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EPN Comments on Draft Revised 1,4-Dioxane Risk Evaluation and Draft Unreasonable Risk Determination Chapter 6

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The Environmental Protection Network (EPN) harnesses the expertise of more than 600 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

Background

1,4-Dioxane was selected to be among the first ten chemicals mandated to be evaluated in the Toxic Substances Control Act (TSCA) Existing Chemicals Review Program. The agency published a risk evaluation for 1,4-dioxane in December 2020, in spite of continuing criticism that it had not adequately considered and incorporated exposures to the chemical in ambient sources (air, soil, and, particularly, water) in the risk assessments for both occupational and consumer conditions of use (COUs), impacting both workers, consumers, and the general population along with relevant subpopulations, such as fenceline communities. Some of these exposures are occurring as the consequence of more than one of the COUs.

Exclusion of incorporation of ambient exposures in air, water, and soil to a chemical under evaluation in an exposure assessment was standard practice in the early stages of the Existing Chemicals Review program, and often a point of contention included in the public comments (including EPN's) submitted for most of the first ten chemicals. Much welcomed policy changes on this issue were issued in June 2021, although they have not been fully applied retroactively in the evolution of the first ten chemicals. Before the December 2020 1,4-dioxane risk evaluation was issued, the agency did modify the general population risk assessment to include an assessment of exposure while swimming and pledged to include exposure in drinking water in a final revised risk evaluation. The document that is the subject of this current request for comment does include consideration of exposure in drinking water from both surface and groundwater sources, along with the air pathway.

However, the questions now become: "Did the agency use the best available science in appropriate ways to most accurately characterize exposure and risk from each pathway for 1,4-dioxane? Did EPA do this only separately for each pathway, as in the past, or also *in the aggregate* as would more accurately reflect real life?"

Expanded Scope of the 2023 draft revised risk evaluation

The draft revised risk evaluation includes assessment of occupational exposure to 1,4-dioxane present as a byproduct in commercial products (corresponding to consumer products considered in the 2020 risk evaluation), and to that produced or present as a byproduct in a few additional occupational COUs.

Assessment of additional general population exposure scenarios include: 1) 1,4-dioxane present in drinking water from surface water sources as a result of all direct and indirect industrial releases and down-the-drain (DTD) releases of consumer and commercial products, 2) 1,4-dioxane present in drinking water from

groundwater sources contaminated as a result of leaching following land disposal, and 3) 1,4-dioxane released to the air from industrial and commercial sources.

However, the 2023 supplement does not reevaluate/update the occupational, consumer, or ecological exposure pathways and risks that were previously assessed in the 2020 risk evaluation.

Also, the agency is not revising, updating, or asking for feedback on other components of the 2020 risk evaluation, such as the physical and chemical properties, life-cycle information, environmental fate and transport information, ecological hazard and risk characterization, or human health hazard characterization for 1,4-dioxane, including points of departure and dose-response analysis. However, the agency is asking for comments on a new draft Section/Chapter 6 entitled "Unreasonable Risk Determination," which can only be prepared once all other components of the risk evaluation are finalized.

EPN Comments

1. Environmental releases and occupational exposure assessment

EPA requested comments on their method for developing Monte Carlo simulations for the exposure and release estimates and for population exposures and risks, its reliance on "reasonably available information" for model input parameters, and any scientific considerations EPA should contemplate in using Monte Carlo methods in future TSCA risk evaluations.

EPN offers this general overview on the Monte Carlo assessment used. Monte Carlo simulations were conducted for each COU including fracking fluids, detergent uses, etc. These simulations were conducted using various distribution assumptions when data were available. In the absence of robust input data for distribution assumptions, the Monte Carlo simulations assumed a discrete value. The Monte Carlo simulations attempted to account for autocorrelations between input parameters using Pearson correlation coefficients between model input parameters. This modeling approach should limit the prediction of improbable situations in the Monte Carlo modeling.

As with any exposure assessment method, the Monte Carlo assessment is only as good as the available data going into it. The assessment provides an excellent vetting of the available data using a semi-quantitative analysis of data confidence assessment for model input parameters. The foundational aspects of the Monte Carlo simulations provide a comprehensive and defensible approach for predicting distributions of concentrations of 1,4-dioxane. Additional data would improve the robustness of the assessment.

2. Surface water exposure assessment

For the Surface Water Exposure Methods, EPA requested comments on using NHDPlus V2.1 flow database in estimating surface water concentrations, evaluating DTD releases to surface water, and probabilistic modeling of chemical releases using multiple years of release data and aggregation of chemical concentrations occurring in the proximity.

Rather than commenting on the individual points, EPN offers these general comments on the Surface Water Exposure Assessment.

