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March 1st, 2021

James Avery
Chemical and Pollutant Assessment Division
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

RE: Availability of the ORD Staff Handbook for Developing IRIS Assessments; Docket ID: EPA-HQ-ORD-2018-0654

Dr. Avery,

The National Tribal Toxics Council (NTTC) appreciates the opportunity to provide comments on the ORD Staff Handbook for Developing IRIS Assessments. NTTC is an EPA Tribal Partnership Group (TPG), supported by the EPA Office of Pollution Prevention and Toxics (OPPT), that works to provide Tribes with information on issues and rulemakings related to toxic chemicals and pollution prevention. On behalf of Tribes, the NTTC works to ensure that tribal risks are accurately characterized and evaluated in EPA's risk assessment process by informing and educating the EPA on tribal lifeways, exposures, and risks.

In November of 2020, EPA released the ORD Staff Handbook for Integrated Risk Information System (IRIS) Assessments. As stated in the Handbook, the "IRIS Program develops evidence-based, scientific human health assessments that focus on hazard

identification and dose-response analyses for chemicals found in the environment¹. IRIS is a non-regulatory program that provides review of chemical hazards and scientific expertise to EPA scientists, other offices within the federal government, States, and communities and implements recommendations and input from the National Academies of Sciences, Engineering, and Medicine (NASEM), as well as from EPA review boards and reviewers from other Federal Agencies.

Recently, in their review of the Systematic Review process for TSCA risk evaluations, NASEM recommended that the TSCA systematic review protocol incorporate approaches from the IRIS Program, which EPA has already begun to develop². NTTC has submitted detailed comments on several EPA risk assessment actions under TSCA, highlighting the increased exposure and susceptibility of tribal populations to certain toxic chemicals and the lack of consideration of tribal risks.

On the IRIS website, EPA explains that characterizing risk involves integrating information on hazard, dose response, and exposure, and that an IRIS assessment includes the first two components: “Hazard Identification, which identifies credible health hazards associated with exposure to a chemical, and Dose-Response Assessment, which characterizes the quantitative relationship between chemical exposure and each credible health hazard. These quantitative relationships are then used to derive toxicity values.”³ The hazard information and toxicity values from an IRIS assessment can then be combined with an Exposure Assessment performed by other EPA offices to assess potential risk. The IRIS Handbook provides information that, along with exposure assessments, is used in risk evaluations by EPA, which in turn inform risk management decisions.

NTTC's recommendations for the IRIS handbook are contained below.

1 Recommended: A Separate Tribal Susceptibilities Section

Susceptibility is incorporated into the IRIS hazard identification process, as well as in the dose-response analysis, and thus the derivation of toxicity values. The Handbook states that “the term susceptibility is used...to describe populations at increased risk, focusing on biological (intrinsic) factors, as well as social and behavioral determinants that can modify the effect of a specific exposure”⁴. Multiple factors make tribal populations susceptible to chemical exposure in ways that are different from the general population, including many of the individual and social factors listed in Table 9-2 of the Handbook, especially the Demographic, Health Status,

¹ Ibid., page XI

² The Use of Systematic Review in EPA’s Toxic Substances Control Act Risk Evaluations (2021). National Academies Press. <http://nap.edu/25952>

³ <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#risk>

⁴ Ibid., page 9-5

Behaviors/Practices, and Social Determinants factors⁵ (e.g. race/ethnicity, education, income, geography, genetic variability, higher incidence of pre-existing conditions, higher incidence of chronic disease, psychosocial stress, elevated body mass index, diet, mouthing in traditional practices, smoking, alcohol consumption, subsistence hunting and fishing, socioeconomic status, neighborhood factors, health care access, as well as social, economic, and political inequality). While this may seem an exhaustive list, it does not include psycho-social aspects such as impacts from prejudice and inter-generational trauma from government policy of 'assimilation/boarding schools programs' or attempted genocide. These increase susceptibility in Native Americans.

In addition to susceptibility, Tribal populations have increased chemical exposure due to their unique lifestyles yet are largely unconsidered by EPA risk assessors - assumedly due to lack of knowledge and a greater effort required to access tribal focused data. EPA's Risk Evaluation Framework rule⁶ charges EPA to apply best available science, conduct aggregate (or at least sentinel) exposure assessments and use reasonably available information on hazard and exposure. EPA is obliged by this rule to reach out to stakeholders for information pertinent to the nature and extent of exposure. Tribal participation is most often confined to post-assessment commentary without opportunity for pre-assessment contributions, in spite of the willingness of Tribal representatives to provide information, perspective, and guidance before and during the assessment process. Changes to the IRIS Handbook offer an opportunity to address this bias and NTTC strongly suggests that Native American lifeways, ceremonies, and both subsistence practices and subsistence food species be included at every level.

