



National Tribal Toxics Council

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May 5, 2021

Jeffrey Putt

Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

RE: Chemical Category for OctahydroTetramethyl-Naphthalenyl-Ethanone (OTNE);
Manufacturer-Request for Risk Evaluation Under TSCA;
Docket ID: EPA-HQ-OPPT-2020-0738

The National Tribal Toxics Council (NTTC) appreciates the opportunity to provide comments on the manufacturer request for a risk evaluation of the OTNE category of chemicals under the Toxic Substances Control Act (TSCA). NTTC is an EPA Tribal Partnership Group (TPG), supported by the 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.

On November 16th, 2020, EPA received a request for a risk evaluation under TSCA of the OTNE category of chemicals from three manufacturers through the OTNE Consortium. OTNE is a high production volume chemical that is widely used as a fragrance ingredient in personal care products. The ethanone family of chemicals is listed in EPA's 2014 Work Plan Chemicals update as widely used in consumer products and is estimated to have high releases to the environment with high to moderate bioaccumulation potential. These properties are particularly concerning to the NTTC and seem contrary to the information provided in the manufacturer's request.

The NTTC is also concerned that the manufacturer's request for risk evaluation of a high production volume chemical is only supported by three members of the OTNE

Consortium. It is unclear what percentage of the production volume of OTNE chemicals in the United States is represented by these three members of the Consortium. It is also unclear whether other OTNE Consortium members with fragrance compounding facilities and consumer product manufacturing facilities across the United States support the best management practices and engineering controls described in the request. The request states that "Storage of OTNE occurs at manufacturing and process sites, where it is stored indoors in structurally sound, non-leaking tanks and containers."¹ These standards were not met by a DRT America facility in 2018 when multiple residents living near the facility in Effingham, GA reported sickening odors from chemical vapor releases². Issues in 2018 appeared to be partially related to the DRT America facilities' unpermitted release of wastewater to a public POTW. NTTC is concerned that this manufacturer-request for risk evaluation is made by only three OTNE facilities and the health and safety requirements, including engineering control practices and waste treatment parameters used to support the request do not represent the current practices and standards of all OTNE facilities. The NTTC requests EPA confirm all OTNE facilities have proper health, safety, and engineering control standards, and are in compliance with all environmental regulatory requirements.

The purpose of risk evaluations under TSCA is for EPA to determine, without consideration of costs or other non-risk factors, whether a chemical substance presents an unreasonable risk of injury to human health and the environment under the conditions of use, *including an unreasonable risk to any relevant potentially exposed or susceptible subpopulations*. In the Agency's Request for Comments³ notice, EPA specifically invites public comments on the inclusion of any additional potentially exposed and susceptible subpopulations and additional conditions of use to what the manufacturer-request for risk evaluation of OTNE identified.

The Notice also states that:

"The Agency is in the process of broadly re-examining how it intends to implement these and other provisions of amended TSCA including determining how new executive orders and other direction provided by the Biden-Harris Administration will be addressed. This process would benefit greatly from stakeholder feedback... All TSCA risk evaluations, whether EPA-initiated or manufacturer-requested, will be conducted in the same manner."

NTTC has provided detailed comments to EPA on the risk evaluations that were completed for the first 10 high priority chemicals, outlining multiple chronic tribal exposures and how

¹ Request for Risk Evaluation under the Toxic Substances Control Act; Octahydro-Tetramethyl-Naphthalenyl-Ethanone Chemical Category; <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0738-0002>

² Lasting, M. (2018). DRT America still sniffing out odor problem, Effingham Herald. <https://www.effinghamherald.net/local/drt-america-still-sniffing-out-odor-problem/>

³ Chemical Category for OctahydroTetramethyl-Naphthalenyl-Ethanone (OTNE); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments; <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0738-0001>

they differ from those of the general population, as well as highlighting the fact that risks to tribal populations have not been evaluated in EPA's risk assessment process thus far. NTTC continues to raise the issue that tribes may be potentially exposed and susceptible subpopulations, because of their unique, multiple, and high-duration exposures to chemical releases in the environment, as well as a variety of higher susceptibilities presented by a vast array of environmental health disparities. As EPA OPPT's tribal partnership group, we appreciate the opportunity to provide this information to the EPA on behalf of tribes across the nation. NTTC is willing and able to assist EPA in obtaining or generating relevant data on tribal risks and exposures that EPA can use in order to accurately determine tribal risks in future risk evaluations under TSCA.

