TIERRA SOLUTIONS, INC.

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Office of Management and Budget
725 17th Street, NW
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Room 10201
Washington, DC 20503

VIA Electronic Submittal: www.OMB_RAbulletin@omb.eop.gov

Subject: Comments on OMB's *Proposed Risk Assessment Bulletin*

Dear Dr. Beck:

Tierra Solutions, Inc. appreciates the opportunity to comment on the *Proposed Risk Assessment Bulletin* (hereafter referred to as the Bulletin) released for public comment by the Office of Management and Budget (OMB) on January 17, 2006. The OMB is to be commended to for its effort to improve the risk assessment process. While the risk assessment process has evolved substantially since the release of the National Research Council's seminal report titled *Risk Assessment in the Federal Government: Managing the Process* in 1983, additional steps can be taken to improve the process even further. Such efforts are critical given the increased reliance on risk assessment in the decision-making process in many and varied applications within the federal government. We fully support the OMB's efforts to "enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards." Having uniform, minimum standards will serve to further increase the quality, consistency, completeness, objectivity, and transparency of risk assessments conducted by federal agencies. Clearly these are all laudable goals that should be embraced and welcomed by those within regulatory agencies, as well as those subject to federal regulations. Ensuring that risk assessments incorporate the best available science and are based on overall weight of the scientific evidence is essential to achieving these goals.

While there are many issues that warrant comment, we have focused our comments on the following issues that we consider to be of high importance: 1) not limiting some of the standards to "influential" risk assessments or risk assessments used to support regulatory analyses but rather applying the goals and standards outlined in the Bulletin to all risk assessments; 2) not limiting the applicability of the requirements specified in the Bulletin to risk

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assessments conducted in-house by federal agencies but applying all of the goals and standards outlined in the Bulletin to risk assessments that external parties are required to conduct by federal agencies; 3) maintaining a broad definition of the term "risk assessment"; 4) requiring that ranges of plausible values be included in all risk assessments to more objectively characterize risk; 5) basing risk assessments on the best available science rather than relying on the status quo practice of always using standard conservative default approaches and assumptions to avoid exaggerating risks; 6) requiring the conduct of cost benefit analyses prior to taking action based on the results of a risk assessment; 7) requiring that population risk estimates be included in all risk assessments to facilitate decision-making regarding real health threats and the need for regulatory action; 8) requiring that all risk assessments are transparent and reproducible; 9) requiring that all risk assessments include uncertainty analyses to ensure that risk are accurately represented; 10) requiring that adverse health effects be clearly identified and justified in all risk assessments designed to address human health effects; and 11) requiring that all risk assessments include a comparison to risks associated with alternate mitigation measures. Our specific comments are provided in Attachment A.

Again, we appreciate the opportunity to comment on this important document and respectfully request that you carefully consider our comments as you work to finalize the *Risk Assessment Bulletin*. If you have any questions, please do not hesitate to contact me at 732-246-5851 or via email at cefirstenberg@cox.net.

Sincerely,

Laurie C. Haas
for Cliff Firstenberg

Clifford E. Firstenberg
Tierra Solutions, Inc.

Attachment A

Tierra Solutions, Inc. Comments on the OMB's *Proposed Risk Assessment Bulletin*

Background

On January 17, 2006, the Office of Management and Budget (OMB) released a *Proposed Risk Assessment Bulletin* (hereafter referred to as the Bulletin) for public comment. Along with the main text of the Bulletin, the agency also released supplementary information that further describes and explains the goals and standards articulated in the Bulletin, as well as provides a discussion of the uses and types of risk assessments and the legal authority for issuing the Bulletin. The stated purpose of this Bulletin is "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards." This is accomplished by laying out a series of goals and standards applicable to certain types of risk assessments. The Bulletin focuses on specific technical aspects of risk assessment but does not address risk management or risk communication. The Bulletin builds upon guidance provided in OMB's *Information Quality Guidelines* and *Information Quality Bulletin on Peer Review* and is intended to be a companion to OMB *Circular A-4* (2003), the purpose of which was to establish guidelines for the conduct of regulatory impact analyses and cost benefit analyses.

General Comments

The Bulletin and supplementary information lay out a series of goals and standards that all risk assessments are to meet, as well as provides additional standards for those risk assessments used to support or aid decision-making related to regulatory analysis and those risk assessments determined to be "influential." The Bulletin is comprehensive, well-written, and establishes requirements that are not only desirable for all risk assessments but are also attainable given the current state of the science of risk assessment.

