "procedural safeguards" available in such proceedings, the risk assessment should be based on high quality information and state-of-the-art risk assessment. Accordingly, the Bulletin should apply to risk assessments that arise in the context of adjudicatory or permit proceedings.

12. The Public Should Be Involved "Early And Often". In describing its "Goals Related to Peer Review and Public Participation," the Bulletin states correctly that "[w]hen people are engaged early in the process, the public typically has an easier time concurring with government documents and decisions." PB at 11. However, the language preceding this sentence suggests that federal agencies need involve the public only when a draft risk assessment is distributed for peer review. GE's experience has been that both peer review and public comment are of little effect after an agency has completed a draft risk assessment – agency personnel are much more resistant to changing their positions after they have publicly stated their conclusions. The public should have an opportunity for input into risk assessment at all times during the risk assessment process, including during the problem formulation or planning stage. In fact, EPA guidance states that it is "important that all involved parties contribute to the problem formulation phase" and that parties should include regulators, potentially responsible parties, and stakeholders, including communities, state agencies, and any other potentially affected groups.[32] In short, public input should be vigorously solicited by federal agencies from the outset.

---

enforcement action against that person. That means that a person who has been ordered by EPA under Section 106 of CERCLA to clean up a site, under threat of penalties of $27,500 per day of non-compliance plus triple the cost of the remedy, refuses to comply at his serious peril.

[32] EPA. 1997. *Ecological Risk Assessment Guidance for Superfund. Process for Designing and Conducting Ecological Risk Assessments.* U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. EPA 540-R-97-006. June.

Early public comment is particularly important in the case of ecological risk assessment. It has been widely-noted that the ultimate results of an ecological risk assessment are strongly dependent on problem formulation (EPA, 1998).[33] This includes defining assessment endpoints, populations to be assessed, and the assessment methods to be employed. In ecological risk assessment, decisions made at the outset of the process are closely linked to assessment results. According to EPA[34], the problem formulation provides the focus and the scope for the risk assessment and defines the chemicals of potential concern, the possible fate and transport mechanism that may be present, receptors that could be affected, the exposure pathways that are possible, and the endpoints that may need to be considered. Clearl, problem formulation is one of the most critical steps of an ecological risk assessment. Early public input is essential.

13. <u>"Quality" Should Be An Independent Criterion.</u> In the first sentence under "Section IV: General Risk Assessment and Reporting Standards," the Proposed Bulletin states that OMB's Information Quality Guidelines require that risk assessments "meet the three key attributes of utility, objectivity and integrity." Admittedly, this is consistent with both the draft and final OMB Information Quality Guidelines that state that "OMB defines 'quality' as the encompassing term, of which 'utility,' 'objectivity,' and 'integrity' are the constituents." However, as GE noted in its comments on OMB's draft Information Quality Guidelines, the Data Quality Act requires OMB to issue guidelines assuring "*quality*, utility, objectivity and integrity" and that "quality" means more than "utility, objectivity and integrity." *Comments of the General Electric Company on the Office of Management and Budget's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* (Oct. 26, 2001)). Specifically, the attribute of "quality" includes excellence, completeness, and accuracy. As discussed in GE's comments on the draft Information Quality Guidelines, the term "quality" is most commonly used to refer to "degree of excellence" or "degree of conformance to a standard." When used alone – e.g., a "quality automobile" -- the term "quality" typically refers to "inherent or intrinsic excellence of character or type." We believe that when Congress required that agency guidelines be adopted to ensure and maximize "quality," it intended that the federal agencies strive to provide excellent, complete, up-to-date and accurate information. OMB should recognize that "quality" is an independent criterion in the Proposed Bulletin.

14. <u>Risk Assessment Scenarios Should Be Reasonable and Probable.</u> In the third and fourth paragraphs in "Section 2, "Standards Relating to Scope," PB at 12-13, the Proposed Bulletin states, appropriately, that a risk assessment's statement of scope should identify the entities or groups that will be the subject of the risk assessment as well as the "type of event-consequence or dose-response relationship for the exposure or event ranges that are relevant to the objectives of the risk assessment." The Proposed Bulletin should go further and provide guidance regarding the advisable scopes of federal agency risk assessments. As the American Chemistry Council ("ACC") discussed in its previous comments to OMB (ACC, *Comments to the Office of Management and Budget Draft 2003*

---

[33] EPA. 1998. *Guidelines for Ecological Risk Assessment*. EPA/630/R-95/002F. April. [http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=36512]; EPA. 1991. *EcoUpdate. Ecological Assessment of Superfund Sites: An Overview*. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. Publication 9345.0-051. December; EPA. 2001. *EcoUpdate. The Role of Screening-Level Risk Assessment and Refining Contmiants of Concern in Baseline Ecologcial Risk Assessments.* U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. EPA 540/F-01/014. June.

[34] EPA. 1997. *Ecological Risk Assessment Guidance for Superfund. Process for Designing and Conducting Ecological Risk Assessments.* U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. EPA 540-R-97-006. June.

Report to Congress on the Costs and Benefits of Federal Regulations, (Feb. 3, 2003)), EPA risk assessments frequently focus on highly improbable exposure events and, accordingly, merely hypothetical people. Examples of four such risk assessments are provided in Exhibit 3. To control against such use of highly improbable risk assessment scenarios, the Bulletin should stress that all exposure assumptions used in federal agency risk assessments must be based on actual data or, at a minimum, be probable and reasonable.

