December 30, 2019

Stan Barone  
Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Washington, DC 20460-0001

Subject: RE: Methylene Chloride, Draft TSCA Risk Evaluation

Dear Dr. Barone,

The National Tribal Toxics Council (NTTC) appreciates the opportunity to provide comments on the Methylene Chloride Draft Risk Evaluation under TSCA. As an EPA Tribal Partnership Group (TPG), supported by the EPA Office of Pollution Prevention and Toxics (OPPT), NTTC works on issues related to chemical safety, toxic chemicals, and pollution prevention for Indigenous people of the U.S. Through this partnership, we assist OPPT with education and outreach to tribes and, in turn, educate and inform EPA on the effects of chemicals and pollution upon tribal people.

In October 2019, the EPA released a draft risk evaluation on methylene chloride. The purpose of risk evaluations under the Toxic Substances Control Act (TSCA) is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to any relevant potentially exposed or susceptible subpopulations. Methylene chloride is found in a wide variety of consumer and commercial products, mostly as a solvent in sealants, automotive products, and paint and coating removers. In a previous risk assessment under TSCA, EPA finalized an unreasonable risk determination for consumer paint and coating removers containing methylene chloride in 2014. A final rule banning the sales of methylene chloride in consumer paint and coating removal was issued in March 2019. While NTTC believes that was a step in the right direction, by not making an overall unreasonable risk determination in the draft risk evaluation of methylene chloride, EPA has left tribal populations, as well as workers and the general population, unprotected from this dangerous chemical that clearly poses unreasonable risks to human health and the environment.
Based on our initial review of the draft risk evaluation, NTTC is concerned that EPA has once again left out tribal populations’ exposures to a toxic chemical and the risks they face have not been evaluated. We will take this opportunity to make 6 major points in this comment letter:

1. Disposal is a condition of use
2. Tribes are a potentially exposed subpopulation
3. Exposures Covered by Other Environmental Statutes
   a. General Population Exposures
   b. Worker Exposures
4. Risks from Aggregate and Cumulative Exposures
5. Legacy Use
6. Systematic Review

**Disposal is a Condition of Use**

Recently, the Ninth Circuit Court of Appeals affirmed that “TSCA’s definition of ‘conditions of use’ clearly includes “spills, leaks, and other uncontrolled discharges” from landfills, Superfund sites, and other disposal sites. EPA’s Science Advisory Committee on Chemicals (SACC) similarly noted in its report on the 1,4-dioxane and HBCD risk evaluations that the EPA failed to consider releases associated with disposal. However, despite TSCA and that Court decision, the draft methylene chloride risk evaluation also does not evaluate the risks associated with disposal-related releases. In this draft risk evaluation, the EPA stated that “Studies clearly associated with releases from Superfund sites, improper disposal methods, and landfills were considered out of scope due to being regulated under other environmental statutes administered by EPA and excluded from data evaluation and extraction” (Page 81). The EPA also ignored available data on methylene chloride in leachate because it was deemed “an off-topic media” (Page 85).

In order to make an accurate risk characterization of tribal communities, EPA needs to consider releases of methylene chloride from landfills. As NTTC has described in detail in previous comment letters, the disposal circumstances on tribal lands are different from those of urban areas with municipal landfills. All products (commercial and consumer) containing methylene chloride will eventually be disposed in a landfill or other disposal site and, in the case of many tribal and rural communities, the disposal site may be in close proximity to residents, may be unlined, may be open access, and may include open burning as a management practice, all of which present multiple exposure pathways and routes for intake and uptake. Native Americans are more highly exposed to contaminants with environmental fate and transport than other populations, and in unique ways, because their lifeways revolve around environmental activities for dietary sustenance, socio-cultural activities, ceremonial and spiritual purposes, recreation, and general well-being. Tribal lifeways are not a choice and there is no alternative to them for the over 6.5 million Native Americans across the USA. Tribal lifeways can lead to chronic exposures to toxins in the environment, due to the much longer duration and higher frequency of exposures tribal people may experience, as well as the higher cumulative dose from multiple exposure pathways. As disposal is the main route contaminants enter the environment, it is unacceptable to exclude disposal, and the resulting exposures to toxic chemicals like methylene chloride, from consideration.
EPA is mandated by TSCA to determine whether the disposal of toxic chemicals presents unreasonable risk to human health and/or the environment. NTTC strongly urges that environmental release from waste management sites, including transfer sites, C&D sites, materials recovery facilities, and landfills be evaluated in the light of unlined facilities with resulting leachate subsurface flow, ponded water, direct surface water and snowmelt runoff, ambient emissions from uncovered disposal areas, and untreated waste burning emissions. A large portion of such sites have open public, as well as proximate general populations, unprotected workers, and occupational bystanders. NTTC has in previous comment letters informed EPA in detail about the unique characteristics of disposal sites on tribal lands and in tribal communities and we are able and willing to provide extensive photographic and narrative evidence that exposure through disposal is very likely for tribal people.