Assessment of risk to a given population (and subpopulations within the affected population) is defined by EPA as a quantitative consideration of both exposure to the contaminant (by duration, magnitude, periodicity) and the biological response of that population to the exposure (defined by route and magnitude over the temporal patterns of that population's exposure). Risk assessments of a given chemical (or family of chemicals) must consider potential adverse effects and must be aggregated across all sources of that chemical. The unique and wide range of environmental exposures that tribes generally face and the increased burden from chemical hazards that have resulted in disproportionate negative health effects from environmental contaminants must be explicitly addressed and incorporated into such an aggregated assessment for it to be accurate and protective.

Therefore, NTTC recommends that a section specific to tribal susceptibility and hazards be included in the IRIS Handbook. EPA has not evaluated tribal risks in risk assessments thus far and a section on the susceptibility of tribal populations in the IRIS Handbook will be a step in the right direction to remedy such an important oversight. Without explicitly considering tribal susceptibility and making a focused effort to determine what it is, NTTC is concerned that risk assessors will use parameter values that are not representative of tribal populations, in which

⁵ Ibid., page 9-6

⁶ 40 CFR Part 702, Subpart B

case tribal risk to toxics exposure will continue to be excluded or inaccurately determined, perpetuating the well-documented health disparities between Native Americans/Alaska Natives and the general US population.

2 Recommended: Additions to the IRIS Handbook

Section 1.1.1 of the IRIS Handbook gives examples of factors that can determine the scope of an assessment. The last bullet point on that list is “Are there communities, populations, or lifestages that are known or suspected to have disproportionately large exposure or are disproportionately sensitive to the chemical’s toxicity?”. NTTC recommends adding “such as Tribes” to that question.

Similarly, Section 1.1.2 of the IRIS Handbook has a bullet list of questions used to identify particular concerns and priorities of EPA/EPA Clients, which are used to identify the populations, exposures, comparators, and outcomes (PECO) for a given assessment. The fourth bullet in that section states “Are there early indications that there may be greater risks to susceptible subpopulations or other issues that might affect dose response, potentially impacting risk management decisions?”. NTTC recommends adding “such as Tribes” after “susceptible subpopulations” in that question and recommends that management decisions should take into consideration Treaty rights and Federal obligations. The seventh bullet states “Do EPA’s needs include occupational risks or other exposures that may be at ranges above typical environmental exposures?” and NTTC recommends adding “such as in the case of tribes” here, as well. The Webster definition of indigenous is 'produced, growing, living, or occurring natively or naturally in a particular region or environment'. Tribes are indigenous, and they depend fully or substantially on the local environment for nearly every aspect of their members’ lives. This fact leads to tribal populations experiencing higher environmental exposures of greater array and longer duration than the general population. Of special concern to NTTC are exposures due to procurement of traditional and subsistence foods, such as for example fishing with nets that require upper body immersion into potentially contaminated surface waters.

For example, tribal workers often work near or in their homes, at small businesses lacking PPE, returning home on unpaved dusty roads to substandard housing with older furniture, eating a dinner of plants, meat, and fish that they locally caught after multiple hours submerged in sediment and water which was then locally prepared using the same local untreated water to drink and cook, which is the same water source used when completing their day with a DIY steam bath/sauna. Tribal children may spend hours playing in local soils due to absence of yards and sidewalks and then spend hours swimming in the local river and have greater absorption and/or ingestion of chemicals from increased mouthing behaviors. Pastimes may include masticating basket reeds obtained from the same sediment within which tribal

members were immersed digging for shellfish. Inuit infants may teeth on whale muktuk, drink breastmilk from their mother whose primary protein source is that same single whale for half a year and consume small bits of whale meat themselves. Unlike the grocery store-dependent general population with non-place-based cultures, dependence on local foods from particular animals and specific locations in itself results in higher dose and duration of exposure to toxic chemicals.

Section 2 of the IRIS Handbook, Problem Formulation and Development of an Assessment Plan, includes a bulleted list of the activities performed during the problem formulation stage and the first bullet is “A broad, preliminary literature survey is typically carried out to identify health effects or types of toxicity that have been studied in conjunction with exposure to the chemical or substance as well as key toxicokinetic and mode-of-action (MOA) issues, susceptible populations and lifestages, and differences in scientific interpretation or controversies that the assessment may need to address.” NTTC recommends that ORD include a specific explicit reminder to risk assessors to seek studies relevant to tribes, referring them to a list of tribal susceptibilities. These include studies specific to tribes, as well as studies that involve populations having some various shared demographic susceptibilities, such as low income housing, high poverty rates, and high rates of certain diseases.