Tribes as a potentially exposed and susceptible subpopulation

The ultimate purpose of the new TSCA risk assessment process is to evaluate toxic chemical risks to Americans and then to use that information to make decisions that protect them from unreasonable risk. Because the intent and letter of TSCA is to protect all Americans, not simply those Americans that can be represented through general population exposures, TSCA requires that EPA identify PESS and protect such populations⁴. Without evaluating risks to PESS, it would be impossible to propose risk management actions that are protective of PESS, beyond a full chemical ban. NTTC's position is that risks to tribal populations from environmental releases of chemical substances need to be evaluated, even if resulting risk management decisions may present a challenge.

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."

Tribes meet this definition for the majority of chemical substances that are released into the environment but have not been considered as PESS in any TSCA risk evaluations thus far, leaving risks specific to tribes unevaluated and thus, leaving tribes out of any risk management actions. The decision of what population should be considered as PESS should be an unbiased decision and not the choice of chemical manufacturer associations. Guidance should be made available to chemical manufactures that describes what data the EPA will need to fully evaluate risks to PESS from chemical releases into the environment.

⁴15 USC §2604 [a][3][A]; 15 USC §2605 [b][1][B][i], [b][4][A], and [h][1][B]) [35–38]. EPA's g (15 USC §2604 [a][3][A]; 15 USC §2605 [b][1][B][i], [b][4][A], and [h][1][B]) [35–38]. See Koman PD, Singla V, Lam J, Woodruff TJ (2019) Population susceptibility: A vital consideration in chemical risk evaluation under the Lautenberg Toxic Substances Control Act. *PLoS Biol* 17(8): e3000372. <https://doi.org/10.1371/journal.pbio.3000372>

In all risk evaluations, EPA needs to identify all PESS and analyze their risks, as required by TSCA, and tribes should be explicitly considered as such. As NTTC has informed the EPA in previous comment letters and presentations to the Agency, tribes have unique lifeways that place them at different risk due to multiple exposure pathways not experienced by the general population. For example, these lifeways include differences in:

1. Diet, such as significantly higher consumption of fish and other aquatic life that is typically harvested locally;
2. Higher consumption of deer, elk, and other wildlife that is harvested locally and may be contaminated from industrial releases to tribal lands;
3. Housing, which is often substandard, with older household furniture and products, may lack garages (resulting in product storage inside the home), and can be associated with dirt yards and unpaved roads;
4. Worker safety protocols, which are often less stringently practiced and less stringently enforced due to multiple small businesses, self-employment, and do-it-yourself practices, and remote access locations not visited by OSHA;
5. Water use for:
 - Drinking, which can be from untreated and unregulated small systems (less than 15 homes), or private well water, surface haul water, and spring water systems;
 - Hygienic use, through daily steam baths and/or immersion in surface water flows that may contain high levels of contaminants;
 - Ceremonial use through steam baths and full body immersion in surface water flows that may contain contaminants that exceed human health risk levels;
 - Multiple cultural activities (e.g. reed harvest, mouthing, weaving);
 - Subsistence activities (e.g. hunting, gathering);
 - Recreational activities (e.g., swimming in natural waters that may contain toxic substances);
 - Other lifeways.

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. While each tribe has unique exposures due to its unique culture, it is possible to distinguish broad categories of tribal exposure scenarios that tribes are likely to face and that differ from those of the general population.