Many, if not all, of the goals and standards outlined in the Bulletin are not new but rather reflect the evolution and practice of risk assessment through the years. However, while practiced by some, most risk assessments, especially those developed by government agencies, seldom meet all the applicable goals and standards prescribed in the Bulletin. As such, the Bulletin and supplementary information serve to articulate these desirable attributes of risk assessments in a single guidance document, provide clarity as to the types of risk assessments to which these goals and standards should apply, and provide a detailed description of what each goal and

standard represents. Clearly the goals and standards outlined in the Bulletin are all laudable goals that will only serve to improve that risk assessment process and should be embraced by government agencies, the regulated community, and the public. Having uniform, minimum standards will undoubtedly serve to further increase the quality, consistency, completeness, objectivity, and transparency of risk assessments conducted by federal agencies. Tierra Solutions, Inc. supports the goals and standards set forth in the Bulletin. Further, we believe that many of the goals and standards prescribed in the Bulletin should not be limited solely to those risk assessments conducted by federal agencies but should also be applied to those risk assessments that external parties are required to conduct and submit as a part of a regulatory action or requirement. We also believe that the standards that have been proposed for risk assessments that are either influential or that are used to support regulatory analysis should be extended to all types of risk assessment as they clearly represent basic, minimum standards that should be embodied in all risk assessments. Requirements like those specified in the Bulletin are necessary as government agencies have a tendency to take the easy road, conducting conservative worst-case-type risk assessments without regard for the impact of their actions. Clearly this is a disservice to the American public. They deserve to be told not only what their risk is but also how confident we are in those risk estimates, how the risk may vary, what the uncertainties are, how the risks compare with those associated with other actions as well as with other known activities, and what the costs and benefits are for the various mitigation alternatives. Detailed comments related to specific attributes of the Bulletin are provided below. While there are many issues that warrant comment, we have focused our comments on those issues that we consider to be of high importance.

Specific Comments

Comment 1: The Fundamental Tenets Underlying the OMB's Desire to Establish Uniform, Minimum Standards Are So Important as to Warrant Inclusion in the Main Text of the Bulletin

In the Introductory Section of the supplementary information issued with the Bulletin, the OMB states that there is general agreement that the risk assessment process can be improved such that the process is better understood, more transparent, and more objective. OMB goes on to state that risk assessments are most useful "when those who rely on [them] to inform the risk management process understand its value, nature and limitations, and use it accordingly." OMB follows this with a discussion of the evolution and purpose of the Bulletin. Specifically, OMB states that the "purpose of this Bulletin is to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards." These fundamental tenets are so important that we believe that the OMB should include a statement as to why the Bulletin is necessary, in the main text of the Bulletin, rather than limiting it to the supplementary information. Further, this statement should include the key points underlined in the preceding sentences.

Comment 2: The Goals and Standards Set Forth in the Bulletin Should Not Be Limited to Risk Assessments Conducted In-House By Federal Agencies

The Applicability section of the Bulletin indicates that "all agency risk assessments available to the public shall comply with the standards of this Bulletin." Further, OMB states in the section titled "The Requirement of this Bulletin," which is provided as a part of the supplementary information issued with the Bulletin, that the "Bulletin addresses quality standards for risk assessments disseminated by federal agencies." While this language could be construed to cover risk assessments conducted by federal agencies as well as those conducted by external parties and submitted to federal agencies as a part of some sort of regulatory activity or action, a subsequent discussion concerning the intended audience of the Bulletin seems to imply that the guidance is limited to risk assessments conducted by the federal government As the goals and standards articulated in the Bulletin represent uniform, minimum standards that will undoubtedly serve to further increase the quality, consistency, completeness, objectivity, and transparency of risk assessments, these standards should apply to risk assessments conducted by external parties and submitted to federal agencies for review and approval, as well as to those conducted by the agencies themselves. For risk assessments conducted by external parties, it is equally important to present ranges of plausible risk estimates, to characterize uncertainty, to put risks into perspective, and to describe the costs and benefits associated with various actions resulting from the assessment. Such attributes should not be limited to risk assessments conducted by the agencies themselves. The language in the Applicability section of the Bulletin should be revised to include risk assessments that external parties are required to conduct by federal agencies.