3 Recommendation: Addressing Miscalculation of Tribal Risk Due to Unaccounted Uncertainty

EPA’s Exposure Factors Handbook thoroughly discusses the variability and uncertainty in quantifying risk, relying heavily on EPA policies, the National Research Council, WHO, IPCS and other assessment authorities. Variability around a risk assessment value is dependent on the variability in human exposure factors and their susceptibility⁷. Variability can be large, especially if multiple components of the risk assessment contain significant variability and if the source of the exposure and/or toxicological data is not necessarily representative of the population under consideration. *Utilizing non-representative data introduces not just variability but also uncertainty, which itself can be significant.* Sources of the contaminant, conditions of contamination, and exposure scenarios for Tribal communities may not be represented in exposure data or assumptions representative of non-Tribal communities, leading to errors of omission in the risk assessment value.

Omission of a significant exposure source for a population (as measured by magnitude and/or duration of exposure) introduces potentially consequential impacts on the calculated risk value and its associated health consequence prediction. Unaddressed variability, uncertainty, and errors of omission will render risk assessments unrepresentative for Tribal communities experiencing the contamination. Remedies for this miscalculation of risk, consistent with EPA’s own policies and guidance, exist and should be employed to improve the risk assessments and

⁷ EPA’s Exposure Factors Handbook, Chapter 2, Section 2

improve predictions of health consequences. EPA has already supported development of region-based and ethnicity-based databases such as Tribal dietary profiles and activity profiles. NTTC notes that these can be applied to assessment models expressly designed to utilize Tribal-specific exposure scenarios and data relevant to Tribal communities.

4 Recommendation: Assignment of Tribal Susceptibility Factors

It is apparent that Tribal populations should be considered independently from the general US population for exposure and risk assessments. Ideally, exposure and risk should be assessments with probabilistic models employing representative data for Tribal Communities. When that is not possible, a 100,000X Safety Factor should be assigned to the assessments. Justification for consideration of Tribal populations separately from the general US population includes the following points:

4.1 Variation

EPA's risk assessments must recognize the significant differences between (and among) Tribal scenarios and the US "general population and its subgroups". For over two decades, EPA has recognized the uniqueness of many Tribal lifeways, ranging from diets, sources of food, and community health, to construction and maintenance of homes, proximities to contaminant sources, and other key exposure factors. Yet, no formal status as a Special Subgroup has been assigned to Tribal populations for risk assessment, nor have these recognized, significant differences been adequately compiled for representative, aggregate exposure and risk assessment procedures.

4.2 Uncertainty

Uncertainty is inflated when assessments do not utilize exposure data representative of unique scenarios, or when surrogate data from different populations' lifeway and exposure scenarios are employed. For example, comparisons of exposure estimates to presumed "safe levels" do not consider the pre-existing health challenges in most Tribal communities, co-existing non-chemical stressors commonly found in Tribal communities, or the uncertainty introduced by assumptions and use of non-representative data. Whether these issues reflect uncertainty, variation in susceptibility or impacts of newly recognized factors in assessing consequences of exposure to toxins, the consequence is the underassessment of risk for the Tribal Community.

4.3 Errors of omission, disaggregation, and exclusion

EPA has an obligation to conduct risk assessments with temporally appropriate aggregated exposure assessments considering multiple sources of the same or related chemicals⁸. Disaggregated exposure and temporally inappropriate aggregation mischaracterize and minimize the exposure potential.

⁸ 40 CFR Part 702, Subpart B

Exposure scenarios formulated from general US population circumstances may not be appropriate for Tribal circumstances. For example, occupational exposures that occur in occupational settings of the “general US community” paradigm may occur in home-based scenarios in Tribal communities. Industrial chemicals and equipment may be stored in homes and community buildings rather than assumed workplaces independent of the non-working community members. Working hours may not follow assumed “shift-based” durations in Tribal settings. Unintended contamination of homes can be commonplace—exposing family members 24/7 rather than for typical “shift work durations”. Unique lifestyles, community activities, and subsistence practices create exposure opportunities that must be considered in the assessment. The most significant exposure routes may be different than those experienced in the general US commercially based communities and work forces. To date, EPA assumptions reflect non-tribal housing, employment, food sources, activity profiles and other parameters intrinsic to exposure assessments. The possible variation and error in risk assessment consequential to such limitations should be estimated for Tribal assessments.

