National Tribal Toxics Council

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RE: Tribal Comments on U.S. EPA Peer Review Draft of *Guidelines for Human Exposure Assessment*

Dear Dr. Broder,

Thank you for the extended opportunity for tribal consultation on the U.S. EPA's Peer Review Draft of *Guidelines for Human Exposure Assessment*. We appreciate the thorough efforts of your office in conducting tribal consultation and outreach, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes. This monumental update to the Guidelines is critical to the health of tribal members and the resources they depend on for their tribal lifeways: physically, culturally, and spiritually. Since it has been nearly 25 years from the first release of the Guidelines, exposure assessment has evolved tremendously, and we support official recognition in the updated Guidelines of that advancement. The Council recognizes and encourages your efforts for the timely revision and release of the document.

The National Tribal Toxics Council (NTTC), an EPA Tribal Partnership Group, focuses on issues related to chemical safety, toxic chemicals, and pollution prevention for Tribes. A key priority issue for the NTTC is identifying ways to reduce tribal exposure to toxic chemicals in Indian Country. American Indians and Alaska Natives rely heavily upon healthy and safe ecosystems to sustain their human health, aboriginal and indigenous lifeways, treaty rights and cultural practices. Healthy and safe ecosystems provide clean water, healthful traditional food sources, natural medicines, pesticide and herbicide free native plants for weaving, contaminant free clays for pottery, and other natural resources that sustain tribal cultural practices. As a result, they face substantial impacts from exposure to toxic chemicals through ecosystems that have been degraded by legacy contaminants and the continued release of unregulated chemicals of emerging concern. Among the numerous concerns of tribal human exposure to toxic chemicals, the Council's priorities are the protection of tribal water resources, traditional subsistence foods, and tribal traditions.

The Council is happy to revisit the Guidelines after revisions are made to offer insight and assistance regarding its application in working with tribal communities.

Sincerely,

Dianne C. Barton, Chair
National Tribal Toxics Council

Attachment

Note: The Members of the Council are offering their opinions on toxics issues and do not speak for individual tribes.

In reviewing the U.S. Environmental Protection Agency (EPA or Agency) draft *Guidelines for Human Exposure Assessment,* three concepts are of particular concern for Tribal and ethnically dominant communities:

1. Principles underlying the concept of data quality,
2. the rules of peer review, and
3. making exposure assessment relevant to the communities of concern.

The Council's specific comments in relation to these overarching concerns are as follows.

1. **The NTTC supports the role of exposure assessment as a decision making driver and risk mitigation guide even in the face of limited toxicology information.** With decades between this draft Guidelines update and the first Guidelines publication in 1992, we applaud and thank the authors and contributors for the hundreds of hours of work conducted to create this draft. The 1992 Guidelines for Exposure Assessment was a modest beginning which legitimized exposure assessment as a component of EPA program thinking. One of the most significant positive contributions made by this updated document is about the importance of exposure assessment – stated in the introduction and by inference throughout the document. This document represents a significant repositioning of the role that "exposure assessment" could play in the regulatory functions of EPA (or at least across many programs) and the maturing of the relatively new science of exposure assessment as compared to the long-standing "toxicology" component of risk assessment.

   Optimistically, this document could have significant implications and encourage the improvement of the exposure sciences to serve the program thinking and Agency objectives. It is also an outstanding opportunity for all other stakeholders to contribute to the process by engaging the principles and providing information, perspective and credible thinking to address and improve on the exposure sciences. Most stakeholders cannot **influence** the pace of data production or interpretation of toxicology science, but there is great opportunity for all stakeholders to address the exposure assessment sciences, data and thinking. Even if this document does not permeate the thinking of other Agency offices, the overall statement in this document is a prize to quote when debating specific Agency decision-making that otherwise employs little of exposure assessments to inform their risk mitigation options.

2. **The Council stresses the importance of including the contributions made by other EPA programs, Europe, Canada, the individual States, Universities and other stakeholders to Exposure Science regarding data, modeling, understanding principles of chemical use, developing libraries of activity patterns and many other principles not mentioned in the document.** The document needs more attention given to exposure assessment principles which evolved in EPA program offices or to data and approaches undertaken at the regional level. Some offices and regional programs have had extensive experience with many of the issues discussed in this document. EPA national and regional offices have funded relevant data, including that which is collected by tribes through these programs and efforts as examples: IGAP and Office of Water Quality grants and fellowships, Science to Achieve Results data, and the EPA Exposure Factors Handbook. The Guidelines need to reflect these resources, including a more specific citation, and discussion or attribution to those efforts. It is of utmost necessity to recognize the importance of REACH, EU modeling, and Health Canada's reviews on toxic chemicals because many of the principles, databases and models used