15. The Bulletin Appropriately Incorporates SDWA Quality Standards. We strongly agree with OMB's Standards Related to Characterization of Risk, PB at 13-14, especially the requirement that the SDWA quality standards should be met in all risk assessments that address potential adverse health effects.

16. The Standards Related To Objectivity Will Reduce Bias. We agree with OMB's Standards Related to Objectivity, PB at 14-15, especially that risk assessments should[35] give weight to both positive and negative studies, and must "neither minimiz[e] not exaggerat[e] the nature and magnitude of risks." As discussed in Comment 8 regarding weight-of-evidence assessment, bias is manifest in EPA IRIS risk characterizations that cite only small portions of the available data. Bias continues to be a problem within EPA, as evidenced by the draft dioxin risk assessment. That draft proposes new cancer slope factors for certain PCB congeners without even citing the Agency's own 1996 reassessment of the cancer risks of PCBs,[36] or discussing most of the voluminous human epidemiological evidence relating to the cancer risks of PCBs. The Proposed Bulletin should make clear the close relation between objectivity and comprehensive weight-of-evidence assessment.

17. Standards Related To Objectivity. Three additional comments are relevant to the Proposed Bulletin's discussion of the topic of Objectivity:

- The Proposed Bulletin states in the second paragraph under "Standards Related to Objectivity" that risk assessments "should use the best available data and should be based on the weight of the available scientific evidence." The Proposed Bulletin should clarify the relationship between "best available data" and "weight of the available scientific evidence" – namely, that weight-of-evidence analysis is the essential tool for determining what constitutes the best available data.

- OMB should note in the Proposed Bulletin the need for federal agencies to remove bureaucratic or programmatic obstacles to the use of the best available data. For example, it is recognized, even by EPA, that many of the Agency's IRIS chemical risk characterizations are many years out of date. Nevertheless, EPA risk assessors performing site-specific risk assessments continue to rely on IRIS data, and are highly resistant to using the results of more recent studies. OMB should direct agencies to consider the full weight of the evidence.

- The Proposed Bulletin states in the third paragraph under "Standards Related to Objectivity" that information about risk presented in risk assessments should be "presented in proper

[35] Note, however, that the Bulletin should say "weight *must* be given to both positive and negative studies" rather than "weight *should* be given to both positive and negative studies." This change would be consistent with the OMB IQA guideline requirement that agencies "adopt or adapt", for purposes of analyses of human health, safety, or environmental risks, the SDW A quality principles. The principles include the requirement that agencies "specify, to the extent practicable . . . peer-reviewed studies known to the (agency) that support or fail to support any estimate of (risk) effects and the methodology used to reconcile inconsistencies in the scientific data."

[36] EPA. *PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures* (Sept. 1996).

context." OMB should clarify and explain further what it means by this statement. In our view, "context" should include (1) the assumptions underlying the risk assessment (e.g., all safety factors used in deriving the RfD and all conservative assumptions employed in the exposure assessment), as well as (2) a comparison of the risk projected by the risk assessor to arise from the circumstance or exposure under consideration to the baseline risk. A good example of the latter is EPA's claimed human health benefit arising from the "arsenic in drinking water" rule. According to EPA, the rule is estimated to reduce deaths from bladder and lung cancer by 20 individuals per year. This estimate must be assessed against the total annual deaths from these two types of cancer per year – 175,500, based on estimates of the American Cancer Society for 2006.[37] Even if EPA's estimate of the benefits of the arsenic in water rule is accurate, the rule would reduce annual deaths from bladder and lung cancer from 175,520 to 175,500, or by about one one-hundredth of one percent. The risk reduction achieved by this rule for the average American – who does not drink arsenic contaminated water – would be zero. This is the sort of context that the Proposed Bulletin should require.

- The Bulletin states in the next sentence that the agency must provide data and models supporting the risk assessment so that the public can judge the agency's objectivity. We agree, but suggest that OMB make clear that this requirement is closely related to the reproducibility requirement –- all of the underlying data and models, including model input and code, must be provided so that the public has an opportunity to determine whether the agency's results are scientifically based, reproducible, and objective.

18. Comments On Standards Related To Critical Assumptions. Modifications should be made to OMB's brief discussion of "Standards Related to Critical Assumptions." PB at 15. The main premise of the section is certainly correct -- all risk assessments should thoroughly consider and discuss any important assumptions that are being made, as well as the impacts of using alternative assumptions and of using multiple assumptions. However, one statement made by the Proposed Bulletin should be revised. The Proposed Bulletin states that "[i]f the assumption is supported by, or conflicts with, empirical data, that information should be discussed." The Proposed Bulletin should be revised to state that if an assumption conflicts with the weight-of-evidence of empirical data, the assumption should be *rejected*.

We also recommend that this section of the Proposed Bulletin include the recommendation that the uncertainty section of the risk assessment contain: (1) a quantitative assessment of the impact of using varying exposure assumptions; (2) an explanation of whether the exposure assumptions are based on the use of alternative datasets; and (3) a statement as to whether the assumptions represent a departure from the use of empirical data. There are far too many examples of CERCLA risk assessments in which the uncertainty section is merely a qualitative listing of different exposure assumptions, with no quantitative discussion of the choices that have been made.