Comment 3: OMB Should Maintain a Broad Definition of the Term "Risk Assessment"

In the Bulletin, the OMB has defined "risk assessment" to mean a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists. In the supplementary information released with the Bulletin, the OMB states further that this definition applies to documents that could be used for risk assessment purposes such as exposure or hazard assessments, even though such assessments may not constitute a complete risk assessment. Further, in describing influential risk assessments, the OMB provided several examples including margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments that support EPA National Ambient Air Quality Standards, FDA tolerances, ATSDR toxicological profiles, HHS/NTP substance profiles, NIOSH current intelligence bulletins and criteria documents, and risk assessments performed as a part of economically significant rulemakings. As the goals and standards articulated in the Bulletin represent uniform, minimum standards that will undoubtedly serve to further increase the quality, consistency, completeness, objectivity, and transparency of all of these types of risk assessments, the OMB is encouraged to maintain a broad definition of the term "risk assessment." Additionally, to avoid confusion, the OMB is encouraged to incorporate all of the aforementioned language, including the examples, in the

main text of the Bulletin rather than limiting it to the supplementary information. Further, as one of the most common uses of risk assessment in the federal government is in assessing contaminated sites as a part of a number of EPA regulatory programs (e.g., Comprehensive Environmental Response, Compensation, and Liability Act [CERCLA], Resource Conservation and Recovery Act [RCRA], Voluntary Cleanup Program [VCP], Petroleum Storage Tank [PST] Program), we recommend that OMB specifically include these types of risk assessments in their list of examples. We believe that presenting ranges of plausible risk estimates, characterizing uncertainty, putting risks into perspective, and describing the costs and benefits associated with various actions resulting from the assessment are equally important for all of the types of risk assessments listed in the proposed Bulletin, as well as for the additional examples that we have recommended.

Comment 4: All Risk Assessments Should Present Ranges of Plausible Risks Including Central Estimates of Risk

OMB makes reference to the importance of presenting ranges of plausible risk estimates in several sections of the Bulletin. First, in their discussion of standards related to the characterization of risk applicable to all risk assessments (Standard #3 in the General Risk Assessment and Reporting Standards section of the supplementary information), OMB states that "When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided." They go on to state further that "Expressing multiple estimates of risk (and the limitations associated with these estimates) is necessary in order to convey the precision associated with these estimates." OMB also requires that ranges of risk estimates be presented for risk assessments used to support or aid decision making related to regulatory analyses as described in Standard #7 in the General Risk Assessment and Reporting Standards section of the supplementary information (Point #5 within Standard #7). In this section, the OMB elaborates further on what a central estimate is and provides some general guidance on how it can be determined. The importance of including ranges of plausible risk estimates is emphasized again in the section pertaining to standards for influential risk assessments (Standard 3-Standard for Presentation of Numerical Estimates). Here, OMB states that "Presenting the range of plausible risk estimates, along with a central estimate, conveys a more objective characterization of the magnitude of risks." OMB also introduces the concept of using formal probability analyses to obtain central or expected risks. This is a tool that, while supported in theory by the EPA with the release of guidance documents dealing with the conduct of probabilistic assessments, has yet to enjoy widespread use despite its value and utility. The fact that OMB emphasized this one particular attribute in three different sections of the Bulletin indicates its importance. As articulated by the OMB, when there is uncertainty inherent in the risk estimates, and there always is, presenting a single point estimate of risk gives a false sense of precision and, as such, is misleading to the public. As such, we believe that it is essential that all risk assessments include information on the range of plausible risks.

Comment 5: All Risk Assessments Must Be Objective, Neither Minimizing or Exaggerating Risks

In their discussion of standards related to objectivity for all risk assessments as described in the General Risk Assessment and Reporting Standards section of the supplementary information, OMB states that "All risk assessments must be scientifically objective, neither minimizing nor exaggerating the nature and magnitude of the risks." This is a critical point. Risks are often greatly exaggerated as a result of using extremely conservative (worst case) approaches and assumptions. While using worst case approaches and assumptions may be appropriate for screening-level risk assessments, they should never serve as the basis for regulatory action. Nonetheless, regulatory agencies continue to require actions based on such worst-case risk assessments. In fact, companies are required to spend billions of dollars remediating contaminated soils and sediments based on such risk assessments. One example of the routine use of a conservative default approach is the widespread use of the linearized multistage model to estimate cancer potency. Despite the emphasis on incorporating consideration on modes and mechanisms of action in the dose-response modeling in the most recent EPA cancer risk assessment guidelines (USEPA, 2005), EPA continues to rely almost exclusively on the linearized multistage model, even when there is compelling evidence supporting the use of an alternative model. This can be demonstrated by examining EPA's calculation of a cancer potency value for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD or dioxin). In this case, EPA has continued to rely on the use of the linearized multistage model to estimate the potency of TCDD, despite the overwhelming evidence that TCDD acts through a receptor-mediated, non-genotoxic (or promotional) mode of action. While a linear model is generally considered appropriate for genotoxic carcinogens, non-linear models such as threshold models are more appropriate for substances like TCDD that act through a non-genotoxic mode of action. In reviewing the evidence concerning the mode of action for TCDD, the EPA concludes in the Dioxin Reassessment that "Empirical dose-response data from cancer studies-both human epidemiological and bioassays-do not provide consistent or compelling information supportive of either threshold or supralinear models and are insufficient to move from EPA's default linear extrapolation policy" (USEPA, 2003). The irony of this statement is that the evidence supporting use of a linear model is in fact much weaker than the evidence supporting use of a threshold model. Nonetheless, EPA refuses to move away from the standard conservative default approach. Such an approach is clearly not grounded in science but rather reflects the status quo. Despite tremendous strides and advances in science there is a general unwillingness to move away from the standard defaults that have been used for decades. Requiring that agencies consider alternate approaches and assumptions when justified based on the best available science will help ensure that risks are not exaggerated. This point should be emphasized in the Bulletin.