and developed there will be fundamental tools for exposure assessment and risk mitigation strategies that industry will present to EPA. Canada's toxic substances review and principles developed for consumer products would be valuable to consider and acknowledge. There has been considerable work in states and in universities around the world on many of the issues mentioned. Existing references are dated and ignore recent developments and authors. Readers unfamiliar with these global advances could mistakenly believe that EPA is the only institution doing exposure assessment. Familiar readers may mistakenly believe that EPA is unware of this other work. From a public relations perspective, this document is EPA-ORD centric and will likely seem narrowly focused to the many non-EPA scientists and global partners making outstanding contributions in this field and its regulatory applications.

These far-reaching sources and important works must at the very least be acknowledged as existing. Failure to acknowledge these works will suggest that EPA's approaches are inherently superior to others and put non- EPA thinking on the defensive. Health Canada's work with First Nations communities is another example not noted in the Guidelines. Also, the work of arctic communities in global scientific initiatives is not acknowledged.

Examples of other sources of data and information:
The Council would like to include below relevant sources that should be cited and used in redrafting the Guidelines.

Regarding Tribal communities and resources, particularly in light of the treatment in the document of tribes as similar to minority communities, it would be fitting for the document to include a written definition that constitutes the unique legal status of American Indian Tribes, Alaska Natives, and Native Hawaiians*:*

- EPA's definition of Indian Country as defined at 18 U.S.C. § 1151: (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation; (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

Regarding updated and relevant information on tribes and human health risk, this source was funded by the U.S. EPA, the U.S. Department of Defense, the U.S. Department of Energy, and ITRC's Industry Affiliates Program:

- Interstate Technology & Regulatory Council. ITRC. 2015. *Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment*. RISK-3. Washington, D.C.: Interstate Technology & Regulatory Council, Risk Assessment Team. www.itrcweb.org/risk-3.

Regarding fish consumption and adequate and appropriate rates:

- *Fish Consumption Rates Technical Support Document: A Review of Data and Information about Fish Consumption in Washington.* Version 2.0 Final January 2013 Publication No. 12-09-058.

https://fortress.wa.gov/ecy/publications/documents/1209058.pdf

Regarding Penobscot consumption of fish, turtle, and eel:

- *The Penobscot River and Environmental Contaminants: Assessment of Tribal Exposure through Sustenance Lifeway.* U.S. EPA Region 1, Regionally Applied Research Effort, Final RARE Report. August 2015. https://www.epa.gov/sites/production/files/2015-12/documents/final-rare-report-august-2015.pdf

3. **Regarding Principles underlying the concept of data quality, introduce the concept of Relevance to be of equal weight to Precision/Uncertainty and Variability.** The importance of *relevance* is imbedded in some of the document's discussions, but not recognized as a critical quality element. Raising this principle to equal status with the statistical perspectives of *precision/uncertainty* and *variability* addresses many of the points discussed in the document, points about different environments, different scenarios, different populations, etc. Relevance also may be a driving element in any risk assessment's credibility thus, it should be explicitly cited, discussed and evenly ranked with Uncertainty and Variability. There are many examples of the importance of Relevance in contemporary exposure assessments. Data which is irrelevant, no matter how mathematically tidy, are not quality data. Data must describe the conditions and exposure opportunities of the people being exposed as a fundamental principle of quality. Variability and certainty are important, but secondary to the cornerstone of Relevance.

   Until the importance of data *Relevance* is recognized, Agency decision making will continue to focus on databases that exclude Tribal and ethnically dominant communities. We recognize that Tribal community conditions, along with ethnically dominant and economically challenged "unique communities" bring "uncertainty and variability" to databases, rendering them less attractive and of lower quality to typical scientists or risk assessors. Also the data collection for these communities may be less standardized than historically utilized "national databases". Nonetheless, the standardized national databases exclude Tribal communities and under-represent ethnically dominant and underserved communities whose information may exist only in non-traditional formats and harvesting the information may require different techniques than employed by the traditionalist scientists at EPA who authored this report.