19. Comments on Standards Related To Regulatory Analysis. The section "Standards Related to Regulatory Analysis" provides a concise summary of elements essential to risk assessments intended to support regulatory action. We offer the following comments:

- In item 1), OMB should make clear that the baseline risk analysis must be based on conditions as they exist at the time of the risk assessment (i.e., present-use conditions) and reasonable potential future-use conditions. For example, in an area that is industrialized (and zoned as such), it is highly unlikely that an industrial property would be converted to a residential

[37] http://www.cancer.org/downloads/stt/CAFF06EsCsMc.pdf.

property. As noted in an EPA Brownfields guidance document: "Future land use holds the key to practical brownfields redevelopment plans. Knowledge of federal, state, local or tribal requirements helps to ensure realistic assumptions. Community surroundings, as seen through a visual inspection will help provide a context for future land uses, though many large brownfields redevelopment projects have provided the catalyst to overall neighborhood refurbishment."[38]

- Baseline risk assessments also should recognize mitigation measures that already are in place. In several cases, one of which is documented in Exhibit 4, EPA has refused to recognize mitigation measures that it ordered or approved, and has assessed risks based on previously existing conditions.

- We strongly agree with item 4), i.e., that estimates of human population risks are absolutely necessary to compare the overall costs and benefits of regulatory alternatives. The SDWA quality standards adopted by the OMB IQA guidelines require agencies to specify to the extent practicable "each population addressed by any estimate [of applicable risk effects]" and the "expected risk or central estimate of risk for the specific population [affected]."

- We strongly agree with item 5), which states that "t]he central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk." This discussion would benefit from being expanded and separated into discussions of central estimate RfDs and CSFs and central estimates of the risks to populations or individuals subject to particular chemical exposures.

- EPA's practice of ignoring true central estimates of risk when determining RfDs and CSFs appears to be endemic, and is particularly troublesome. For example, EPA typically uses the precautionary lower bound LED_{10} (or LED_{01}) instead of the central estimate ED_{10} (or ED_{01}) as the Point of Departure (POD) for low dose cancer risk extrapolation in which a curve-fitting procedure is applied to tumor data or to other toxicological incidence data. The ED_{10} is typically the lowest effect level observable in tumor bioassay studies and is the dose associated with 10% extra risk adjusted for background. Thus, the ED_{10} represents the best estimate of the dose associated with the 10% risk level under the precautionary assumptions of a linear, nonthreshold cancer model. The $LED_{10,}$ on the other hand, represents the 95% lower confidence limit on the ED_{10}. While the ED_{10} represents the best estimate of the target dose, the LED_{10} represents a dose intended to fall below the target dose. In effect, EPA's use of the LED_{10} adds an additional uncertainty factor that is not transparent and might be of a large magnitude. As such, the use of the LED_{10} reflects a target dose estimate that inappropriately builds a risk management assumption into the risk assessment process.

  EPA also fails to define central tendency RfDs, primarily through its reluctance to consider the range of toxicity data that are commonly available. Based on EPA policy (EPA 1999, 2001), the Agency has been unwilling to use probabilistic risk assessment (PRA) techniques to characterize the full range and uncertainties associated with toxicity values, despite the availability of such techniques in the peer reviewed literature. For example, in the recent EPA staff paper that describes how EPA currently conducts risk assessments, *An Examination of EPA Risk Assessment Principles and Practices*, there is a discussion about developing a

[38] *USEPA. 2001. Technical Approaches to Characterizing and Cleaning up Brownfields Sites.* EPA/625/R-00/009. November, Chapter 5, p. 27. [http://www.epa.gov/ORD/NRMRL/Pubs/625R00009/625R00009.pdf]

probabilistic approach for characterizing noncancer dose responses. In this report, EPA incorrectly dismisses at least one of the important papers (Swartout et al., 1998) that developed a framework for expressing a probabilistic RfD as only a "preliminary work." That paper won an award from the Society of Toxicology as the best published paper in the field of risk assessment in 1998, and was more than "preliminary work." Indeed, the major focus of Swartout et al. (1998) was the development of a methodology for expressing the RfD, in probabilistic terms, for practically any chemical. This methodology uses the typical RfD equations but replaces the uncertainty factors with distributions. It can be used to determine toxicological uncertainty for use in non-carcinogenic risk assessments. Such probabilistic RfDs should be presented as an integral part of the toxicity information for chemicals published on IRIS. We urge OMB to expand its guidance to insure that central estimates of risk are indeed not blatant overstatements or understatements of risk.

Similar approaches should be used in exposure assessment to determine a central estimate of the risk to the particular exposed population being evaluated or to smaller subpopulations subject to different , typically higher than average, exposures. Such risks are characterized by combining a dose-response estimate with a measurement of exposure. The central estimate of the risk to the exposed population should be calculated by combining the best estimate of dose-response with the central estimate (i.e., true average) exposure of individuals within the population based on actual data or probable and reasonable assumptions. The central estimate of the risk to any higher exposed sub-populations should be calculated by combining the dose-response with the central estimate (i.e., true average) exposure of individuals within the sub-population(s) based on actual data or, again, based on probable and reasonable assumptions. All of these risk estimates need to be provided by the risk assessor to the risk manager. In addition, so that the risk manager can perform an appropriate and informed evaluation, the sizes of the population and any relevant sub-populations evaluated must be provided.

