



National Tribal Toxics Council

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July 30, 2021

Lawrence Martin, Ph.D.
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Policy and Engagement
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

RE: Guidelines for Cumulative Risk Assessment Planning and Problem Formulation
Submitted via email to Martin.Lawrence@EPA.Gov

The National Tribal Toxics Council (NTTC) appreciates your meeting with the Council in June and the opportunity to provide early input on the draft version of the Guidelines for Cumulative Risk Assessment (CRA) Planning and Problem Formulation (Guidelines). The draft Guidelines describe an approach to risk assessment that reflects many of the objectives of the NTTC. These include consideration of vulnerable tribal communities and nonchemical stressors in EPA risk evaluations and risk management actions. The NTTC has provided detailed comments to EPA on many of the TSCA risk evaluations that were completed in the past 4 years, outlining multiple chronic tribal exposures and how they differ from those of the general population, as well as highlighting the fact that risks to tribal populations have not been fully evaluated in EPA's risk assessment process thus far.

Please accept the following comments and suggestions on the draft Guidelines:

The Guidelines (page 7) discusses two areas of advancement in CRA methodologies. One of these is how CRA methods can be used to evaluate the combined effects of chemical and nonchemical stressors. EPA's EJ 2020 Action Plan¹ and National Research Council papers are referenced here as being supportive of work that will develop data and methods to assess cumulative risks from nonchemical stressors. However, the description of this area of research (page 7 – line 36, page 17 – line 16)

¹ U.S. EPA. (2016). EJ 2020 Action Plan. The U.S. EPA's Environmental Justice Strategic Plan for 2016 - 2020. Washington, D.C.: U.S. EPA.

does not reference work that has been published since 2009. Have there been any significant advancements in this area since that time? It would be interesting to include such work in this 2021 version of EPA's Guidelines.

The Guidelines (page 9, line 17) discusses initiating factors that could lead to the consideration of CRA. TSCA as amended by the Lautenberg Act should be included under the sub-heading of **Statutory Provisions**. TSCA requires the EPA to consider potentially exposed, or susceptible subpopulations in chemical risk evaluations and this mandate is repeated in multiple sections of the law. TSCA defines a "potentially exposed or susceptible subpopulation" (PESS) as:

"a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

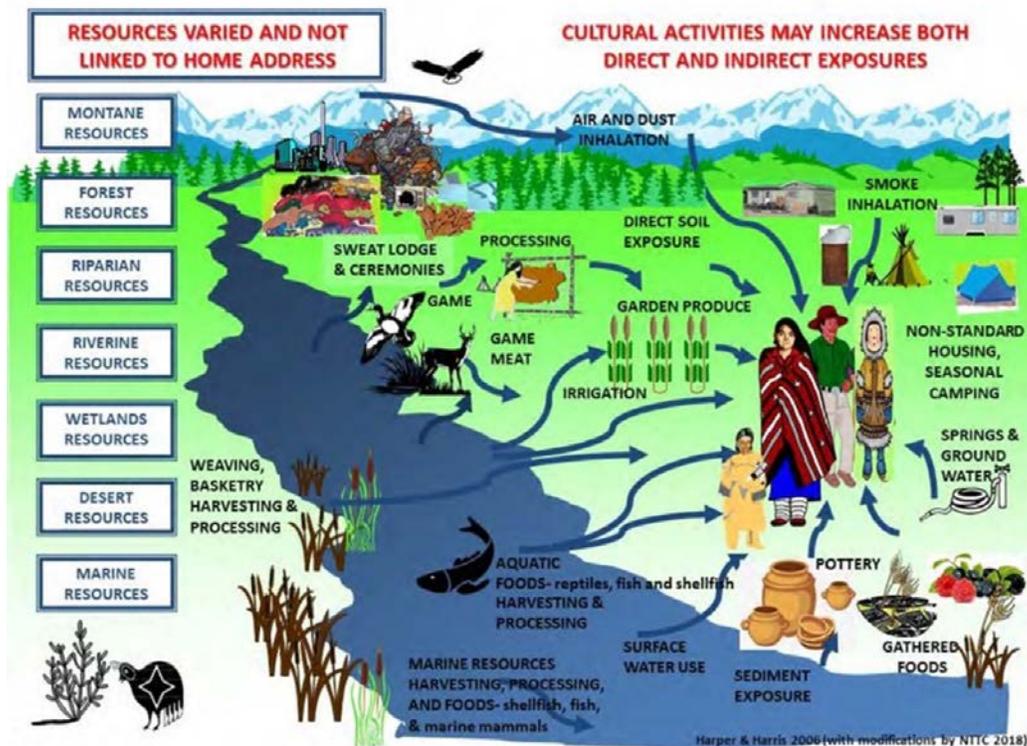
Consideration of aggregate exposures is also mandated by TSCA Section 6(b)(4)(F) but were not considered in the TSCA risk evaluations for the first 10 high priority chemicals. How EPA will meet these PESS and aggregate exposure statutory requirements could be directly related to the CRA methods as described in the Guidelines. For the same reasons, TSCA should be included in the section entitled **Major Policy Provisions/Directives** (page 12 – line 28).