4.4 Probable magnitude of underassessment

EPA guidance for best practices to estimate exposure and risk while facing uncertainties and variability⁹ explicitly recognizes the importance to utilize data most representative of the populations of interest. Creation of appropriate subgroups characterized by similarities of key exposure profile commonality reduces the variation for the subgroup and reveals the drivers of variation among subpopulations. But that assumes representative data of population characteristics and exposure profiles are utilized in appropriate exposure models. Assessments relevant to Tribal populations must use temporal assumptions appropriate to Tribal community lifestyles, aggregated exposure scenarios and consideration of contaminant sources unique to the Tribal community. Without that, the true magnitude of underassessment is not calculable. But even without perfectly representative data, better approaches exist and are expected to be employed in contemporary standards of practice for risk assessment.

4.5 Alternative approaches

Following the guidance in EPA’s Exposure Factor’s Handbook, exposure and risk can be assessed with probabilistic models and distributions (or ranges) of values for key parameters in the exposure and risk algorithms. This produces a distribution of risk answers from which the assessor chooses the percentile most inclusive of variation. That would be at the high end of the distribution (97th percentile or 99th percentile) but not the mean value, which reveals no variation. Deterministic calculations also conceal variation and confer a false sense of confidence on the answer. Confidence intervals around the chosen percentiles can also be calculated to estimate uncertainty using the probabilistic models already available in EPA and indeed, globally. EPA has developed such models and they are available from multiple sources, some of which are designed to utilize customized data bases for unique community scenarios. EPA adopted this approach, along with aggregated assessments in its Risk Assessment Principles and Practices: Staff Paper (U.S. EPA, 2004). The consequence of utilizing high end

⁹ Exposure Factors Handbook, Chapter 2, Section 2

percentiles of estimations for aggregated exposure and risk rather than the mean values would be a minimum of 3 fold and could be much greater, even 100 or 1000 fold. If the underlying data applied to the algorithms' parameters are distinctly unrepresentative of the Tribal community or exposure is disaggregated, even this approach is inadequate to encompass the probable underassessment.

4.6 Safety Factor approach

EPA and other regulatory authorities sometimes assess risk with less sophisticated methods than described above for critical risk assessments under multiple human health protection laws and regulations. Those assessments usually employ generous (and sometime mandated) minimum Safety Factors to “correct” for acknowledged but unquantified variabilities in population susceptibility, lack of quality or representative data, use of surrogate data, use of unsubstantiated assumptions, and other suspected but unquantified factors important to delineate variability in exposure or toxicological calculations. Some safety factors became “traditional” for application to most risk assessments—10X for interspecies extrapolation, 10X for species variability, etc. Some were assigned for Special Risk Groups such as children (minimum 10X) where both susceptibility and exposure profiles often differ from adults and variability exists from age to age. Risk assessors acknowledged the existence of the variability issues and applied the handy 10X (sometimes higher) to enhance the buffer between exposure calculations and dose levels which could introduce adverse health effects. This approach should be applied to risk assessments for Tribal populations, as well. Tribal populations experience exposure differently than suggested by surrogate data from non-tribal communities (**10X**), and EPA acknowledges the variability among Tribal Communities (**10X**), and claims it has little data or does not employ data for key exposure parameters representative of the Tribal lifeways (**10X**). There is abundant evidence (highlighted recently because of the COVID 19 community tragedies) that Tribal populations are likely to have pre-existing health challenges affecting their vulnerability to toxins (**10X**), and experience multiple non-chemical stressors which exacerbate the vulnerability even further (another **10X**). Hence, employing traditional EPA approaches for assigning safety factors to risk assessments designed to protect people from potential adverse health effects, accrued Safety Factors for Tribal populations are easily 10^5 or 100,000X. This Safety Factor should be applied to the risk assessments for Tribal populations until such time as it can be reduced with scientifically meritorious methodology or countervailing data.

5 Conclusions

It is our position that it is incumbent upon EPA to ensure that the intended and reasonably foreseen audience of risk assessors who reference the IRIS Handbook understand that tribal susceptibilities must be considered when deriving and selecting representative parameters that appropriately characterize tribal risk.

We look forward to the Agency's written response to these comments within 90 days. Should you or your staff have questions or comments regarding our letter, please contact myself, Dianne Barton, NTTC Chair, at (503) 731-1259 / bard@critfc.org.

Sincerely,

A handwritten signature in cursive script that reads "Dianne C. Barton".

Dianne C. Barton, Ph.D.
Chair, National Tribal Toxics Council