Comment 6: All Risk Assessments Should Include An Analysis of Associated Costs and Benefits

In their discussion of the standards applicable to risk assessments being used to support or aid decision making related to regulatory analyses (Standard #7 in the General Risk Assessment and Reporting standards section of the supplementary information), OMB states that a formal

quantitative analysis of the costs and benefits should be conducted for major rules that have an economic impact of $1 billion or more as prescribed in *OMB Circular A-4*. Clearly this is a standard that should apply to all risk assessments. The requirement for formal cost benefit analyses should not be limited to risk assessments associated with rulemaking, nor limited to actions that have an impact of $1 billion or more, nor limited to risk assessments conducted by the agency. Rather, cost benefit analyses should be required as a part of all risk assessments that result in the initiation of a regulatory action and should be required for risk assessments that external parties are required to conduct by federal agencies, as well as for those conducted by the agencies themselves. This is not an unreasonable requirement as the complexity of analysis should be commensurate with impact/costs associated with action required based on results of the risk assessment.

The importance of conducting cost benefit analyses as a part of all risk assessments is demonstrated by way of the following example, which involved assessment of different risk assessment approaches for two chromium sites in NJ (Williams and Proctor, 2001). These authors evaluated the cost/benefit of a regulatory/remediation approach mandated by that state of New Jersey which required that all soil samples meet a specified chromium soil clean-up concentration as opposed to the more traditional approach utilized by USEPA whereby the site average is required to meet a specified chromium soil clean-up concentration. In this case, the authors evaluated two chromium sites located in NJ and found that the New Jersey approach greatly increased remediation costs but offered little additional health benefits. In fact, there was a negative net benefit for each site evaluated. Thus, this approach, when applied across hundreds of sites, results in significant costs for the both the State of New Jersey and private entities, while offering little or no additional health benefits to the citizens in New Jersey. A copy of Williams and Proctor (2001) is provided in Appendix 1.

As such, the OMB should insist that cost-benefit analyses be performed whenever the results of a risk assessment conducted by or for the federal government indicate that some sort of mitigation activity or action is necessary. Additionally, OMB should insist that Federal Agencies evaluate risk assessment methods (e.g. compliance algorithms) from a cost benefit perspective.

Comment 7: All Risk Assessments Should Include a Comparison of the Baseline Risk to the Risk Associated with the Alternative Mitigation Measures Being Considered – This Should Include an Assessment of Risks Posed by Implementation of Remedial Actions

In their discussion of the standards applicable to risk assessments being used to support or aid decision-making related to regulatory analyses (Standard #7 in the General Risk Assessment and Reporting standards section of the supplementary information-Point #2), the OMB states that "The risk assessment shall include a comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered, and describe, to the extent feasible, any significant countervailing risks caused by alternative mitigation measures." This is

an important concept that the OMB should insist remain part of the final Bulletin. The OMB should clarify the text to ensure that risks associated with remedial actions are covered by this guidance. The importance of characterizing risks associated with remedial actions was demonstrated in Hoskins et al., (1994) and Leigh and Hoskins (1999). These authors evaluated and compared the risks associated with various remedial actions at a given site to the risks associated with actually conducting the remediation. In a number of instances, risks to workers conducting the remediation outweighed the risk to hypothetical residents living nearby the site. The abstract from Leigh and Hoskin (1999) states that:

> "This study weighs the risks to workers of cleaning up Superfund sites against the risks to residents if the sites were not cleaned up. Risks are measured by the number of deaths and disabilities due to injuries and diseases, as well as by the costs of these deaths and disabilities. We posit three methods to clean up the sites: one that is labor-intensive and two that are not. We posit 24 hypothetical sites, with varying numbers of residents and levels of cancer death and cancer disability rates. Depending on the cleanup method, the number of residents, and the rates, we find that the risks to workers frequently outweigh the risks to residents. We conclude that risks to workers should be accounted for in Environmental Protection Agency judgments regarding which and how Superfund sites should be cleaned up."

