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EPN Comments for the Public Meeting of the Science Advisory Committee on Chemicals Regarding Draft 1-Bromopropane Risk Evaluations Under the TSCA

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The Environmental Protection Network (EPN) is an organization comprised of over 450 EPA alumni volunteering their time to protect the integrity of the U.S. Environmental Protection Agency (EPA), human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current Administration efforts to undermine public health and environmental protections.

EPN is submitting these general comments to the Science Advisory Committee on Chemicals (SACC) to aid in their review of the 1-Bromopropane (1-BP) draft risk evaluation during their scheduled September 10-12, 2019, meeting.

1-BP is a solvent used in degreasing, dry cleaning, spray adhesives, and aerosol solvents that has been linked to neurological illnesses and may cause cancer and reproductive disorders.

On August 12, 2019, EPA published a Federal Register notice announcing the availability of documents and dates for the peer review of the draft risk evaluation for 1-Bromopropane (1-BP). While the official comment period on this draft risk evaluation is open until October 11, 2019, any commenters who wish for their comments to be considered by the SACC during their public meeting must submit their comments by August 30, 2019. While comments submitted after the August 30, 2019, deadline will still be provided to the SACC, they will not be able to contribute to any public dialog. EPN may prepare more detailed comments on this draft risk evaluation by the October 11, 2019, deadline; we are concerned, however, that the SACC will have concluded their review before the public comment period closes.

Once again, the agency is implementing a schedule for review that is inconsistent with best management practices. As EPN stated in its July 19, 2019, and August 30, 2019, comments on the 1,4-Dioxane and HBCD draft risk evaluations, we continue to be concerned that this process deprives the SACC of scientific and policy input that would be valuable in informing its review of the two draft evaluations and, thus, greatly reduce the value of the public comment process. This reoccurance reinforces the view articulated by commenters that the current agency approach seems to value an arbitrary deadline for a decision over the integrity of the information going into the decision. Furthermore, the process appears to be a mechanism to discourage comments from the stakeholder community that wishes to see a standardized risk evaluation process followed.

EPN is focusing these initial comments on the most critical policy issues that affect not only 1-BP but all future chemical risk evaluations under the Toxic Substances Control Act (TSCA).

1. As it has before, the agency is not using the best available tools by continuing to use the non-peer reviewed, flawed draft guidance document entitled "Application of Systematic Review in TSCA Risk Evaluations" to identify, sort, select, and exclude studies and other information to be used in the risk evaluation and, then, to grade their quality and acceptability for inclusion in the assessment.

As stated initially in comments submitted on August 16, 2018, and on several occasions since, EPN and other scientific groups presented detailed criticisms of that draft systematic review process. Our comments documented EPA's failure to follow necessary internal and external peer-review procedures in developing this process, described serious flaws permeating the entire TSCA systematic review process, and noted critical flaws in evaluating individual studies for use in toxicity assessments (such as failure to assess for bias). This draft guidance remains inconsistent with best practices in systematic review and should not be used for any purpose until peer reviewed and revised in accordance with the feedback received.

2. As with all chemicals selected for review in the Existing Chemicals Risk Evaluation program, EPN is concerned about the adequacy of the toxicity database used to assess potential for human health hazard. We have previously articulated our views on what constitutes a minimum database with which to estimate a high-confidence POD/reference value/MOE based upon animal studies.

   The draft risk evaluation includes the assessment of risk to workers and occupational non-users (ONUs) from acute and chronic inhalation and dermal exposures. EPA also evaluated the risk to consumer populations from inhalation and dermal acute and chronic exposures. Lifestages from infants to adults were included in the draft evaluation, by comparing the estimated exposures to acute and chronic human health hazards. However, pregnant women and workers considering a family were not specifically analyzed.

   What, then, would constitute a database adequate for assessing hazard to these (sub)populations? Our answer is that, absent fulsome observations in humans, the following types of information are needed:
   a. Studies that would illuminate the potential for general systemic toxicity over an exposure duration commensurate with that of the actual exposure scenario or that could be extrapolated from shorter-term exposure studies accompanied by the application of an uncertainty factor representing that extrapolation (e.g., acute short-term or subchronic to chronic);
   b. For chronic exposures, studies that would adequately test for carcinogenic potential by the relevant route(s) of exposure or could be extrapolated to those routes of exposure;
   c. For acute and chronic exposures, at least one developmental toxicity study;
   d. For shorter-term and chronic exposures, a one- or two-generation reproductive toxicity study, and;
   e. If nervous system effects are observed in exposed humans or animals, a more systematic evaluation of neurotoxicity and developmental neurotoxicity, since the worker population includes women of child-bearing age and the general population includes infants and young children.

3. EPN continues to be concerned about the agency's approach for determining unreasonable risk to workers. It underestimates that risk by assuming workers will use personal protective equipment (PPE) for the entire duration of the work activity throughout their careers, even when such equipment is not required, provided or used. EPA continues to discount the risks to workers by assuming constant use of respirators. (See the testimony of Adam Finkel, former Regional Adminstratorand Director and Director of Health Standards at OSHA)We would argue that while EPA may assess and characterize worker risk with and without the use of PPE, it should make its

unreasonable risk determination based upon the "no PPE" scenarios. This would re-focus attention on many occupational use scenarios following non-cancer acute inhalation exposures to workers and ONUs that often included a "with PPE" component. Most consumer use scenarios constituted an unacceptable acute inhalation risk. PPE was not considered an option in these situations. There also are a substantial number of occupational use scenarios in which the non-cancer chronic inhalation risks were unacceptable for the unprotected worker and ONU at high end exposure levels, with worker risk unacceptable at central tendency levels. Sometimes the worker risk remained unacceptable even with PPE.

Most cancer risk estimates following chronic inhalation exposure without PPE (both central tendency and high end) in occupational scenarios were unacceptable while some scenarios assuming PPE resulted in acceptable risk. Lacking the guarantee of consistent use of respirators, EPA should focus its regulatory options on mitigating risk to the unprotected individual.