20. Variability And Uncertainty Must Be Addressed Clearly. We agree with the Bulletin's statement in Section V under "Standards for Presentation of Numerical Estimates" that influential risk assessments "should characterize uncertainty by highlighting central estimates as well as high-end and low-end estimates of risk." However, to be consistent with the OMB's IQA guidelines, the word "should" needs to be replaced with the word "must." OMB Guidelines, §V.3.b.ii.C; 67 Fed. Reg. 8457-58.

We also recommend that this section of the Bulletin include some discussion of the distinction between variability and uncertainty in the risk assessments. For example, high- and low-end estimates of risks based on quantified distributions of exposure assumptions having high confidence would capture the potential variability in the risks with minimal uncertainty. If any of the assumptions include uncertainty (e.g., based on a limited, or less representative, dataset) the high- and low-end risk estimates using variability alone might not fully represent the likely bounds of the potential risks.

21. Averaging Uncertain Models Is Unlikely To Produce Reliable Results. In Section V, under "Standard for Presentation of Numerical Estimates," the Proposed Bulletin states that "[w]hen model uncertainty is substantial, the central or expected estimate may be a weighted average of the results from alternative models." PB at 17. This statement requires support and clarification. It is unclear why one would expect that the average of the results of several uncertain models would provide a more accurate prediction than the results of the best available model. Presumably, a risk assessor's time would be better spent developing the best possible model than running several uncertain

models and averaging the results. It also is unclear on what basis the models' results would be weighted in the averaging process.

22. Risk Assessments Should Focus On True Adverse Effects. We strongly support OMB's statements in Subsections 5 through 9 of Section V. We particularly commend OMB on its recognition of the importance of basing risk assessments not on mere biological events of unknown significance, but on adverse effects such as functional impairments or pathological lesions that reduce an organism's ability to withstand or respond to environmental challenges. PB at 20.

III. Editorial Comments

1. The Proposed Bulletin defines the term "risk assessment" as a "*document* that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment." PB at 1 & 8. This definition should be revised to state that the term "risk assessment, depending on context, refers to both (1) the process by which scientific information is synthesized to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment, and (2) the document that reports the results of that process."

2. The Proposed Bulletin states that where real world toxicity data are not available, risk assessments may be performed using rodent (rat and mice) data. PB at 6. The Bulletin should be reworded to make clear that other genera (including primates) have been, and can be, used in important animal experiments.

3. The first sentence of Section IV, item 5, should be revised. That sentence states that "[r]isk assessments should explain the basis of each critical assumption and those assumptions which affect the key findings of the risk assessment." It is not clear what the distinction is between "each critical assumption" and "those assumptions which affect the key findings of the risk assessment."

4. In the second sentence of section 3, "Standards Related to Characterization of Risk," PB at 13, the second clause of the second sentence should read "the full range of plausible risk estimates should be provided" instead of "a full range of plausible risk estimates should be provided."

II. Conclusion

When implemented, the Proposed Bulletin should lead to higher quality, objective risk assessments that are more likely to be generally accepted by the scientific community and interested members of the public. GE appreciates the opportunity to comment on the Proposed Bulletin.

EXHIBIT 1

Example of Inappropriate Use of a Screening-Level Assessment for Developing Remedial Action Decisions

A recent example of EPA's inappropriate use of a screening-level risk assessment as the basis for remedial action decisions is the Baseline Ecological Risk Assessment that EPA (1999a) conducted for the Hudson River PCB Superfund Site (Hudson BERA). The Hudson BERA was peer reviewed by seven independent peer reviewers who were ecological risk assessors or researchers with demonstrated expertise in fields relevant to the evaluations performed in the Hudson BERA (EPA, 2000; ERG, 2000).

According to the report of the peer review panel, "a common theme expressed throughout the peer review was that the Hudson BERA provides a very conservative account of ecological risks, which the reviewers felt was appropriate for a screening-level risk assessment, but not for this baseline ecological risk assessment." (ERG, 2000, at p. v) Furthermore, "the reviewers unanimously agreed that EPA should not base remedial decisions on the current version of the ecological risk assessment." (ERG, 2000, at p. v.) According to the reviewers, to ensure that potential risks are accurately portrayed and that appropriate risk management decisions can be made, it is critical that the Hudson BERA use accurate dose and toxicity estimates. Throughout the Hudson BERA, EPA used conservative estimates of dose and toxicity, which overestimated the potential risk. Four examples of the over-conservative, screening-level approach taken in the Hudson BERA are summarized below.

Use of a Generic Conceptual Site Model: The Hudson BERA used a generic screening-level Conceptual Site Model (CSM) that was not representative of the Hudson River's ecological resources. The CSM is one of the critical elements in the development of a BERA, because it establishes the potential fate and transport exposure routes for the receptors of interest, and ultimately shapes remedial decisions.

Area Use Factors: The dose calculation in an ERA is adjusted to reflect the percentage of time the receptor may spend at the site. This value, called the area use factor (AUF) is calculated by dividing the receptor's home range by the site area. An AUF of one or greater implies that the receptor spends its entire life at the site. For the Hudson BERA, all of the AUFs were set to one, regardless of the size of the receptor's home range. For receptors with large home ranges, such as eagles, an AUF of one overestimates the potential exposure and calculated risk. While it may be appropriate to set an AUF equal to one in a screening-level risk assessment where specific use information is unavailable, this is not appropriate for a baseline ecological risk assessment in which more detailed analysis is expected.