4. **Expand the Principles of Peer Review to include the concept of relevance and expand the peer reviewer process to include people who can give credible, contemporary opinion on the concept of relevance of data (and approaches and models) used in an exposure assessment.** The rules of peer review provided are incomplete and far too limiting as it relates to Exposure Science and its many issues, some of which are set forth, and some of which are omitted from the Guidelines. In this document, the definition of "peer review" (pp. 31) requires that the peer reviewers "*are collectively equivalent in technical expertise to those who performed the original work*". This may leave no room for testimony of relevance or completeness of the data. Rather, technical expertise can be viewed and measured as equivalent academic credentials, position within organizational hierarchy or such definitions. Examination of relevance of key exposure-related information may best reside with persons outside of the technical domains of the exposure assessor. For

example, business owners understand product formulation, import/export dynamics over time, and factors defining product use which are critical to accurate and relevant exposure assessments about chemicals in commercial products. Such information is unlikely to be part of the knowledge base of most professional exposure assessors. Similarly, community elders and nutritionists may be "experts" on age-dependent activity patterns, traditional and pre-dominant food sources, and dietary profiles in their unique communities (Tribal, ethnically dominant, economically challenged, institutional living scenarios). Such information is unlikely to exist at all in the national databases and is easily overlooked or misunderstood by most professional exposure assessors.

Default values which have long been used in exposure assessments to represent the "typical US community" need revision and who better to make those observations than business owners, engineers, nutritionists, community elders, environmentalists, and other non-exposure assessment professionals. These "experts" may not have equivalent Western academic pedigrees to match the EPA's exposure assessor, but they may know far more about the relevance of the assumptions, data, and defaults used in the assessment. Indeed, this principle was formally presented to the EPA Science Advisory Panel and the Agency Risk Assessment Forum as part of the process used in developing the dietary profiles for Mexican-Influenced, Tribal and Arctic communities as part of the OCSPP Tribal Program (AKA OPPTS Tribal Program).[1]

Additionally, the issue of "experts" and characterizing quantitative metrics for exposure and risk assessments were extensively studied as part of EPA's Science Policy Council, publicly presented in January 2009 in its "Expert Elicitation Task Force White Paper", and published in final form in 2011.[2] The study was referenced by the authors of the Guidelines, but the Guidelines do not reflect the conclusions of the study. Expert elicitation – the process used extensively in science, engineering and research – is the synthesis of opinions of authorities of a subject where there is uncertainty due to insufficient data. The principles discussed in Expert Elicitation study enforces the concept that an expert must have extensive experience in the topic, but does not embrace the idea that they must compete with the credentials of the author of the exposure assessment. For all communities, but especially for the Tribal communities, it is necessary to employ Expert Elicitation principles to construct *Relevant* exposure assessments, starting with recognition of *Relevant* experts.

5. **The entire conversation about Tribal communities and exposure, risk, data, etc. related to Tribal communities, other ethnic communities and socioeconomic communities must be rewritten.** Within EPA itself, there are dozens of staff who work as Tribal liaisons, Tribal coordinators or other positions in frequent contact with Tribal and other unique communities. Their review and editing of Chapters 3 and 4 and perhaps the document overall would have significantly improved the discussion regarding Tribal communities and sensitive subpopulations. Additional EPA-related resources of information, counsel and data can be reached through EPA's multiple Tribal partnership groups, both office-specific, such as the

[1] Compendia of Alaska Traditional and Subsistence Dietary Files, Compendium of Traditional Dietary Files for First Nations and Inuit in Arctic Canada, Compendium of Dietary Files for Mexican-Influenced Communities, Compendium of Dietary Files for the American Southwest, The LifeLine Group, 2004-2012, freely available at The LifeLineGroup.org.

[2] US EPA Expert Elicitation Task Force White Paper, EPA Science Policy Council, Washington, DC, August 2011.

NTTC, and overarching like the National Tribal Caucus and the National Tribal Operations Committee.

Note that Chapter 4 specifically addresses Tribal populations (section 4.3.5). Yet statements pertaining to "unique communities" in sections 4.3.6 (Other Racial and Ethnic Populations) and 4.3.7 (Socioeconomically Disadvantaged Populations) are relevant to Tribal and arctic communities as well.

The discussions reflect an elementary understanding of Tribal communities in terms of their Tribal lifeways, including diets, lifestyles, community management, and the federal trust responsibilities of EPA. "Tribal" seems to be a descriptor encompassing all groupings of Native American and Arctic communities, as well as our indigenous neighbors in Canada, Mexico/Central and South America. In discussion of collaboration with Tribal communities and utilization of risk assessment conclusions, the tone is condescending, and even at times disrespectful.