The Guidelines suggest that characteristics of vulnerable populations be defined as part of CRA scoping (page 13, line 7). The Guidelines go on to reference the goal of the Agency to address age- and gender-specific issues in risk assessments and risk-management decisions per EPA's Policy on Evaluation Health Risks to Children². Additional considerations for defining vulnerable populations should be further described in this section such as the risks to overburdened fenceline communities from geographic proximity to conditions of use and environmental releases, the disparities seen in economically limited communities, and the exposure risks to subsistence populations. Even if information or methods for addressing nonchemical stressors is limited, strategies to include these populations should be considered during scoping.

Conceptual models that represent pathways connecting stressors for fate and transport in the environment are depicted in the Guidelines in Figure 3, page 24. This conceptual model in the draft Guidelines refers to a general population exposure and does not present a complete picture of cumulative risks from environmental exposures. The NTTC has previously expressed concern that tribal people are underrepresented or absent from consideration as a vulnerable population in risk assessments. Native Americans are at higher risk generally from chemical releases to the natural environment due to aggregate exposures via multiple pathways, many of which have greater frequency and duration than those of the general population or other human receptor populations. The practice of leaving them out of representative conceptual

² EPA [Policy on Evaluating Health Risks to Children; Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping](#).

models contributes to unawareness on the part of risk assessors. For convenience, we include a conceptual that depicts many of these exposures for tribal lifeways.



The NTTC appreciates the discussion of vulnerability in human populations that experience increased risks from environmental stressors through cultural practices such as subsistence fishing in the **Exposure-Response Modifiers** section of the Guidelines (page 30, line 44). The Guidelines also presents a framework from Segal et al. (2015)³ for evaluating the effect of nonchemical stressors that offers a method for considering vulnerability factors. EPA and other regulatory authorities have employed generous 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. This approach should be applied to risk assessments for Tribal and vulnerable populations, as until such time as it can be reduced with scientifically meritorious methodology or countervailing data.

³ Segal, D; Lin, Y-S; Ginsberg, G; Sonawane, B. (2015). A conceptual framework for evaluating the interaction of a chemical and nonchemical stressor in human health risk assessments: A case study for lead and psychosocial stress. *Human and Ecological Risk Assessment: An International Journal* 21: 1840-1868.

The Guidelines address uncertainty and variability at **Section 3.9 Uncertainties and Variability** (page 40). The NTTC recommends that EPA's risk assessments must also 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. 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. Whether these issues reflect uncertainty, variation in susceptibility or impacts of newly recognized factors in assessing consequences of exposure, the consequence is the underassessment of risk for the Tribal Community.

Conclusion

EPA should ensure that the intended and reasonably foreseen audience of risk assessors who reference the Guidelines understand that susceptibilities unique to tribes and other fenceline communities must be considered when characterizing the risks to health and the environment from multiple agents or stressors. Our Council is ready to support EPA in this effort. 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 or Susan Hanson, NTTC Co-Chair, at susanthanson9@icloud.com.

Sincerely,



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