The results of Leigh and Hoskin (1999) and Hoskin et al (1994) provide justification for OMB to clarify in the final Bulletin that "alternative mitigation measures" includes assessment of risk associated with conducting a remedial action.

Comment 8: All Risk Assessments Should Include Estimates of Population Risks

In their discussion of the standards applicable to risk assessments being used to support or aid decision making related to regulatory analyses (Standard #7 in the General Risk Assessment and Reporting standards section of the supplementary information-Point #4), OMB states that "When estimates of individual risk are developed, estimates of population risk should also be developed." Their rationale for requiring the estimation of population risk is that such estimates are necessary to compare the overall costs and benefits of regulatory alternatives. Given the importance of putting estimated risks into perspective, as well as the need to use limited financial resources wisely, focusing on those situations that pose the greatest real threat to society as a whole, we believe that it is critical that population risks be included in all risk assessments.

Currently, the USEPA does not calculate population risks for Superfund sites. Rather, the agency calculates risks for individuals and makes remedial decisions based on those estimates. Because of this approach, USEPA may inappropriately conclude that remediation is necessary at a given site. For example, at a hypothetical urban river site, the cancer risk from ingesting fish from this urban river for an individual might be determined to be 1×10^{-3}. Based on this cancer

risk estimate, the USEPA would likely require that remedial actions be undertaken. While the specific type of remedial action implemented at this site might be different from that implemented at other sites, the one constant is that all such remedial actions are all very expensive. However, if the agency considered the population risk, the decision might be different. If, at this hypothetical site, the population of anglers numbered only 300 (not an atypical number for an urban river location), then the population risk would be less than one ($1 \times 10^{-3} \times 300 = 0.3$). This result would suggest that the risk posed by the hypothetical site is insignificant and might cause the USEPA to reconsider spending large sums of money (e.g., hundreds of millions of private or public dollars) to address sediment in the urban river. At a minimum, it might provide a basis for alternative remedies that are less costly.

Requiring that population risk estimates are included in all risk assessments will provide risk managers with a tool that will allow them to determine which sites require remediation and which ones do not. This can lead to a better allocation of public and private resources (dollars, labor etc.). The final OMB Risk Assessment Bulletin should include the requirement that population risks be calculated for all risk assessments, including those conducted as part of the CERCLA process.

Comment 9: All Risk Assessments Should Be Transparent and Reproducible

In their discussion of the standard for reproducibility for all influential risk assessments (Standard #1 in the Special Standards for Influential Risk Assessments section), the OMB states that "Influential risk assessments should be capable of being substantially reproduced." This of course requires that the risk assessment is wholly and completely transparent in terms of the approaches and assumptions relied upon and that the original data be accessible. The ability to reproduce results, and in this case risk calculations, is an essential component of the scientific method and, as such, should be applicable to all risk assessments, not just to those deemed to be "influential."

An example of a risk assessment approach that is neither transparent nor reproducible is the establishment of toxic equivalency factors (TEFs) for dioxin-like compounds. The TEFs currently in use are those recommended by the World Health Organization (WHO) in 1998. While this approach represents a refinement of earlier TEF schemes (USEPA 1987 and 1989; NATO/CCMS 1988; Ahlborg et al. 1994), the subjective nature associated with a qualitative approach based on scientific judgment has led to controversy concerning the validity and applicability of the recommended TEFs (Starr et al. 1999). Another shortcoming of the WHO process is that because of the qualitative approach used to establish the TEFs, it is difficult to determine which studies received the greatest weight and how each study affected the derivation of the final consensus-based TEF value for a particular congener. Given the widespread use of the WHO TEFs by numerous governmental agencies and others to regulate or otherwise assess potential health risks associated with exposures to PCDDs, PCDFs, and dioxin-like PCBs, it is critical that the approach used to establish the TEFs be transparent, reproducible, and consistent.