The Council is happy to revisit your document once these comments are addressed, to better convey a respectful and informed tone to Tribal peoples. As one example in the leading sentence to Section 4.3, the following is written, emphasis the Council's:

> Sections 4.3.1 to 4.3.7 present detailed discussions on exposure concerns for lifestages (particularly children), tribal populations (e.g., American Indian, Alaska Native, other indigenous populations), ***other*** racial and ethnic groups…

Tribes are not a racial or ethnic group, but are indigenous peoples governing federally recognized sovereign nations. Use of the term "other" belies a fundamental misunderstanding of Tribes and could be construed by many Tribal peoples as ignorant.

In Section 4.3.5, it is written that Tribal communities may not accept proposed risk management solutions because they "*may be unwilling to discontinue traditional practices that they consider essential to their existence*" (pp 49). Yet this section does not note that the EPA does not yet require as the ***determinant*** for decision assembly the consideration of Tribal communities, or other "unique communities" in conducting their risk based decision making for registration of pesticides, nor in the consideration of consumer product exposure and risk assessment, national risk scenarios, water safety assessment, or any other major program utilizing "exposure and risk to the population".

There is no mention of, or reference to, the ground-breaking document, *Fish Consumption and Environmental Justice (2002),* a report developed by one of EPA's own federal advisory committees, the National Environmental Justice Advisory Council. This document is relevant to the Guidelines and would be educational for its authors in that it covers the impact of contaminated and depleted aquatic ecosystems on tribes, other indigenous communities, as well as other unique communities as described in the Guidelines. While the title and the report reference fish and aquatic resources, it actually encompasses all components and resources of aquatic ecosystems.

While fish may be a large component of some Tribal diets, it is not the only wild food consumed by all tribes. In this document, frequently, diet is portrayed as a function of eating fish. This inaccurately implies that when risk assessors understand fish consumption they'll understand Tribal dietary exposure

assessment. No mention is made of the full varied range of subsistence diets, nor of the increasing contamination and bioaccumulation of marine mammals and grazing animals which are important parts of many unique community diets.

There is much known about the age, economic and seasonal influences on choices between western diet foods and subsistence/traditional foods in these communities. The blending of these diets for any given person is the norm (not one or the other) and the balance between those types of diets are influenced by many factors. Consideration of blended diets (both traditional and western) at different percentages by season and/or age can be quantified using the LifeLine Community Based Assessment Software. This was not noted in the text and is an important capability for exposure assessment models to have in order to appropriately reflect the possible exposures presented to people from their mixed diet—both traditional and western.

The reliability of "self-reported" information provided by members of Tribal communities is called into question. (pp 50) The NTTC considers this paternalistic and a gross misunderstanding of Tribal communities. Why would EPA consider self-reported information by Tribal members to be any less credible than self-reported information from any other community? What kind of evidence does this condemning conclusion draw on to warrant inclusion in a federal guidance document? Unfortunately, this reflects antiquated methods of survey-development and interactions with Tribal governments and communities.

In fact, we underscore that the comments in this entire section—Challenges in Conducting Exposure Assessments for Tribal Populations—require close examination and re-write. Why are any of these elements different for Tribal populations, as opposed to white suburban populations and other ethnic communities, etc.? After all, distrust of government agencies is not only represented in relationships with Tribal communities.

Exposure and risk assessments for these communities and the data needed for the assessments are discussed as almost a footnote to the "real risk assessments". This may not have been the intention of the authors but surely this entire section deserves better construction for all of these topics. The uniqueness of "Tribal" communities and the resulting exposure and risk assessments are iconic of all communities who are, in one way or another, "unique". The issues can be framed differently, noting the past limitations and the room for future improvement:

After decades of designing dietary consumption surveys and other exposure related data collection to include only non-Tribal participants, EPA has accrued volumes of information focused primarily on subpopulations that are not Native American, not socioeconomically challenged, and not ethnically dominant. Exposure and risk assessments, until fairly recently, used only models where those data were imbedded, making the assessments irrelevant to any subpopulations not represented in the data.

Fortunately, many strides were made in some areas with Tribal and other underserved communities that generated useful information or approaches for better exposure assessment where previously, EPA offices and scientists had little truly collaborative work and distrust between the groups may have grown. These positive steps forward are not reflected in the discussion in the Guidelines. Examples of good data derived from Tribal and arctic communities (and from any other ethnically dominant community) for use in exposure assessments, and the processes used were not considered. This is a grave omission that could

serve as important lessons for future emulation. These data include multiple works, include EPA-funded work some of which was previously referenced.