Derivation of Toxicity Reference Values: Toxicity reference values (TRVs) are one of the benchmarks used in ecological risk assessment to assess potential risks. The TRVs used in the Hudson BERA, like those used for screening level assessments, were based on studies of a sensitive receptor that is not present at the site (e.g., chicken studies were used to derive TRVs for less-sensitive raptors). As in the case of AUFs, using conservative TRVs is not unreasonable in a screening level assessment where the objective is to identify chemicals and exposure pathways in need of more detailed analyses. However, for a baseline ecological risk assessment, a risk assessor should use TRVs that are relevant for the receptors of concern.

Overdependence on one line-of-evidence: The ratio of the dose to the TRV is the hazard quotient (HQ), which is used as a benchmark for assessing potential risks. Typically, when the HQ is greater than one, it is assumed that there may be a potential for harm, thereby calling for additional scrutiny.[1] However, it is not uncommon to calculate HQs greater than one in a screening-level assessment, due to the use of conservative dose or toxicity estimates, and then to observe no manifestation of harm in field surveys performed in the follow up baseline ecological risk assessment. The Hudson BERA focused almost solely on the HQ approach, disregarding or undervaluing other independent lines-of-evidence. These included *in-situ* toxicity studies and, of particular importance, biological surveys.

[1]The need to use multiple lines-of-evidence for remedial decision making is clearly stated in EPA's guidance document "*Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites*" (EPA, 1999b):

> Superfund remedial actions generally should not be designed to protect organisms on an individual basis (the exception being designated protected status resources, such as listed or candidate threatened and endangered species or treaty-protected species that could be exposed to site releases), but to protect local populations and communities of biota. Levels that are expected to protect local populations and communities can be estimated by extrapolating from effects on individuals and groups of individuals using a lines-of-evidence approach.

EXHIBIT 2

Example of EPA Over-Reliance on Animal Data

In January, 2002, EPA published a toxicity assessment for perchlorate, an anion that mimics iodide and may affect thyroid hormone levels. EPA recommended an RfD of 0.00003 mg/kg-day. This value equates to a drinking water level of 1 ppb. There is no supportable scientific basis for the draft perchlorate RfD because: (1) the RfD is based on a NOAEL from highly suspect rodent data and application of an uncertainty factor of 300; and (2) the human data indicate that perchlorate is not toxic at levels at least 200 times higher than EPA's RfD. The evidence of substantially lower human toxicity for perchlorate is discussed below.

Perchlorate has been used as a medication to treat hyperthyroidism associated with Grave's disease. As noted in EPA (2002a), when used to treat Grave's disease, perchlorate inhibits the excessive synthesis and secretion of thyroid hormones by inhibiting the uptake of iodide into the thyroid, causing an efflux (discharge) of accumulated iodide in the gland.

A summary of human clinical treatment dosages follows:

- Adult dosages of potassium perchlorate of 200-900 mg/day (≈3 to 13 mg/kg-day) produce the desired clinical effects in Grave's disease patients - inhibition of excessive synthesis and secretion of thyroid hormones (EPA, 2002a).

- Two human studies indicate no adverse thyroid or other health effects at perchlorate dosages up to 0.7 mg/kg-day (Crump, 1999).

- A human volunteer study with 10 mg/day (≈0.14 mg/kg-day) perchlorate dosing for two weeks showed no changes in thyroid hormone levels (Lawrence et al., 2000).

- Another human volunteer study, which EPA helped design, involved doses ranging from an equivalent of 200 ppb to 17,000 ppb perchlorate in water. No hormone effects were observed at the high dose (Greer et al., 2002).

- Perchlorate occurs naturally in northern Chile. There were no adverse thyroid or any other health differences attributable to life-long exposure to perchlorate at concentrations of 110 ppb (Crump et al., 2000).

- No differences in neonatal thyroid hormone levels or Medicaid data regarding prevalence of thyroid diseases or cancer were found in exposed and non-exposed infants from Las Vegas and Reno, Nevada, respectively (Li et al., 2001).

- There is no increase in neonatal hypothyroidism in southern California in zip codes associated with elevated perchlorate exposure (Lamm & Doemland, 1999).

If the RfD were based on the human studies and appropriate uncertainty factors, it would likely be in the range of 0.005 to 0.17 mg/kg-day. This is equivalent to 175 to 6,000 ppb in drinking water.

EXHIBIT 3

Examples of Risk Assessments That Focus on Highly Improbable Exposure Events And "Protect" Hypothetical People

Gas Turbine MACT

When the Gas Turbine Association petitioned to de-list gas turbines from the Maximum Achievable Control Technology (MACT) standard, EPA required that a risk assessment be conducted to ensure that there would be no risk to the public if the de-listing were to occur. As part of this risk assessment, EPA required that the highest possible emission factor for gas turbines be used to estimate potential exposure point concentrations. In addition, EPA required that it be assumed that an individual lived at the point of maximum impact for a period of 70 years. Finally, EPA required that it be assumed that an individual was present at that point 24 hours per day. It is reasonable to assume that an individual might live in the same location for 70 years. Similarly, it is reasonable to assume that the maximum emission factor might occasionally occur. It is also plausible to assume that some individuals may be present in a home constantly for a 24-hour period. It is not reasonable to assume, however, that there is even a single individual who will remain at the point of maximum impact for 24 hours per day, 365 days per week for 70 years and that throughout that time, emissions will occur at the maximum possible rate. Yet this is what is modeled when these three default assumptions are combined.

