

Comments of the Leech Lake Band of Ojibwe
Regarding the U.S. Office of Management and Budget Document
“Proposed Risk Assessment Bulletin”

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Comment 1

Leech Lake Division of Resources Management staff have experience with risk assessment in a number of venues, including both voluntary and involuntary risk. As with all human endeavors, our experiences provide a reference point for our communications. Perhaps our most extensive risk assessment experience is in the involuntary risk venue of contaminated resources. Most particularly, the St. Regis Superfund Site (Site), located entirely within the Leech Lake Indian Reservation, is a multiple contaminant Site we have endeavored to clean up for more than 20 years. In recent years, we report reasonable success in our cleanup efforts due in large part to a multi-jurisdictional effort to properly characterize the Site. Proper Site characterization enabled development of a risk assessment process that considers Tribal human health and ecological resource protection as the baseline. Tribal members following traditional knowledge practices are susceptible to significantly greater environmental contaminant exposure than the general U.S. population. Furthermore, our traditional knowledge of toxins instructs that if the children in our exposed population are protected from the involuntary risks posed by Site contaminants then the rest of the population will be protected. This is because children are substantially more exposed and more vulnerable to contaminants than the general Tribal population. Children eat more food, drink more water and breath more air per kilogram of body weight than adults. The detoxifying systems of children are not fully developed; this greatly reduces their biological ability to remove toxins. Indeed, for some contaminants such as dioxin there is no known safe exposure level during critical fetal development. The importance of protecting children is recognized by the Federal Government in the 1997 Executive Order (E.O.) 13045 (FR62:(78)19883). While OMB does mention “developmental” effects (page 6) and “that children are more exposed and/or susceptible to adverse effects than are adults” (page 12) we are disappointed that OMB does not champion this important E.O. regarding the protection of children’s health in this draft proposed bulletin. We urge you to include E.O. 13045 in any successive OMB bulletins or other documents that pertain to risk assessment.

Comment 2

Little more than a decade ago, it was not uncommon to hear statements from the risk characterization and management community such as “You are more likely to be injured while driving a car than be injured by ingesting contaminants.” We have endeavored to educate people who hold such sentiments as to the difference between voluntary and involuntary risk scenarios, not dissimilar to your “fundamental point” (pages 9 and 15) “...that risk should be placed in a context that is useful and relevant for the intended audience.” We choose to drive a car. It is not difficult to understand the risks associated with that process. Driving instruction, tests and licensing is required and crashed cars are

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often displayed to learning drivers and on highway billboards as reminders of the dangers associated with driving. Drivers are urged to be precautionary and exercise due diligence when undertaking this voluntary risk activity.

Contrastingly, we do not choose to eat, drink and breathe. These are requirements for life. Contamination of our food, water and air creates involuntary risks. Often the contaminants cannot be seen or tasted or smelled. It is becoming ever more common to find Federal, Tribal and State food consumption advisories for Tribal traditional as well as commercial foods, advisories made necessary due to chemicals released into our environment such as mercury and dioxins. Aggregating all risk activities poses ethical issues that may or may not be apparent in a budget and management perspective. We believe OMB should reconsider and address Federal voluntary risk assessment activities separate from Federal involuntary risk assessment activities.

Comment 3

We find statements in the proposed bulletin that appear uninformed. Perhaps some of OMB’s statements are constructed in this manner out of the perceived necessity to address all relevant risk assessment activities of the Federal Government in one concise document. We believe OMB should reconsider and address Federal voluntary risk assessment activities apart from Federal involuntary risk assessment activities as stated in Comment 2, seeking consultation from agencies involved in each of these processes. Based on our experience, a significant portion of the fundamental risk assessment activities OMB is proposing are current standard practice.

