

June 14, 2006

RE: Comments to the OMB's Proposed Bulletin on Risk Assessment

To Whom It May Concern:

As an Environmental Specialist for the Swinomish Indian Tribal Community in La Conner, Washington, I work with human health risk assessments in the context of contaminated subsistence foods. There are several points in the OMB's Proposed Risk Assessment Bulletin that are of concern and warrant comment.

My comments will address the following issues of concern: that the proposed rules would weaken current risk assessment rules that are in place to protect all Americans; the inappropriate conflation of risk assessment and risk management; the costliness of imposing the proposed, burdensome rules; the rules are one-sided in that they are applied only to government agencies and not industry-generated risk assessments; and, the promotion of the "central tendency" discriminates against vulnerable sub-populations and it a negation of Treaty trust and responsibility to Native Americans.

1. Weakening the current risk assessment rules that are in place to protect all Americans

The purpose of risk assessments is "as an organizing framework for the scientific analysis of the potential for harmful impacts to human health and the environment..." (Cirone 2005). Yet the language used in the Bulletin shifts the purpose of risk assessments from determining the *potentially* harmful health effects to focusing much more narrowly on determining "adverse" health effects. This is in essence a redefinition of risk assessment because it forces risk assessors to ignore initial indicators of many disease pathways, while solely illustrating the outcomes that are already apparent. Thus, only analyzing at the "adverse" impacts level is not protective of the American population because it missing a large portion of the risk that leads to adverse outcomes. In addition, the language used in the Bulletin shifts the focus of risk assessments from determining potential harmful risk to determining which risks are "unreasonable or unacceptable risks." This shift forces risk assessors to ascertain not only the risks, but also which of the risks are "acceptable." The job of a risk assessor is not to rank risks, but to elucidate them. Ranking risks is a much more subjective measure and falls under the risk management sphere, which is a separate phase in the risk process.

2. The inappropriate conflation of risk assessment and risk management

Under the current risk process, risk assessment and risk management are two separate but related spheres, with risk management only occurring after the completion of the risk assessment. The separation is an important one, enacted to disconnect the subjectivity of the decision-making and policy processes from the more objective and scientific realm the risk assessment process. Granted, risk assessment has its share of subjectivities, but the conflation suggested in the proposed Bulletin completely disregards the work to keep

subjectivity at a minimum, and will significantly slow down the entire risk process, making it more costly and burdensome for all involved.

### 3. The costliness of imposing the proposed, burdensome rules

The proposed rules are eminently more costly than current practices for government agencies, and thus the American public. Examples are: forcing risk assessors to determine risk management options, which is not their field of expertise; requiring reproducibility, which opens the doors to years of industry litigation; requiring baseline risk and exposure analysis, which incorrectly assumes that baseline indicators always exist; and, requiring all diseases or conditions to be identified, even though toxicology and epidemiology have made it abundantly clear that it is impossible to identify and accurately correlate all chemicals with disease outcomes as there are simply too many unknowns, multiple stressors, disease co-factors, and a host of other related agency risk assessments in such burdensome work that progress toward any determination will be extremely difficult and costly and when reached, will be easily open to appeal by industry.

### 4. The rules are one-sided in that they are applied only to government agencies and not industry-generated risk assessments

The proposed Bulletin favors industry by requiring that the rules only be applied to government agency risk assessments, not industry-run risk assessments. In addition, exemptions are listed for industries, such as pesticide registration, licensing and inspections of hazardous facilities and FDA drug approvals. The proposed Bulletin fails to justify or even explain these exemptions.