Human Health Risk Assessment for the Housatonic River

In completing the Human Health Risk Assessment (HHRA) for the Housatonic River, one of the exposure pathways evaluated by EPA was the potential consumption of fish from the river (EPA, 2003). EPA based its fish consumption rates on region-specific, long-term, sport-caught freshwater fish consumption data provided in a survey of Maine anglers that was conducted by Ebert et al. (1993) and recommended in EPA's Exposure Factors Handbook (EPA, 1997) and Massachusetts risk assessment guidance (MDEP, 1995). Ebert et al. specifically designed the survey to be able to differentiate fish consumption behaviors for sport anglers who fished different types of water bodies, in addition to estimating their total fish consumption rates. Rates derived by Ebert et al. (1993) were based on total fish harvested over a one-year period, taking into consideration the mass of the fish reported consumed by each survey respondent and the numbers of individuals who shared in that consumption. Ebert et al. (1993) published specific and discrete fish consumption rate distributions for fish consumed from flowing waters (rivers and streams), fish consumed from standing waters (lakes and ponds), and total fish consumption, including fish harvested by those individuals from all types of water bodies combined.

While EPA appropriately based its exposure estimates on the data collected by Ebert et al. (1993), it selected a point estimate fish consumption rate of 32 g/day based on the assumption that no sharing of fish occurred, and assumed that 100 percent of the fish consumed were harvested from the single reach of the river being evaluated. Each of these individual assumptions is reasonable in light of the actual survey data. Of the 1006 who reported that they consumed fish during the survey period, there were 36 individuals who ate fish at a rate of 32 g/day or higher. Thus the assumption of 32 g/day represents the 96th percentile of the consumption distribution. Similarly, there were 194 fish consumers who only fished one water body during the survey period. Thus, the assumption of fishing a single water body throughout the year is representative of the 81st percentile of the population. However, when these two factors are combined, the result is that there were only two

individuals in the Ebert et al. study who consumed fish from a single water body during the year who also consumed fish at a rate of 32 g/day or higher. Thus the combination of just these two assumptions used by EPA represents greater than the 99.8th percentile of the actual survey population upon which the estimates are based. On top of this, EPA assumed that 100% of the fish consumed contained PCBs at the 95th percent upper confidence level (UCL) of the mean, and that this behavior was repeated every year for 60 years. It is highly unlikely that this modeled exposure profile would be representative of even a single individual in the fish consumer population that might use the Housatonic River.

Human Health Risk Assessment of Housatonic River Sediment, Bank Soils and Floodplain Soils

Another example is the risk assessment set forth in EPA's and the Commonwealth of Massachusetts Department of Environmental Protection's (MDEP) "Evaluation of Human Health Risks from Exposure to Elevated Levels of PCBs in Housatonic River Sediment, Bank Soils and Floodplain Soils in Reaches 3-1 to 44-6 (Newell Street to the Confluence of the East and West Branches)" (EPA and DEP, 1998). This HHRA covered a two-mile stretch of the Housatonic River within the City of Pittsfield, Massachusetts, and was used by EPA as the basis for the required cleanup of that stretch of the river. The HHRA included several hypothetical receptor scenarios involving exposure to PCBs along different areas of the river reach in question.

One of these hypothetical receptors was a "youth trespasser" scenario that was applied to a reach of the river that is bordered primarily by commercial properties. Under this scenario, the Agencies assumed that individuals between the ages of 9 and 18 years would contact soils and sediments along the river two days per week, every week, from April through October. They assumed that this behavior would continue yearly for nine years and that during each visit, the trespasser would get soil or sediment all over his hands, arms, feet and lower legs and that soil/sediment would remain on the skin for 24 hours without washing or being rubbed off. The scenario also assumed that the trespasser would obtain his entire daily soil ingestion rate during his brief time spent trespassing along the river. Finally, it was assumed that the soil or sediment contacted would contain PCBs at virtually the highest concentration that had been detected in the soils and sediments of that river reach.

As with the scenarios discussed, none of these assumptions is outrageous when considered alone. One can envision that any one of these circumstances might occur in an area such as this (e.g., for example, individuals may take a shortcut through such an area 2 days/week and on occasion might stop to play in the area and receive substantial dermal contact with soils and sediments). It is not likely, however, that all of these conditions will occur on every trespassing occasion. This is particularly true when one considers the differences in behavior between the ages of 9 and 18 years. While a 9-year-old child may stop and play on the riverbank while passing through the area, it is very unlikely that an 18-year-old will do the same. The reason that trespassing was chosen as the exposure scenario for this reach was because the area is not an attractive or easily accessed area and is not likely to be regularly used as a play area. Thus, when all of these assumptions are considered as a composite, one can see that it is highly unlikely that any individual living near the river will actually match all of the assumptions used.