As such, efforts should be made eliminate some of the subjectivity that is inherent in the WHO TEFs. This would include developing quantitative descriptors of study quality and relevance and applying such quantitative criteria in the determination of TEFs for each congener.

Comment 10: Uncertainty Analyses Should Be Required as an Essential Part of All Risk Assessments

The importance of characterizing uncertainty is captured in Standards #3 & 4 in the Special Standards for Influential Risk Assessments section. In their discussion of the standard for presentation of numerical estimates for all influential risk assessments (Standard #3), the OMB states that "Influential risk assessments should characterize uncertainty by highlighting central risk estimates, as well as high-end and low-end estimates of risk." As a means of obtaining central estimates of risk, the OMB recommends conducting formal probability assessments. In their discussion of the standard for characterizing uncertainty for all influential risk assessments (Standard #4), the OMB states that "Influential risk assessments should characterize uncertainty with a sensitivity analysis and, where feasible, through the use of a numeric distribution." As already discussed, probabilistic approaches, while supported in theory by the EPA with the release of guidance documents dealing with the conduct of probabilistic assessments, have yet to enjoy widespread use despite their value and utility. In finalizing the Bulletin, the OMB should strongly encourage the use of probabilistic approaches. Sensitivity analyses are a useful tool to help risk assessors focus on those specific parameters that contribute most to the estimated risk. This ensures efficient use of resources. The characterization of uncertainty provides risk managers with information that is critical for decision making and is an essential aspect of all risk assessments, especially those that have far reaching implications. As such, the requirement to include a characterization of uncertainty should apply to all risk assessments not just to those that are deemed to be "influential."

An example of a case where characterization of uncertainty is essential is in the derivation of toxic equivalency factors (TEFs) for dioxin-like compounds. Such characterizations are important given the significant resources that have been and will continue to be expended by Federal, State and private entities to address concerns about dioxin-like compounds. Characterization of uncertainty is likely to be especially important in settings where numerous PCDD/F and PCB congeners contribute to potential health risk. The current approach for addressing this class of compounds is based on an approach where the potency (or toxic equivalency factor) of each member of this class of compounds is based its toxicity relative to that of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), the most toxic member in the class. The specific TEFs currently in use are those recommended by the WHO in 1998 (Van den Berg et al, 1998). In establishing these TEFs, the WHO expert panel considered all the underlying potency estimates and distilled the data down to a single point estimate. This was done based on consensus expert scientific judgment. Because this approach was qualitative in nature, it is not possible to quantify the uncertainty associated with risk estimates that result from using these consensus-based TEFs. In addition, it is not possible to characterize the degree to which the current "point-estimate" TEFs introduce variability and uncertainty into the health risk assessment process in a quantitative fashion. Yet, there is in fact substantial uncertainty inherent in the point estimate TEFs established by the WHO. As indicated by a number of

investigators, the REP values for many congeners are derived from a highly heterogeneous data set, and for most TEFs, the range of underlying REP values often spans several orders of magnitude (Haws et al. 2006; Birnbaum et al. 2004; Finley et al. 2003; USEPA 2000; and van den Berg et al. 1998).

We believe that the use of REP distributions, as a supplement to or in place of "point-estimate" TEFs, would allow for better characterization of uncertainty. Specifically, use of a range of REP values, perhaps with a clearly identified "central tendency" (e.g., 50^{th} percentile) and/or "upper bound" (e.g., 90^{th} or 95^{th} percentile) would permit more informed discussions regarding the degree to which the TEFs contribute to variability and uncertainty in health risk estimates. Developing distributions of REP values and deriving TEFs for all congeners based on a consistent percentile would also address the inconsistencies in the degree of protection afforded to PCDD/Fs vs. dioxin-like PCBs that have been identified by various investigators (Haws et al 2006; Finley et al. 1999 and 2003). The use of distributions would also give risk managers the flexibility to tailor the desired level of protection to the specific situation under evaluation. Clearly, the characterization of uncertainty through the use of sensitivity analysis and, where feasible, through the use of a numeric distribution, will serve to improve the risk assessment and, as such, the final Bulletin should require the inclusion of uncertainty analyses.