**Tribes as a potentially exposed subpopulation**

Tribes must be considered as a sensitive subpopulation under TSCA. 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 locally caught;
2. **Housing**, which tends to be more often substandard, with older household furniture and products, to lack garages (resulting in product storage inside the home), and be associated with dirt yards and unpaved roads;
3. **Worker safety protocols**, which tend to be less stringently practiced due to multiple small businesses, self-employment, and do-it-yourself practices, and remote access locations unvisited by OSHA;
4. **Water use for**:
   - Drinking, which can be from untreated and unregulated small systems (less than 15 homes), including well water and surface haul water
   - **Hygienic use**, through daily steam baths
   - **Ceremonial use** through steam baths
   - **Multiple artisanal activities** (e.g. reed harvest, mouthing, weaving);
   - **Subsistence activities** (e.g. hunting, gathering)
   - **Recreational activities** (swimming in natural water)
   - **Other lifeways**.

For convenience, we include a graphic that depicts many of these exposures.

EPA’s Science Advisory Committee on Chemicals, in its report on the HBCD and 1,4-dioxane draft risk evaluations, strongly agreed with NTTC that EPA must consider all exposure routes and give “special consideration to specific populations (e.g., tribal, arctic inhabitants, etc.) who depend on fish as a major source of food because of cultural considerations and provide some quantitative sense of how much extra risk exists for these populations. In considering special and susceptible population exposures, more consideration needs to be given to populations with specific preexisting conditions, such as metabolic disease and obesity, as well as to tribal,
ethnic and other subpopulations that depend heavily on potentially contaminated foods, such as Native American subsistence fishers”. The SACC also recommended that “the context of the assessment would be improved by including a graphic similar to the one presented by the National Tribal Toxics Council at the public meeting, that illustrates exposure routes for potentially sensitive or highly exposed populations” (reference to the conceptual model above).

TSCA states that “the term ‘potentially exposed or susceptible subpopulation’ means 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.” In its draft risk evaluation, EPA limited its analysis to only the first half of that definition. EPA discussed whether people might have higher susceptibility to methylene chloride, but, other than the consideration of worker and consumer exposures, EPA did not consider whether any subpopulations might face greater risk due to greater exposure. EPA must consider and analyze each of these types of subpopulations.

EPA also needs to analyze those potentially exposed or susceptible subpopulations that face greater exposure due to their proximity to conditions of use, particularly disposal. In the Problem Formulation for methylene chloride, EPA acknowledged that it should analyze these vulnerable populations by identifying “Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures
(e.g., individuals who live or work near manufacturing, processing, use or disposal sites)” as a “potentially exposed or susceptible subpopulation that EPA expects to consider in the risk evaluation due to their greater exposure” (Page 40). In the draft risk evaluation, however, EPA did not identify these populations as potentially exposed or susceptible subpopulations (pp. 385-87) and did not provide any analysis of whether those living in proximity to conditions of use like disposal are at a greater risk due to higher exposure. Many tribal communities live in close proximity to a disposal site or a transfer station. Three quarters of tribal communities in Alaska have residents living within 1 mile of unlined landfills that are open access and typically practice burning without emissions treatment as a volume reduction management technique. Drinking water sources and primary diet sources for these close-set communities are also typically proximate. The multiple exposure scenarios associated with proximity to unlined disposal site releases to environmental media must be analyzed for both individual exposures and the cumulative exposures tribal members face from their customary and traditional tribal lifeways (inhalation, dermal, ingestion). If these exposures are not analyzed, then no determination can be made on the risks these vulnerable populations face. As part of this analysis, EPA should identify all populations living near disposal and other waste management sites as potentially exposed or susceptible subpopulations. Groups living near National Priority List sites and proposed National Priority List sites should be included as well.

**Exposures Covered by Other Environmental Statutes**

**General Population Exposures**

In this draft risk evaluation, EPA has excluded all general population risks from exposures due to releases of methylene chloride to land, air, and water, based on the assumption that other statutes adequately address these exposures. EPA has made the assertion “that chemicals present in various media pathways (i.e., air, water, land) fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes and have been assessed and effectively managed under those programs.” (p. 428). Yet, no analyses or data have been presented to show that other statutes are protective.