Human Health Risk Assessment for Lower Fox River and Green Bay

As a final example, RETEC, Inc., on behalf of the Wisconsin Department of Natural Resources (WDNR) and EPA Region V, prepared an HHRA for the Lower Fox River and Green Bay Site that evaluated potential risks to individuals who consumed fish from the river and bay (WDNR, 2002). While there were site-specific data available for use in the risk assessment, EPA instead ignored those data and reverted to using more generic data and default parameters to estimate risks:

- EPA relied on fish consumption data provided in the West et al. (1989a, 1993) surveys of Michigan anglers despite the fact that the data collected were short-term data, and despite the availability of more relevant and reliable long-term consumption data for Wisconsin anglers. The West et al. studies collected data on the consumption habits of Michigan anglers using a one-week recall period. As EPA acknowledged in its Exposure Factors Handbook (EPA, 1997), "the distribution of average daily intake reflective of long-term consumption patterns cannot in general be estimated using short-term (e.g., one week) data." EPA (1997) itself concluded that the West et al. (1993) study should not be used to estimate long-term consumption rates, stating that "the resulting distribution [of the West et al. (1993) study] will not be indicative of the long-term fish consumption distribution and the upper percentiles reported from the EPA analysis will likely considerably overestimate the corresponding long term percentiles" (EPA, 1997).

  At the same time, data were available from the Wisconsin Fishing and Outdoor Recreation Survey (WFORS), which collected specific consumption information from Wisconsin anglers over a four-month period through the use of monthly diaries. This data collection methodology both minimized potential recall bias and provided data on long-term behavior. As a result, far fewer simplifying assumptions are needed to extrapolate these data to annualized fish consumption rates. Despite this, EPA continued to use the poorer quality West et al. data in the Fox River HHRA despite the availability of better state-specific data. Based on comments received on the HHRA, the use of the WFORS data would have resulted in lower risk estimates by a factor of at least 2.

- EPA relied on 1990's fish tissue data to conduct the risk assessment, thereby ignoring newer data that indicated that fish tissue concentrations had declined substantially since that time. Had the newer data been used, risk estimates would have been reduced by a factor of 10.

- EPA assumed that a significant portion of the anglers' diets were comprised of carp despite the fact that available regional fish consumption surveys, including data collected in the West et al. (1993) study upon which EPA based its consumption rates, indicated that carp was rarely consumed. Available data indicated that this assumption of carp consumption increased risk estimates by a factor of 1.3 to 30.

- In selecting exposure durations of 50 and 30 years for RME and CTE exposures, respectively, the HHRA ignored census information on population mobility. These data indicate that these assumptions likely overestimated risks by a factor of 1.5 to 3.

While none of these factors seems overly substantial when considered alone, when they are combined, as they must be in the exposure and risk calculation, they substantially overestimate

potential risks. In this case, it is likely that risks were overestimated by as much as two orders of magnitude.

EXHIBIT 4

Example of EPA Using Temporally Irrelevant Data in a Baseline Human Health Risk Assessment

The Centredale Manor Restoration Project Superfund Site includes the Woonasquatucket River in North Providence, Rhode Island, as well as its downstream mill ponds, and approximately 9 acres of land proximate to the river where the original discharges of hazardous materials presumably occurred. Prior to 1936, the property was occupied by Centredale Worsted Mills, a woolens mill, which used the river as a source of power. This type of historical industrial use was typical for the Woonesquatucket River, and is the reason why a series of mill ponds and dams were constructed on the river to provide power to the mills. The most notable mill ponds include Allendale Pond, which is immediately adjacent to the site property. Below the Allendale Dam is Lyman Mill Pond, followed by Dyerville Pond further downstream. The dams act as barriers to potential downstream transport of contaminated sediment, and because no fish ladders are installed, the dams also minimize the potential for transfer of fish from pond to pond.

In November 2005, EPA Region I released the Interim-Final Baseline Human Health Risk Assessment for the Centredale Manor Restoration Project (EPA, 2005). Among other exposure pathways, EPA's Baseline Human Health Risk Assessment (BHHRA) evaluated the potential exposure to chemicals from the consumption of fish. The BHHRA found that 2,3,7,8-TCDD is the major chemical of concern. However, the data used by EPA in the BHHRA to assess the potential exposures from the fish ingestion exposure pathway were collected under conditions that are not consistent with the conditions present at the time the BHHRA was prepared.

In the BHHRA, EPA assessed potential health risks on a pond-by-pond basis. For the fish ingestion exposure pathway, EPA used the concentrations of 2,3,7,8-TCDD in fish caught from each pond to assess the hypothetical risks for each pond. This approach is logical if it is certain that the fish collected from a given pond is representative of that pond. This, however, is not the case for Centredale Site.

In May 2001, the Allendale Dam was breached allowing unimpeded fish migration between Allendale Pond and Lyman Mill Pond. All of the fish tissue samples collected by EPA for Lyman Mill and Allendale Ponds were collected after the breach of the dam, but prior to its repair in February 2002. The February 2002 dam repair, which EPA had ordered the Centredale Manor Responding Parties to re-build at considerable cost in order to reduce downstream exposure to dioxin, eliminated the free passage between the ponds. Because of the nature of the dam during the time period when the sampling occurred, there is no way to determine whether the fish caught in 2001 from Lyman Mill Pond had always resided in that pond. Hence, the dioxin body burdens of those fish could just as likely be due to sediments from an upstream reach as from the sediments in Lyman Mill Pond. If the fish were from an upstream reach and had migrated downstream, the data would not at all be representative of the conditions that currently exist with the dam repaired.

