May 23, 2016

Steven M. Knott, M.S.
Senior Designated Federal Official
FIFRA Scientific Advisory Panel and
Chemical Safety Advisory Committee
U.S. EPA Office of Science Coordination and Policy

Re: *Comments on TSCA Work Plan Chemical Risk Assessment for 1-Bromopropane, Docket ID: EPA-HQ-OPPT-2015-0084*

Dear Mr. Knott:

We are writing to provide comments on the U.S. Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA) Work Plan Chemical risk assessment document for 1-Bromopropane (1-BP), which is currently under peer reviewed by the Chemical Safety Advisory Committee.

We welcome EPA's important efforts to characterize the risks posed by 1-BP. With large quantities of production and import to the US (estimated at over 15 million pounds in 2011) and its high potential for occupational and consumer exposure from to its extensive use in spray adhesives, dry cleaning, degreasing, and other cleaning products, an accurate and comprehensive assessment of the potential risks is extremely important and of great interest to various stakeholders and the public.

We are writing to comment on several aspects of the methods for the risk assessment for 1-BP. Please note that many of our comments apply to the approach that EPA has taken in general to assess risks under the TSCA program.

We recommend that EPA develop estimated risk numbers for the non-cancer health effects.
In its *Science and Decisions* report, the National Academy of Sciences (NAS) recommends that EPA develop risk estimates for non-cancer values, so that decision makers can understand the potential risks posted by various exposure scenarios [1].
Margin of Exposures (MOEs) are hazard values (e.g., LOAELs, NOAELs or BMDLs) divided by exposure values, such as those in the 1-BP risk assessment. The MOEs are compared to the combination of the uncertainty factors, very similar to what is done with an RfD or RfC, both of which the NAS recommended moving away from. The MOE is not an actual estimate of risk, as it essentially does not provide any information about the potential risk at various exposure estimates. Rather, it is another version of the "bright line" approach similar to the RfD. For example, EPA could not conduct a benefits analysis using the MOE because there is no accompanying dose-response information. We strongly advice against representing the MOE as an estimate of risk, and encourage EPA to utilize available analytical methods to develop quantified estimates of risk that can be of use to risk managers and decision-makers.

EPA needs to consider the potential for co-exposures to other solvents that can affect the adverse outcome pathway. This has also been recommended by the NAS in two reports (*Science and Decisions* and *Phthalates and Cumulative Risk Assessment*) [1, 2]. Further, if the agency does not have specific data, the NAS recommends, at a minimum, of using a scientifically-based default value to account for the missing data in order to adequately account for population

exposures and risks. Ignoring the potential for co-exposures essentially assigns these scenarios to having zero risk, while it is known that this is not the case. Defaults can be used to represent these scenarios until adequate data are generated to calculate the potential risk.

The risk assessment should consider other population exposure scenarios, including the general population (as exposure data have been reported via biomonitoring [3-5]) and residents who live in facilities where 1-BP will be used, in particular dry cleaning facilities. This has been done previously by regulatory agencies for other industrial chemicals such as perchloroethylene, and these assessments have identified important risks to these populations. Further, a more systematic evaluation of the exposure information is warranted given the importance of the exposure assessment to the final risk numbers. This recommendation is aligned with our next point, in that this proposed assessment is lacking the incorporation of systematic review methodology.

EPA needs to adopt and consistently apply systematic review methods in their hazard and risk assessments.

We recognize generally that EPA has made attempts to respond to the recommendations in the National Research Council (NRC) 2014 report *Review of EPA's Integrated Risk Information System Process* related to planning and scoping in the risk assessment process and believe that uptake by EPA of these recommendations would undoubtedly strengthen EPA's critical efforts to protect human health from harmful environmental exposures. We also support implementation of the other aspects of the NRC report, including developing a protocol for the review, identifying evidence, evaluating studies, and integrating the evidence, and by making systematic and transparent conclusions about the strength of the scientific evidence related to the health hazards of exposure to environmental chemicals. We encourage EPA to prioritize and adequately support its efforts to advance its strength of evidence methodology to align with the improved approaches recommended by the NRC. We strongly recommend that EPA align its approach with the "Navigation Guide" approach developed by UCSF in collaboration with 22 clinical and environmental health scientists and the methodology developed by the National Toxicology Program's Office of Health Assessment and Translation (OHAT) for systematically and transparently reaching strength of evidence conclusions in environmental health.

In its current proposed state, this risk assessment does not incorporate these recommended approaches, and as such, this can potentially compromise the underlying confidence and quality of the risk assessment.

We appreciate the effort that is made to conduct risk assessments for a complex industrial chemical with high production volume and use such as 1-BP. We also appreciate the potential for impacting the health of those exposed (particularly vulnerable populations and those living in close proximity to these facilities), and as such it is important that EPA apply the most up to date scientific approaches, as outlined by the NAS, in their methodology for this particular assessment and other TSCA chemicals.

Thank you very much for your consideration. We would be happy to provide further details or clarification if necessary.

Sincerely,

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References:

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3. Boyle, E.B., et al., *Assessment of Exposure to VOCs among Pregnant Women in the National Children's Study.* Int J Environ Res Public Health, 2016. **13**(4).
4. Jain, R.B., *Distributions of selected urinary metabolites of volatile organic compounds by age, gender, race/ethnicity, and smoking status in a representative sample of U.S. adults.* Environ Toxicol Pharmacol, 2015. **40**(2): p. 471-9.
5. Jain, R.B., *Levels of selected urinary metabolites of volatile organic compounds among children aged 6-11 years.* Environ Res, 2015. **142**: p. 461-70.