The surface water modeling was conducted to estimate 1,4-dioxane concentrations in surface water at the point of discharge for various conditions of use. The surface water modeling was originally conducted using the EFAST 2014 tool for estimating flow (1:250,000) of waterbodies receiving point source discharges of 1,4-dioxane. The revised modeling used SHEDs-HT model to estimate DTD per capita loading of 1,4-dioxane. These loadings were linked to NHDPlus V2.1 (1:100,000) to provide a finer resolution for estimation of flow paths and hydrologic flow characteristics. The surface water modeling was conducted using two modeling approaches:

A. The individual releases of 1,4-dioxane were estimated using the EFAST model for one-, 30-, and 250-to-365-day releases into water bodies with the lowest monthly average flow from NHDPlus and the harmonic mean flow rate from EFAST.

B. Probabilistic modeling was applied to account for various COUs using SHEDs-HT model.

These modeling approaches were compared to existing ambient surface water monitoring data. The 1,4-dioxane concentrations from ambient surface water monitoring and UCMR3 monitoring of raw drinking water ranged from 1.10 to 470 ug/L (92% non-detects) and 0.035 to 13.3 ug/L (95% detects), respectively. There was good agreement of monitoring and model predicted concentrations of 1,4-dioxane in selected watersheds.

The 1,4-dioxane concentrations in surface-source drinking water ranged from 0.15 to 7 ug/L. In order to address uncertainties in the location of drinking water intake locations relative to National Elimination System permit location, a Geographic Information System analysis was conducted to assess the downstream distance of drinking water intakes to permit discharge locations. These data provide some prediction of potential dilution of 1,4-dioxane concentrations at the drinking water intake. Drinking water treatment effects on removal and transformation were not considered in the assessment. The surface water assessment, therefore, is based on untreated drinking water concentrations of 1,4-dioxane.

While the NHDPlus V2.1 annual and monthly average flow data are the best available national data for flowing water bodies, the annual and monthly average values, by their nature, involve smoothing of flow data. This additional uncertainty in concentration estimates should be noted. Uncertainty can also exist in locating the release facility and the Public Water System (PWS) intake location to the actual NHDPlus reach. In areas where known release points can occur upstream from PWS intakes, additional spatial analysis may be necessary to better ensure that such points are properly located.

The surface water exposure assessment provided good agreement between model prediction and monitoring data. One uncertainty of the surface water assessment is the lack of a watershed-based analysis regarding co-location of various conditions of use among watersheds. Another concern is that the SHEDs-HT model is still a beta version on the EPA website.

3. Groundwater Exposure Assessment

For the Groundwater Exposure Assessment, EPA requested comments on the strengths, uncertainties, and assumptions of their modeling estimates and methods for estimating national-scale drinking water exposure estimates.

The ground water assessment was conducted assuming that 1,4-dioxane could reach groundwater from landfill leaching and releases from hydraulic fracturing either through produced water or gas well failures. The concentrations of 1,4-dioxane were predicted using waste volume loading rate and potential leachate concentrations within a 1-mile radius of a solid waste landfill. This modeling was conducted using the Digital Regulator Assurance System (DRAS) 4 model using an underlying Monte Carlo analysis. An analysis of the monitoring data shows the highest detected groundwater concentration of 1,4-dioxane was 31,000 ug/L from a waste oil refinery site in Indiana in 1997. More recent monitoring data (2003-2022) show the bulk of 1,4-dioxane concentrations in groundwater are equal or less than 10 ug/L. DRAS modeling of landfill applications predicts 1,4-dioxane concentrations exceed 10 ug/L in ground water within a mile radius when 1,4-dioxane loading rates exceed 455 kg. Average concentrations of 1,4-dioxane in landfill leachate ranged from 11.8 ug/L for municipal landfills and 44.6 ug/L for hazardous waste landfills. Monte Carlo modeling of 1,4-dioxane releases of hydraulic fracturing-produced water in a landfill would yield maximum groundwater concentrations of 1.89E-5 ug/L. This analysis shows good agreement between model predictions and monitoring data.

4. Aggregate Exposure and Risk Assessment

EPA qualitatively characterized aggregate exposure and risk across routes and across pathways. While EPA recognizes the importance of identifying and characterizing these aggregate exposures, these were not quantified due to substantial uncertainties associated with aggregating 1,4-dioxane exposures and risks across routes.

In all of the risk evaluations for the first ten chemicals undergoing review, including 1,4-dioxane, EPA defined aggregate exposure as "the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR Section 702.33)."

In the final 2020 1,4-dioxane risk evaluation, as in the risk evaluations for the other nine chemicals, the agency developed risk characterizations and made unreasonable risk determinations for COUs based upon exposures by the inhalation and dermal routes *separately*, even while acknowledging that the inhalation and dermal exposures were occurring *simultaneously* for both workers and consumers. For 1,4-dioxane, dermal and oral exposures were also noted to be occurring *simultaneously* for the general population when swimming. In all cases, EPA chose not to employ (simple) additivity of exposure via multiple pathways within a COU (or swimming), claiming they could not do it due to various uncertainties in the exposure estimation process.