One issue with relying on other environmental statutes is that TSCA tasks EPA with addressing human and environmental health risks, while other environmental statutes may have standards that are not health-based and are different from those under TSCA. TSCA section 6(b)(4)(A) states: “The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.” Many statutes require EPA to in fact consider factors such as cost and feasibility when setting their standards, factors that TSCA explicitly forbids EPA from taking into account when determining risks. EPA is the agency that is mandated to administer TSCA and relying on other statutes that are presumably protective completely ignores significant media releases and the resulting exposure scenarios, which is clearly not the intent of TSCA. The releases and exposures EPA is ignoring are far from
trivial. Based on the most recent data from EPA’s Toxics Release Inventory (TRI) and National Emissions Inventory (NEI), facilities release nearly 4,300,000 lbs/year of methylene chloride to air, water and land. EPA’s approach effectively reduces this quantity to zero.

Furthermore, NTTC would like to take this opportunity to point out that environmental statutes do not guarantee protection from exposures, particularly in the case of tribes, who may be disproportionately impacted. A non-exhaustive list of examples includes the 229 Tribes in Alaska that have landfills in compliance with RCRA, but that are unlined, use no cover material, allow open burning, with no monitoring or leachate collection. Under the Safe Drinking Water Act and the Clean Water Act, multiple tribes use individual groundwater well systems that are not regulated or monitored and have members on remote systems that are not POTWs due to the system size. Multiple tribes live in rural areas and use open barrels for burning. Burnboxes, which are open steel containers designed to accept an entire community wastestream, are employed in Alaska for waste disposal and allowed under a special rule of the Clean Air Act. Burning on the ground is also practiced as a locally authorized waste management practice for a substantial number of Alaska Tribes. Clearly, tribes experience exposures even where responsibility rests on other environmental statutes, and NTTC strongly urges EPA to comply with their statutory obligation to consider all exposures, particularly for susceptible and highly exposed populations, such as tribes.

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 from the general population and 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 chronic exposures tribal people experience. In order to protect tribal communities, the unique tribal lifeways and exposures, including those from disposal of products containing toxic chemicals in open dumps that are unlined and that practice open burning of wastes, have to be considered by EPA.

Worker Exposure
In this draft risk evaluation, EPA has significantly underestimated occupational exposures, both by assuming proper PPE use every time and by not considering cumulative exposures workers routinely face. EPA has assumed proper respirator use for estimating inhalation exposures and proper glove use for estimating dermal exposure, without providing data to support these assumptions. The draft risk evaluation states: “For workers, EPA estimated risks using several occupational exposure scenarios, which varied assumptions regarding the expected use of personal protective equipment (PPE) for respiratory and dermal exposures for workers directly handling methylene chloride.” (Page 30). The risk determination EPA makes is based on this assumption that workers will use effective PPE (both gloves and respirators) at most times when working with methylene chloride. No data or analysis is presented to support this and, in fact, EPA states that “No data were found about the overall prevalence of the use of respirators to reduce DCM exposures and it was not possible to estimate the numbers of workers who have reduced exposures due to the use of respirators.” (p. 690). On page 110, EPA also states
“Regarding glove use, data about the frequency of effective glove use – that is, the proper use of effective gloves – is very limited in industrial settings. Initial literature review suggests that there is unlikely to be sufficient data to justify a specific probability distribution for effective glove use for a chemical or industry.” OSHA itself has highlighted limitations with PPE use. For example, in 2016 OSHA informed EPA that respirators are the “least satisfactory approach to exposure control,” because in order for them “...to be effective, respirators must be individually selected, fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides.” Furthermore, 2018 was the 8th consecutive year violations of the respiratory protection standard were in the top 5 most common types of violations. Even when respirators and gloves are used, workers may still be exposed to methylene chloride. Organic solvents like methylene chloride may break through the medium in organic vapor cartridge respirators, and this can occur without providing any indication to the user that the respirator is no longer functioning. Gloves may also experience chemical breakthrough (p. 110) and provide limited protection from methylene chloride exposure. EPA’s reliance on PPE is a huge assumption, with no data supporting it, that has dramatically affected EPA’s risk characterizations for methylene chloride. NTTC sees this as a major flaw in this draft risk evaluation.