NTTC has expressed concern at the paucity of data on tribal risks, as well as the observation that tribal people are underrepresented or absent from EPA's risk evaluations and proposed actions. It is well documented in the scientific literature that Native Americans experience significant health disparities as compared to the general population. The practice of leaving them out of any protections will only contribute to further health disparities. NTTC has in the past provided detailed information to EPA on the types of exposures tribal people experience. In order to protect tribal communities, unique tribal exposures, including those resulting from

chemical release by products discarded at unlined transfer stations and construction waste landfills, at landfills without groundwater monitoring, liners, regular cover, and at landfills allowing open burning (as is the case in Alaska) must be considered by EPA in all risk assessments.

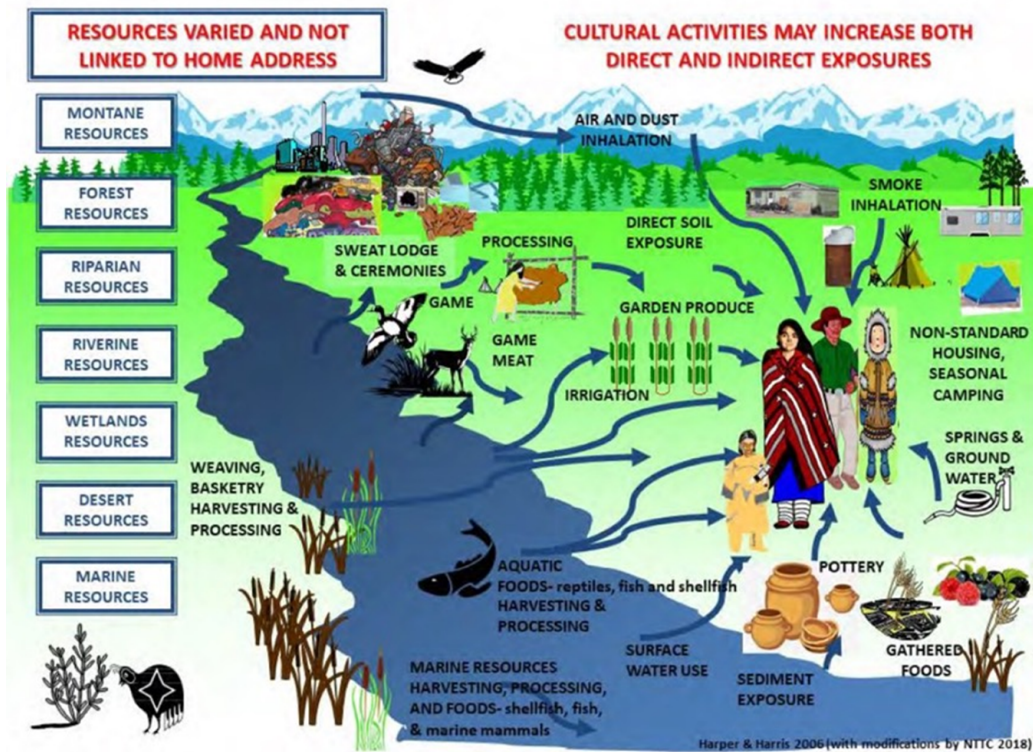
Risks from Aggregate and Cumulative Exposures

Special consideration of the multiple aggregate exposures inherent in tribal lifeways and circumstances needs to be included in all risk assessments in order to adequately represent Native Americans and thus determine the risks they face. Aggregate exposures are defined as “the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways”⁵ and consideration of aggregate exposures is mandated by TSCA Section 6(b)(4)(F).

