September 23, 2024

Submitted via regulations.gov

Ms. Bethany Masten
Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460–0001

Re: U.S. Environmental Protection Agency Proposed Rule: 1-Bromopropane (1–BP); Regulation Under the Toxic Substances Control Act (TSCA); EPA-HQ-OPPT-2020-0471

Dear Ms. Masten:

Dow appreciates the opportunity to provide comments on EPA's proposed risk management rule for 1-BP. Although Dow does not manufacture nor use 1-BP, we welcome the opportunity to provide data that will help inform EPA's prioritization, risk evaluation, and risk management.

Laboratory Capabilities and Cost Estimates

EPA has requested information on the availability of laboratory capacity needed to meet the proposed standard, and the costs associated with such testing. The following information is provided to help meet this request from EPA.

First, to determine if a lab can meet the method sensitivity needs for a lowered exposure limit, a company needs to determine the limit of quantitation (LOQ or reporting limit) that the lab must meet. Standard industry practice for industrial hygiene (IH) sampling methods is to meet 10% of the exposure limit, not the exposure limit. For 1-BP, the Existing Chemical Exposure Limit (ECEL) is 0.05 ppm (0.25 mg/m3), and 10% of the ECEL would be 0.005 ppm (0.025 mg/m3). Following National Institute for Occupational Safety and Health (NIOSH) 1025, this would be a detection limit of 0.3 ug/sample for an 8-hour sample duration (Note, NIOSH 1025 has a maximum 12 L sample volume used in the calculation below). Each lab used would have to be able to quantify 1-BP at 0.3 ug to meet 10% of the ECEL.

Calculating LOQ:

(ECEL)(10%) = [(Needed ug LOQ)(24.45)]/[Maximum Sample Volume in L)(Molecular Weight as g/mol)]
(0.05 ppm ECEL)(0.1)=[(Needed ug LOQ)(24.45)]/[(12 L)(122.99 g/mol)]
Needed ug LOQ= [(12 L)(122.99 g/mol) (0.05 ppm ECEL)(0.1)]/(24.45)
Needed ug LOQ= 0.3 ug

Two labs commonly used for IH sample analysis were contacted regarding their ability to meet the 1-BP ECEL and the 0.3 ug reporting limit (10% of the ECEL). None of the labs could currently meet this low limit. Current analysis uses a Gas Chromatograph paired with a Flame Ionization Detector (GC/FID). One of the labs indicated it may be able to meet the lower limit by conducting a method extension study. The estimated cost for the method extension was $500. This does not include costs for actual sample analysis. However, a simple method extension using existing GC/FID technology is unlikely to work. To detect the low level of 0.3 ug, a more sensitive Mass Spectrometer (MS) detector or Electron Capture detector (ECD) would likely be needed. Estimates for a method extension using GC/MS or GC/ECD technology ranged from $2,500 to $5,000. This does not include cost for actual sample analysis.

It is important to note that each lab that will analyze IH samples needs to conduct its own study to determine if it can meet the lower detection limit. That means the method extension cost of 1-BP for each lab could range from $2,500 to $5,000. Each company would have to pay this cost for the lab it uses. For example, if 10 different IH labs were to analyze 1-BP samples, the total cost would be about $25,000 to $50,000. We are sharing this information because we believe it is important for EPA to understand that when an exposure limit is lowered, companies need to be able to detect 10% of the limit, and each lab used for analysis must modify its methods to detect at the new lower limit. It is an individual cost that each company must pay.

It is also important to note that not all labs will be able to meet the new lower exposure limit. To determine lab capacity and capability, a company needs to contact each lab used for sample analysis to understand if it has the ability to meet the lower limit. It would benefit industry's data collection efforts if EPA could contact some commonly used IH labs during the ECEL setting process to understand if the proposed ECEL limit is technically feasible and get a cost estimate on this change impact. To do this, EPA should consider working with the Wisconsin Occupational Health Lab (WOHL) Lab that analyzes IH samples collected for OSHA's voluntary consultation program.

Setting of a De Minimis Level

Dow urges EPA to set a de minimis level for 1-BP to allow for low level impurities that do not contribute to unreasonable risk. Setting a de minimis not only helps EPA focus its risk management process on the uses and levels that pose risk, but it also helps industry. When there is a de minimis level, industry is able to test whether a product or entity would be regulated, and it targets resources in the areas where they are most needed. It is important to note that without a de minimis, analytical testing and quantification are impractical, as one cannot measure to zero with any analytical technique.

In general, more clarity on how EPA sets de minimis levels is needed so this approach can be leveraged to other chemicals. This would be very valuable to both EPA and industry because it would help focus resources as EPA moves forward in its evaluation of prioritized chemicals. Dow would appreciate the opportunity to work with EPA to develop a framework for setting a de minimis for risk management chemicals.

Thank you again for the opportunity to provide these comments. If you have any questions or would like to discuss further, please contact me by phone at 989.496.8393 or by email at m.lafore@dow.com.

Sincerely,

Mike LaFore
Americas Product Regulatory Services Senior Leader