6. **Include current trends in exposure locations, and future targets**. There is a complete omission of important issues in exposure assessment that will be targets for EPA attention in the near-future. These are issues which will impact global industry, trade, public health, consumer attitudes about product safety, regulatory decisions and possibly Congressional attention. Those include:

   - Nanomaterials. Among other reasons, Tribes' exposures are likely to be different due to the generally greater exposure to the natural environment and wider array of interactions with it.

   - Exposure from chemicals in consumer products, building materials, vehicles, electronics, foods, drinking water, and air quality factors. The discussion should include the latest thinking about global market dynamics of chemical use, functionality of chemicals in products, relationship to product pricing, distribution, and probability of a chemical being in one's close environment (home, school, workplace). These are contemporary issues relevant to good exposure assessment design and on which much work has been accomplished. Tribes have unique issues related here as well. Many Tribal peoples use products differently that is commonly the practice in non-Tribal communities, partly related to our unique lifestyles and customary practices. More accurate portrayals of exposure will benefit us.

   - Home/office, home/workshop trends: Today's reality is that the domains of home, office, and occupational work place are blurred by home-based industries and telecommuting. The document's citations about US activity patterns are outdated and possibly irrelevant in today's world, and certainly not useful for use in prospective analyses. The Guidelines never mention the limitations of these references. This changes everything in terms of the sourcing of chemicals into homes, the assumptions about chemical controls (air venting, chemical supply control) and the populations expected to be exposed. Think about who is exposed when the small engine repair shop is now located in the garage or in the basement of the house. For Tribes, we have many, many small "mom and pop" shops, and other businesses that are under the radar and located in and next to our homes. The economically-depressed nature of most of our communities guarantees this trend will continue.

   In this document, the pervasive context of people's exposure opportunities is via commercial foods and community water, and activities in homes and offices, i.e., the urban/suburban paradigm as representative of US population. Ethnically strong communities, subsistence communities, rural or underserved communities are contextually a footnote to be treated as exceptions or outliers to the prescribed normative exposure assessment approaches.

OTHER NOTATIONS

Editorial issues: There are many inconsistencies in the text. Words like chemical, agent and stressor are used interchangeably but not necessarily meaning the same thing. Many of the citations are old, not accessible,

incomplete, do not operate correctly, or do not reflect the most current references for the item being referenced.

Policy intersects "guidelines". The priority for EPA (pp. 28)"premium is placed on efficiency, cost efficiency, and cost-effectiveness and focus in the exposure assessment process". Efficiency and quality also can be achieved by a willingness to adopt new ideas. Also, objectives of the modeling are set by schedule and budget of the office, presumably EPA (pp. 105 para 3), but these are probably not meant to apply to industry, academics or other stakeholders.

Consideration of the conceptual models, e.g., sources: This is an old and simplistic view. The example (runoff versus pipe) has little bearing on the principles of "sourcing" for the whole range of consumer products, housing, workspace, schools, etc. which are the sites for the major proportion of exposure opportunity. Though the simplistic view of "source" is still true, we now know significantly more about sources of chemicals entering into people's environment and those principles are evolving and proving to be extremely useful. Chemical functionality in a product, is a great example. The collected lessons from REACH have changed the understanding of "source" and is a major contribution that needs to be acknowledged in this document. The collective work of Health Canada's exposure assessments on toxic substances would also be worth including as that has expanded the understanding of when a chemical is in the person's environment and under what circumstances. This is a key point, especially if the agency advocates for "tiered" exposure assessments using upper bound deterministic first cuts.

"*The public, however, expects EPA to make advancements in developing exposure (and risk) assessments that better reflect reality… Tools and methods are available and continue to be developed to incorporate these vulnerability factors in exposure (and risk) assessment and are being applied, particularly by academic researchers and some state agencies.*" (pp. 39, para 1) There are no references here, and no attempt to provide perspective on how this work compares to the works being discussed. This whole chapter is out of date and does not reflect the considerable volumes of work done on this issue. Approaches about "unique exposure opportunities" and "vulnerable populations" are presented as issues only in working with tribes, but these are also prevalent in urban situations. NIH and CDC is leading the work on this yet there is no mention of that in this document. Meanwhile, the related citations which are provided are very old and represent a small part of the available work here. The work of "researchers and some state agencies" (pp. 39) seems dismissive and unimportant. Indeed, this is very important.

The World Health Organization's 2006 document *Environmental Health Criteria 237: Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals*, regarding the proportional contributions of exposure to children does not reflect **contemporary living in** the United States or the mix of populations and living scenarios in the United States.