The SACC, in their report on 1,4-dioxane, expressed concern that, even if PPE use is assumed for larger, industrial facilities, smaller facilities are much less likely to require routine and effective use of PPE or to employ engineering controls, such as closed systems. Smaller businesses and facilities are the norm in Indian Country, including Alaska Native villages, and they are subject to OSHA exemptions to the Respiratory Protection Standard, as well as to reporting and inspection requirements. Self-employed workers are also exempt from many OSHA requirements and self-employment is common in tribal communities. For example, in rural Alaska non-hub communities, where the majority of Alaska’s federally recognized tribes live, OSHA will only provide assistance and compliance visits if three separate entities request them. Most of rural Alaska’s communities do not have three entities to which the workplace exposures discussed in the draft risk evaluation would be relevant. For accurate risk characterization of tribal members, NTTC would like to see a risk determination for workers and ONUs, both self-employed and in small businesses, that incorporates OSHA’s exemptions and practical exceptions. In these communities, take-home exposures are also very likely.

Another way EPA has underestimated the risk to workers in this draft risk evaluation is by not considering the combined risks from inhalation and dermal exposures, even though workers could easily experience exposures by both routes, over the same time period, and for multiple conditions of use. EPA states that it considered exposure “to methylene [chloride via] inhalation and dermal contact separately.” (p. 387) and that “EPA chose not to employ simple additivity of exposure pathways at this time within a condition of use because of the uncertainties present in the current exposure estimation procedures.” (p. 387). EPA does acknowledge in the draft risk evaluation that workers and consumers may experience both inhalation and dermal exposures and also acknowledges that its approach “may lead to an underestimate of exposure” but ultimately dismisses the concern by assuming that the dominant exposure
pathway is inhalation. NTTC finds this reasoning insufficient, especially given that EPA found significant risk from dermal exposure alone for many conditions of use (pp. 344-349). Additionally, not only did EPA not combine exposures via inhalation and dermal pathways, EPA also failed to combine any exposures from multiple conditions of use. EPA looked at each condition of use separately and never considered the possibility that the same individual might be exposed to methylene chloride through multiple conditions of use.

Furthermore, EPA has ignored all non-occupational baseline exposures workers experience by excluding all exposures via environmental releases to air, water, and land. NTTC believes that EPA cannot ignore the risks to individuals, even if EPA chooses to assume that other environmental statutes are protective and does not consider risks from environmental releases of methylene chloride.

To accurately assess overall exposure to methylene chloride, EPA should prepare an exposure assessment that examines aggregate exposure. Aggregate exposure is defined as “the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways” (40 C.F.R. § 702.33). Such an exposure assessment should combine exposures from the inhalation and dermal pathways, including the baseline exposures mentioned above, under all conditions of use.

**Risks from Aggregate and Cumulative Exposures**
NTTC notes that to fulfill the intent of Congress, EPA must evaluate the true risk of a chemical in commerce, and to consider aggregate and cumulative exposures, and not just for workers. Assessment of risk should mirror the real world so that the public is truly protected by agency risk management decisions. For example, in tribal communities, a substantial number of residents have multiple jobs and live near their community facilities, including disposal facilities. A single person may be a landfill worker, an occupational bystander, a near-facility general population, as well as a consumer. They will likely derive their food and water, including untreated water, near-source. Such scenarios are the norm for landfill workers in the over two hundred Alaska tribal communities. The resulting multiple exposures should be considered in aggregate, and in cumulative. In fact, 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.

**Legacy Use**
On November 15, 2019, the Ninth Circuit Court of Appeals released its decision in the challenge to the TSCA risk evaluation and prioritization rules that EPA can no longer exclude “legacy” chemical uses from a risk evaluation, nor can it exclude any conditions of use from consideration”. It also affirmed that “TSCA’s definition of ‘conditions of use’ clearly includes uses and future disposals of chemicals”.

Legacy use of products containing methylene chloride was not considered in this draft risk evaluation. In order to accurately address the risks methylene chloride may pose to human
health and the environment, the use and unsafe disposal of consumer products containing it need to be evaluated. Not considering legacy use, and the risks it poses, disproportionately affects tribes’ exposures, in this case due to the unique disposal circumstances on tribal lands and in tribal communities. NTTC strongly urges EPA to consider the impacts of legacy use of methylene chloride on tribal populations.

Systematic Review
NTTC notes that the criteria EPA has used for datasets are not conducive to the inclusion of reliable and valid tribal data. Tribes are experts for their own people, and when environmental sampling is involved, Tribes develop and follow approved Quality Assurance Plans that are typically approved by EPA, because EPA itself is a major funder of such efforts. NTTC urges EPA to include consideration of Tribal data that may be submitted by the Tribe that produced it. Where data is not available, modeling should be employed so that all significant Tribal exposures are captured. Contaminants end up in the environment where Tribes are highly exposed. Evaluation of these chemicals should then include tribal peoples’ multiple unique exposures.

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 Fred Corey, NTTC Co-Chair, at (207) 764-7765 / fcorey@micmac-nsn.gov.

Sincerely,

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