Comment 11: All Risk Assessments Designed to Address Potential Human Health Effects Should Include a Discussion as to Which Effects Are Considered Adverse and the Determination Should Be Justified Based on the Best Available Science

In their discussion of the standard for characterizing human health effects for all influential risk assessments (Standard #7 in the Special Standards for Influential Risk Assessments section), the OMB states that "Where human health effects are a concern, determination of which effects are adverse shall be specifically identified and justified based on the best available scientific information generally accepted in the relevant clinical and toxicological communities." This is critical given the vast improvements in sensitivities of analytical methods in recent years, which have made it possible to measure lower and lower levels on substances in human tissues. Clearly the mere detection of a specific chemical in the body is not indicative of an adverse effect, nor are all effects truly adverse. Many, in fact, represent adaptive responses that are often reversible when exposure ceases. Given our increased reliance on biomonitoring data in decision making, it is critical that all risk assessments include a characterization of observed effects and clearly identify those that are adverse, substantiating such a classification based on the overall weight of the evidence given consideration of the best available science.

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APPENDIX 1

WILLIAMS & PROCTOR (2001)

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Exponent™

A Cost-Benefit Analysis of Alternative Remediation Goals for Cr(VI) in Soil

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Overview

- More than 200 sites in New Jersey contain hexavalent chromium [Cr(VI)] in soil
- Remediation is performed at these sites to comply with health-based standards
- However, NJ's approach for applying cleanup levels protective of oral Cr(VI) exposures is not consistent with EPA's approach, or with the technical basis for the underlying toxicity criteria

Overview *(continued)*

- NJ requires every soil sample meet the cleanup level for long-term ingestion standards, whereas EPA evaluates compliance based on the average (95% UCL) soil concentration
- The NJ approach may result in an additional level of cleanup that does not provide measurable health benefits
- Purpose of this analysis is to evaluate the costs and benefits of NJ's approach ("alternative") relative to EPA's approach ("baseline")

Remediation Standards for Cr(VI) in Soil

- Differ for each exposure pathway
  - Dermal (allergic contact dermatitis [ACD])
  - Inhalation (lung cancer risk)
  - Ingestion (chronic noncancer toxicity)
- Differ for residential and industrial land use
- Based on default or site-specific analyses
  - Soil cleanup criteria (SCC)
  - Alternative remediation standards (ARS)

Remediation Standards for Cr(VI) in Soil *(continued)*

Standard*	Soil Conc. mg/kg	Description
Dermal (ACD) ARS	501 (#167) 575 (#201)	Protective of acute dermal effects for individuals who are pre-sensitized to Cr(VI)
Inhalation SCC	270	Equivalent to cancer risk of 1 in a million from chronic inhalation exposures
Oral SCC	240	Protective of noncancer health effects from chronic oral exposures

*Applicable for residential land use

Evaluating Compliance With Cr(VI) Soil Standards

- In many cases, sites containing Cr(VI) must undergo some degree of remediation
- However, there are different approaches for evaluating compliance with the standards
- In this analysis, the only difference between the baseline and alternative scenarios is how compliance with the oral SCC is evaluated

Baseline Versus Alternative Scenarios

Baseline Scenario

- Dermal ARS based on "single sample"
- Inhalation SCC/ARS based on "averaging"
- Oral SCC based on "averaging"

Alternative Scenario

- Dermal ARS based on "single sample"
- Inhalation SCC/ARS based on "averaging"
- Oral SCC based on "single sample"

Case Study of Two Sites

- Industrial areas of Kearny, NJ
  - Site 167: Lomma Trucking
  - Site 201: NJ Turnpike #2
- Both sites have Cr(VI) in surface and subsurface soils
- Although both sites are zoned for industrial use, there is no deed notification restricting future residential development, thus residential standards are applied

Site Descriptions

Factor	Site 167	Site 201
Size (acres)	3	12.5
Number samples collected	217	259
95% UCL Cr(VI) soil concentration (mg/kg)	163	72
Number samples ≥ ACD ARS (501 and 575 mg/kg)	17	9
Number samples ≥ oral SCC (240 mg/kg)	23	19
Number samples requiring cleanup AFTER compliance with ACD ARS	6	10

Cost-Benefit Analysis (CBA)

- Purpose is to enumerate all costs and benefits for each site
- Net benefits (benefit – cost) provides a measure of the difference between the alternative and baseline scenarios
- Positive net benefits suggest a worthwhile program, while negative net benefits do not

Cost Assessment

- Estimated based on two factors
  - Remediation costs for *ex situ* treatment and site restoration
  - Volume of soil remediated
- Data obtained from remediation manager and contour maps
- Minimal costs excluded
  - Regulatory oversight fees
  - Remediation worker risks

Remediation Costs

Factor	Site 167	Site 201
Volume (yd^3)		
Baseline	4,200	1,900
Alternative	4,600	2,500
Average costs ($/$yd^3$)		
Prep work	12	12
Excavation/treatment	78	78
Site restoration*	34	20
Engineering/admin	22	22

*Site 167 requires asphalt paving, while Site 201 requires soil (grass) cover.