After their review, the Contaminated Sediments Technical Advisory Group (CSTAG) raised the concern that the fish tissue data may not be representative of current conditions and strongly recommended to EPA Region I that new, co-located sediment and fish tissue samples be collected to assess these ponds in their current condition (i.e., with Allendale Dam repaired) (EPA, 2004). EPA response to this CSTAG comment was that it would conduct a review of data to further determine the potential that the fish tissue are not representative of current site conditions. After a thorough evaluation of this

issue, EPA's contractor reported to EPA that the elevated dioxin concentrations in fish tissue from Lyman Mill Pond are from fish that likely migrated downstream from the more contaminated Allendale Pond to this less contaminated pond (MACTEC, 2005). Nevertheless, with full knowledge of this potentially critical data flaw and having been advised to collect additional data that is consistent with current site conditions, EPA used the post-breach fish tissue data in the BHHRA. EPA's use of the post-breach 2001 fish sampling data is but one example of an EPA risk assessment with substantial financial and regulatory implications having been conducted on the basis of outdated information that is not consistent with the contemporary uses or conditions of the site in question.

Exhibit References

Crump K. 1999. Benchmark doses for perchlorate obtained from Lamm et al (1999) study of thyroid function in perchlorate workers. Comments submitted to EPA external peer review panel.

Crump C, Michaud P, Tellez R, Reyes C, Gonzalez G, Montgomery EL, Crump KS, Lobo G, Becerra C, Gibbs JP. 2000. Does perchlorate in drinking water affect thyroid function in newborns or school-age children? J Occup Environ Med. 42(6):603-12

Eastern Research Group (ERG). 2000. Report on the Peer Review of the Ecological Risk Assessment for the Hudson River PCBs Superfund Site. Report prepared for EPA Region II, Emergency and Remedial Response Division. 18 August. 61p.
[http://www.epa.gov/hudson/pr4-era-text.pdf]

Ebert, E.S., N.W. Harrington, K.J. Boyle, J.W. Knight, and R.E. Keenan. 1993. Estimating consumption of freshwater fish among Maine anglers. N. Am. J. Fish. Mgt. 13:737-745.

EPA. 1997. Exposure Factors Handbook, Volumes 1, II and III. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, D.C. EPA/600/P-95/002Fa,b,c. August.

EPA. 1999a. Further Site Characterization and Analysis, Volume 2E – Baseline Ecological Risk Assessment ("BERA"), Hudson River PCBs Reassessment RI/FS. Prepared for EPA Region 2 and USACOE, Kansas City District by TAMS Consultants, Inc. and Menzie-Cura & Associates, Inc. August.

EPA. 1999b. Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites. OSWER Directive 9285.7-28 P. 7 October. [http://www.epa.gov/oswer/riskassessment/ecorisk/pdf/final99.pdf]

EPA. 2000. Response to Peer Review Comments on the Human Health Risk Assessment, Hudson River PCBs Reassessment RI/FS. Prepared for the EPA Region 2 and USACOE by TAMS Consultants, Inc. and Gradient Corporation. November.

EPA. 2002a. Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization. EPA External Review Draft (Jan. 16, 2002).

EPA. 2003. Human Health Risk Assessment for the Housatonic River – Rest of River. Region I, Boston, MA. June.

EPA. 2004. CSTAG Recommendations on the Centredale Manor Restoration Project (CMRP) Superfund Site. U.S. Environmental Protection Agency. August 18.

EPA. 2005. Baseline Human Health Risk Assessment – Interim Final – Centredale Manor Restoration Project Superfund Site. U.S. Environmental Protection Agency, Region 1. November.

EPA and MDEP. 1998. Evaluation of Human Health Risks from Exposure to Elevated Levels of PCBs in Housatonic River Sediment, Bank Soils and Floodplain Soils in Reaches 3-1 to 44-6 (Newell Street to the Confluence of the East and West Branches).

Greer MA, Goodman G, Pleus RC, Greer SE. 2002. Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans. Environ Health Perspect. 110(9):927-37

Lamm SH, Doemland M. 1999. Has perchlorate in drinking water increased the rate of congenital hypothyroidism? J Occup Environ Med. 41(5):409-11

Lawrence JE, Lamm SH, Pino S, Richman K, Braverman LE. 2000. The effect of short-term low-dose perchlorate on various aspects of thyroid function. Thyroid 10(8):659-63

Li FX, Squartsoff L, Lamm SH. 2001. Prevalence of thyroid diseases in Nevada counties with respect to perchlorate in drinking water. J Occup Environ Med. 43(7):630-4

MACTEC. 2005. Letter from Michael Murphy to Deirdre Dahlen RE: Comparison of Pre-Breach and Post-Breach Data and the Potential Impact of the 2001 Allendale Dam Breach on Preliminary Remediation Goal (PRG) Development – Centredale Manor Superfund Site. April 29.

MDEP. 1995. Guidance for Disposal Site Risk Characterization In Support of the Massachusetts Contingency Plan. Interim Final Policy #WSC/ORS-95-141. Massachusetts Department of Environmental Protection. Boston, MA. July 28.

West, P.C., J.M. Fly, R.Marans, & F.Larhin. 1989a. Michigan Sport Anglers Fish Consumption Survey. Technical Report #1. (Natural Resources Sociology Research Lab)

West, P.C., J.M. Fly, R.Marans, F.Larhin & D.Rosenblatt. 1993. 1991-1992 Michigan Sport Anglers Fish Consumption Study. Technical Report #6. (University of Michigan School of Natural Resources)

Wisconsin Department of Natural Resources (WDNR). 2002. Final Baseline Human Health and Ecological Risk Assessment. Lower Fox River and Green Bay, Wisconsin. Remedial Investigation and Feasibility Study. Prepared by the RETEC Group, Inc. December.