As a general example, on page 3, OMB presents rationale for “Uses of Risk Assessments”. The sentence “Accordingly, the purpose of an assessment should be made clear before the analytical work begins.” The meaning of this sentence is commonly described in science as data quality objectives (DQOs). An indirect reference to DQOs appears again on page 15, in the first sentence of number 1. Standards Relating to Informational Needs and Objectives Reference: “A risk assessment should clearly state the informational needs driving the assessment as well as the objectives of the assessment.” Consulting with and speaking directly to the Federal risk assessment community will undoubtedly increase everyone’s understanding of what OMB is endeavoring to achieve.

It is not clear to us that OMB understands the principles involved in risk assessment and their construction to achieve a final document that communicates an assessment of risk. Risk assessment is not science. Science, such as analytical chemistry, toxicology and biology, are employed early in many risk assessment undertakings. The agreed upon DQOs dictate the methods to be used in these data collection activities. An agreed upon

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quality assurance plan (QAP) specifies procedures and processes to be followed and provides bounds for analytical uncertainty so it is transparent to all technical staff involved that the data collected meets data quality objectives. Results of science are often used in algorithms to calculate risk estimates. Up to this point, if the credibility of the analytical and technical staff is intact, the results are objective. Then begins the more subjective part of risk assessment: risk estimates are characterized, including an uncertainty analysis, prior to risk management and communication. Risk characterization, uncertainty analyses, management and communication are inherently subjective activities. OMB’s desire to make “risk assessments scientifically objective” (page 14) is likely impossible given that the latter stages of risk assessment are not science and involve the activities of persons who bring their (subjective) experiences to the process. Science spells out processes for data collection and analysis (DQOs, QAPs). Risk characterization, management and communication are processes, but not scientific processes.

Comment 4

Section II (page 9) addresses the applicability of this proposed bulletin and states in part that “...all publicly available agency risk assessments shall comply with the standards of this Bulletin.” We assume this means any agency generated assessment or other assessment generated by any other party for a Federal agency for inclusion in any Federal risk decision process, whether or not court ordered. Please clarify.

On page 23, Section II Applicability outlines exceptions to which this proposed Bulletin do not apply, including (2b) “permit proceedings” including registration, approval, or licensing and (2c) product label requirements. These exemptions appear to include a wide range of potential public impacts such as pesticide registrations. Please explain the extent of these exemptions and the rationale for their exclusion from these standard OMB risk assessment practices.

Comment 5

OMB addresses the issue of “central estimate” numerous times throughout this Bulletin (pages 13, 16, 17, 19). It is important to remember that many risk assessments generate individual risk estimates by design. These individual risks may be extrapolated to population risks but for what gain (page 16, item 4)? This exercise only serves to obfuscate (historically termed neutralize) the potential impacts to real people by melting the impacts into the general population. And what advantage to you gain by that exercise when 5% of the U.S. population accounts for 50% of the health care costs and 20% of the U.S. population accounts for 70% of the health care costs. The ability to estimate cost impacts OMB is seeking to improve only disappears in the crowd. Finally on this subject

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matter, we assert that the protection of Tribal populations can only be accomplished by risk assessing and risk managing our children’s health and environment. It is well established that exposure to hazardous and toxic substances early in life may account for a significant amount of a person’s lifetime exposure. These exposures then set the stage for health care, educational and social service expenditures that negatively impact general economic productivity. We recommend that OMB focus on protecting children’s health as ordered in E.O 13045. Please provide any rationale for deviating from that cautionary and economically sound position.

Comment 6

We must ask for you to clarify statements on page 20 (Item 7, Standard for Characterizing Human Health Effects) regarding “demonstration of an adverse effect.” We assume you are implying that the hypothetical exposures you cite are to hazardous or toxic chemicals. Following that logic in a risk characterization scenario, either an exposure passes a threshold for injury to the organism or it does not. Your statement that “Adversity typically implies some functional impairment or pathologic lesion...reduces on organism’s ability to withstand or respond to additional environmental challenges” implies that the adversity caused by an exposure is readily measurable. For many human health related exposures, such as to carcinogens, the adverse impacts may not be measurable for many years subsequent to the exposure. Please explain your rationale in making this statement.

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