Benefits Assessment

- Estimated for cancer and non-cancer effects (latter unlikely)
- Data based on reasonable assumptions and review of literature
  - Post-remediation Cr(VI) soil concentrations
  - Exposed population size
  - Probability of non-cancer effect
  - Value of fatal and nonfatal events
- Non-applicable benefits excluded (e.g., environmental impacts)

Benefits from Reduced Cancer

Factor	Site 167	Site 201
95% UCL post-treatment soil concentration (mg/kg)*		
Baseline	53	45
Alternative	45	37
Individual lifetime cancer risk*		
Baseline	2.0×10^{-7}	1.7×10^{-7}
Alternative	1.7×10^{-7}	1.4×10^{-7}
Number of persons exposed *	48	200
Population lifetime cancer risk		
Baseline	9.4×10^{-6}	3.3×10^{-5}
Alternative	8.0×10^{-6}	2.7×10^{-5}
Value per statistical life ($)	5,000,000	5,000,000

*Assumes post-treatment soil concentration = 130 mg/kg; Cr(VI) concentration of 270 mg/kg = 10^{-6} risk; and single-family home per ¼ acre with 4 persons per household.

Basis for Non-Cancer Benefit

- The oral SCC is based on the EPA's oral reference dose (RfD) for lifetime exposures to Cr(VI)
- The RfD was developed from a one-year rat drinking water study
- In this study, no health effects were observed at any dose level
  - $NOAEL_{rat}$ = 2.5 mg/kg-day (max dose)
  - Uncertainty Factor = 900
  - RfD = 0.003 mg/kg-day

Basis for Non-Cancer Benefit
(continued)

- The RfD is equivalent to chronic exposures to soil concentrations of 240 mg/kg (RME child)
- For both sites, long-term exposures at or above the oral SCC are not likely to result in adverse health effects
- The probability of a non-cancer effect is assumed to be low (1%), and these are assumed be minor in severity

Benefits from Reduced Non-Cancer

Factor	Site 167	Site 201
Fraction of samples greater than oral SCC (240 mg/kg)*	0.3	0.4
Number of persons exposed	2	8
Probability of non-cancer effect	0.01	0.01
Number of persons experiencing non-cancer effect	0.02	0.08
Value per non-cancer effect ($)	5,000	5,000

*Based on ratio of samples exceeding versus not exceeding oral SCC after compliance with the ACD ARS.

Results of CBA*

Factor	Site 167	Site 201
Costs		
Volume (yd^3)	365	616
Cost ($/yd^3$)	145	132
Total Costs ($)	***52,900***	***81,000***
Benefits		
Cancer ($)	7	30
Noncancer ($)	68	418
Total Benefits ($)	***75***	***448***
Net Benefits ($)	**- 52,900**	**- 80,600**

*Represents the additional costs and benefits incurred under the alternative scenario relative to the baseline scenario.

Summary of Key Findings

- The alternative scenario provides some additional benefits, but the magnitude is very small
- The extra cost to obtain these benefits is also relatively high
- In fact, estimated costs are thousands of times greater than expected benefits, resulting in *negative* net benefits at both sites

Sensitivity Analyses

- One-way sensitivity analyses based on "min/max" data for key parameters
  - Remediation costs
  - Post-treatment Cr(VI) concentrations
  - Cancer inhalation potency
  - Value of cancer effect
  - Probability of non-cancer effect
  - Value of non-cancer effect
- In all analyses, net benefits remained negative for both sites

Sensitivity Analyses *(continued)*

- Separate six-way sensitivity analyses were performed to assess the greatest net benefits under the alternative scenario (min costs/max benefits)
- This highly unlikely scenario yielded negative net benefits ($12,000) for Site 167, but positive net benefits ($43,000) for Site 201
- These findings suggest that the alternative scenario only yields positive net benefits under extremely unlikely conditions

Conclusions

- The case study suggests the alternative scenario is not cost-beneficial relative to the baseline scenario
- However, a “single sample” approach is being used to evaluate compliance with oral SCC values for all regulated chemicals at hazardous waste sites in NJ
- The aggregate economic impacts of this policy could be significant, while providing little measurable health benefits

Conclusions *(continued)*

- Importantly, some uncertainties exist in the cost and benefit estimates and the two sites may not be representative of all sites
- Additional site assessments are needed to better understand cost/benefit tradeoffs and inform decision-makers