EPN expressed disagreement with this decision not to proceed with aggregation of exposures in our December 2020 comments on the 2020 risk evaluation. To say the least, EPN is even more disappointed with the current draft supplemental risk evaluation since it, too, fails to aggregate exposures and risks. This trivializes the value of having taken the proper step of conducting assessments and providing risk characterizations for instances in which exposures in ambient air and drinking water are occurring from multiple sources. Furthermore, it exacerbates the underestimation of risk that was pointed out even before the assessments in ambient media were conducted.

Steps that should be taken to more accurately estimate risk for all the relevant 1,4-dioxane exposure scenarios are:

A. Unreasonable Risk determinations should be based upon aggregate combination of exposures, that is:
    a. Aggregation of all multiple pathway exposures for each original (2020) and newly-added (2023) occupational/ONU and consumer/bystander COU scenario.

    b. Aggregation of all exposures occurring when swimming and in ambient air and drinking water for those scenarios resulting in these exposures. All individuals covered in the occupational and consumer use COUs are also members of the general population, and their total exposures/risks should be characterized with that in mind. This has become more important now that the agency has committed to assessing risks to frontline communities. It is not unusual for workers in a particular COU setting to also be further exposed because they live in adjacent frontline communities.

B. As EPN has recommended in earlier comments on the first ten chemicals, the Office of Pollution Prevention and Toxics (OPPT) should consult with other program offices in the agency to learn and apply relevant aspects of aggregate exposure and risk assessment tools and practices that these other programs use regularly in carrying out their assessments. As a reminder, the Office of Pesticides Program is legally mandated to incorporate aggregate exposures in their risk assessments when approving food residue limits and non-food uses for the general population and occupational exposure protocols for mixers, loaders, handlers, and harvesters.

C. As an aside, perhaps TSCA should be amended to mandate characterization and management of risks in the aggregate in recognition of real-life exposure to the chemicals selected for evaluation in the Existing Chemicals Review program, since EPA appears to be reluctant to take this step voluntarily.

D. And, separately, the Office of Water should prioritize the development of a drinking water standard (maximum contaminant level, MCL) for 1,4-dioxane. The existing non-regulatory health advisory is over 35 years old and in need of re-evaluation and upgrading to an MCL. The current efforts by OPPT to assess its presence in U.S. drinking water in the context of its evaluation in the Existing Chemicals Review program should be capitalized upon—in other words, strike while the iron is hot.

Section 5.2.2.5 Aggregate and Sentinel Exposures of the Supplement describes what EPA has not done with respect to aggregate exposure for 1,4-dioxane. As stated on page 164, "EPA considered aggregating cancer risks across inhalation, oral, and/or dermal routes of exposure. There is uncertainty around the extent to which cancer risks across routes are additive for 1,4-dioxane." And "It is therefore unclear the extent to which it is appropriate to quantitatively aggregate cancer risks based on the IUR with liver tumor risks associated with oral or dermal exposures. EPA considers the potential aggregate cancer risk across routes to be a source of uncertainty for 1,4-dioxane cancer risk estimates."

EPA also stated on page 164 that it "also considered aggregating cancer risks across dermal and oral exposures. The dermal cancer slope factor is derived from the oral cancer slope factor by route-to-route extrapolation. Because the systemic effect is assumed to be the same for both routes, EPA determined that it could be biologically appropriate to aggregate risk from dermal and oral exposures. General population scenarios included inhalation and oral but not dermal exposures and occupational and consumer exposure scenarios included inhalation and dermal but not oral exposures. However, this draft

supplement does not include COUs or pathways in which both oral and dermal exposure routes are considered."

And thirdly, EPA stated that it "also considered potential for aggregate exposures across groups. For example, there may be some individuals who are exposed at work as well as through general population air and drinking water pathways or through consumer product use. This is a source of uncertainty. These types of aggregate risks were not quantified and risks for individual exposure scenarios should be interpreted with an appreciation for potential aggregate exposures and risks."

So what might the consequences of failure to incorporate aggregate exposure and risk into the decision-making process be? A negative Unreasonable Risk determination made separately for each pathway may flip to Unreasonable Risk when judging based upon aggregate exposure. This changes the dynamics of risk management decision-making as to whether a COU should be prohibited altogether, retained with a set of mitigation measures imposed, or left untouched.

A risk management proposal to prohibit a COU or modify its retention with imposition of mitigation measures will likely prompt the regulated party(ies) to develop information that will resolve the uncertainties currently claimed by EPA to be inhibiting their ability to use a fully aggregate approach. Quantification of the risk is a particularly important factor in this process. Mitigation measures may be available to reduce the risk to a degree that is at or below the level of concern if judged based upon exposure routes/pathways separately but not if judged in the aggregate. Continued failure to aggregate exposures and risks will mean that people will remain exposed to unacceptable risks.