Consumer and general population aggregate exposures were not considered in the TSCA risk evaluations for the first 10 high priority chemicals. In the case of the OTNE category, NTTC asks EPA to consider dermal, inhalation, and ingestion exposure pathways in aggregate over a lifetime of daily exposure in the case of tribal members. For example, if there is OTNE contamination of water that is used by a tribe, the exposure assessment and risk evaluation need to incorporate aggregate exposures via *daily* direct contact with the water and associated dermal absorption during bathing and also multiple subsistence, cultural, and recreational activities, *daily* ingestion via drinking and use in cooking, as well as via consumption of fish, marine mammal, and other aquatic species, plants and wildlife obtained locally, via dermal contact and inhalation during processing and preparing, via cultural activities like mouthing plants for weaving, and *daily* inhalation during steam bathing and boiling/cooking. Further, the prevalent practice of children participating in all of these activities must be considered. Another factor to consider is that tribal peoples tend to reside on the lands of their ancestors for their entire lifetime. The connection to these lands is paramount to tribal peoples’ well-being and what it means to be a tribal person and needs to be factored into EPA’s chronic exposures assessments.

For convenience, we include a graphic below that depicts many of these exposures. NTTC will welcome the opportunity to work closely with EPA OPPT and assist in providing education and available tribal data for the inclusion of tribes in EPA risk assessments.

⁵ 40 C.F.R. § 702.33



Reliance on Environmental Statutes to Address Tribal Chemical Exposures

It is NTTC's position that when evaluating risks of toxic chemicals to human and environmental health, EPA cannot assume environmental statutes are protective of tribal populations, as it has done for previous risk evaluations and scopes. What protections are provided by the regulatory overlay of the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Clean Air Act (CAA), and the Resource Conservation and Recovery Act (RCRA) should not preclude evaluation of the exposure pathways they cover from consideration under TSCA. NTTC notes that environmental statutes do not guarantee protection from exposures to toxic chemicals, particularly in the case of tribes, who are often disproportionately impacted by these statutes' exclusions, exemptions, and exceptions. NTTC has provided examples of such gaps in the environmental statutes in previous comment letters, and we urge EPA to consider these gaps before assuming that other laws protect the general population, and tribes in particular, from exposure to OTNE. It is not acceptable to assume blanket protections when these statutes wholly or partially exclude the protection of tribal people. NTTC strongly urges EPA to comply with their TSCA statutory obligation to consider all exposures, particularly for PESS, such as tribes. These statutes may reduce chemical releases into the environment for the general population, but with the wide range of exceptions affecting rural facilities and small service

populations, EPA cannot presume the same outcome for tribes, nor for rural and small communities generally.

Closing Remarks

As OPPT's tribal partnership group, the NTTC looks to chemical regulation under TSCA as the most effective means that EPA has to achieving its mission to protect human and environmental health. EPA should take advantage of the authority granted by the Frank R. Lautenberg Chemical Safety for the 21st Century Act and work to improve TSCA risk evaluations by fully applying them to those subpopulations with the highest potential for exposure and those that are most susceptible, thereby modernizing its approach to achieving chemical safety.

Not only would the continued exclusion of tribes from risk assessment be in violation of TSCA, it would be also in violation of EPA's commitment to integrating environmental justice into "the development, implementation, and enforcement of environmental laws, regulations, and policies"⁶. According to the EPA, "no group of people should bear a disproportionate share of the negative environmental consequences resulting from industrial, governmental, and commercial operations or policies"⁷. Executive Order 12898 directs federal agencies to identify and address "the disproportionately high and adverse human health or environmental effects of their actions on minority and low-income populations"⁸. Tribes are a minority and low-income population that experiences well-documented health disparities. If exposure scenarios representative of tribal lifeways are not included in EPA's TSCA risk assessment process, risks to tribal populations will continue to be unevaluated and tribes will continue to be left with a disproportionate share of the negative consequences and effects resulting from EPA's TSCA policies and actions.

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 or Susan Hanson, NTTC Co-Chair, at susanthanson9@icloud.com.

⁶ EPA Environmental Justice webpage: <https://www.epa.gov/environmentaljustice>

⁷ EPA EJ 2020 Glossary: <https://www.epa.gov/environmentaljustice/ej-2020-glossary>

⁸ Summary of Executive Order 12898—Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations. <https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice>

Sincerely,

A handwritten signature in black ink that reads "Dianne C. Barton". The signature is written in a cursive style with a large initial "D" and a long horizontal stroke at the end.

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