In addition, the proposed Bulletin proposes the “scientific” comments and papers that are peer reviewed should hold more weight than public comments; yet it does not define “scientific,” leaving the door open for industry-funded scientists to compose comments that would hold more weight than comments composed by local public interest groups, Tribes, and concerned citizens. Using my experience and position as an example, insinuating that the local knowledge that tribal members and tribal staff hold is not as worthy or valuable is simply erroneous. The knowledge that those labeled as “nonscientists” hold (whatever the definition of science), is equally as valuable and should be placed on a level playing field with knowledge from “scientists.” Sheila Jasanoff makes this same assertion, “Acknowledging the contingency of what we think we know of the world at any given time should go hand in hand with a respect for plurality, for if no single way of understanding complex phenomena is ever adequate, then it is foolish indeed to rule out inputs from diverse sources of knowledge. Science, in particular, should not repudiate other socially sanctioned forms of knowing, such as tacit knowledge of traditional communities whose skilled environmental management had not been certified through canonical processes of scientific fact-making” (Jasanoff 2002). Along the same line of thought, just as different knowledge systems are of equal importance and should hold equal weight, so too should different segments of the population be given equal recognition and protection. Vulnerable sub-populations should

be given equal importance and thus equal protection, even though they do not fall within the “central tendency.”

5. The promotion of the “central tendency” discriminates against vulnerable sub-populations and it a negation of Treaty trust and responsibility to Native Americans

Many government agencies, academics and scientists have acknowledged that the central tendency does not adequately protect many sub-populations of Americans (e.g., see the recent EPA staff document, “An Examination of EPA Risk Assessment Principles and Practices” (USEPA 2004)). Children, the elderly, pregnant women, people with pre-existing health conditions, and those that live adjacent to toxic sources (and whom are also more likely to be economically disadvantaged, minority communities) are all considered to be vulnerable sub-populations and agencies have taken measures to protect them. For example, the EPA Exposure Factors Handbook uses two types of studies: studies that are derived from data of the general population, and studies that target specific sub-populations (e.g., Calabrese’s et al. (1989) soil ingestion study using children from the Amherst, Massachusetts, area). The Handbooks states, “Due to unique activity patterns, preferences, practices and biological differences, various segments of the population may experience exposures that are different from those of the general population, which, in many cases, may be greater. It is necessary for risk or exposure assessors characterizing a diverse population, to identify and enumerate certain groups within the general population who are at risk for greater contaminant exposures or exhibit a heightened sensitivity to particular chemicals” (USEPA 1997).

Tribal communities also have unique exposure factors, as evidenced in Barbara Harper and Stuart Harris’s work (Harris and Harper 1997; Harris and Harper 2000; Harris 2001; Harris and Harper 2001; Harper, Flett et al. 2002). With tribal communities, it is important to recognize that not only are there unique exposure factors, but ignoring these exposure factors by employing the “central tendency” of the average American negates the tribal Treaty and trust responsibility that the United States government is obligated to uphold. By using the “central tendency,” the risk to many Americans will not be determined adequately, thus discriminating against these groups of people. Executive Order 12898 prohibits discrimination against minority groups such as Native Americans (1994).

Another way to observe the fallacy of “central tendency” being adequately protective is to look at the broader context of risk assessments: that determining probably of a loss and amount of loss is dependent on cultural considerations of what is considered a risk. Cultural perceptions of risk are as unique as cultures themselves. As Frederick Gamst has stated, “Shared values and norms foster group apprehensions about particular things and assumptions not to have apprehensions about other things” (page 21 2006). To use an example that I am intimately familiar with, the risk contaminated fish is of much greater concern to Coast Salish tribal communities than to the average American. As fishing depending communities, the Coast Salish tribes are intricately tied to the natural resources for subsistence, cultural, spiritual, social, and economic reasons. Therefore,

giving up fish because of contamination is much more problematic for them than for the average American who does not have these same connections and on average eats one fish meal per month (6.5 grams per day, approximately one fish meal per month is the official US consumption rate according to the EPA Office of Water (Javitz 1980; USEPA 1980)).

In summary, the proposed Bulletin is not protective of the American people and goes against the basic principles of risk assessment. If you have any questions, please feel free to contact me. Thank you for your time and attention to this matter.

Sincerely,

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