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SUMMARY

EPN Additional Comments on Draft Risk Evaluation for Toxic Chemicals 1,4-Dioxane and HBCD

On August 30, 2019, EPN submitted **comments** in response to EPA's **request** for public input on draft risk evaluations for two toxic chemicals—Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane—under the Toxic Substances Control Act (TSCA). TSCA was passed in 1976 to keep dangerous chemicals off the market and protect people from exposure to existing chemicals. It was amended and strengthened in 2016. The reformed act requires EPA to ensure the safety of existing chemicals by setting priorities for which chemicals to assess, evaluating their risks and imposing restrictions to eliminate unreasonable risks. EPN reviews of both draft risk assessments found serious flaws in the overall review process and weaknesses in the quality and quantity of the data EPA is using to determine unreasonable risks.

HBCD and 1,4-Dioxane are the 2nd and 3rd of ten chemicals undergoing EPA risk evaluations. HBCD is a flame retardant used mainly in construction, including insulated panels. 1,4-Dioxane is an industrial solvent also found in sealants and adhesives. HBCD has not been adequately tested for its carcinogenic potential; it has shown the potential to affect human reproduction and development. 1,4-Dioxane is potentially carcinogenic; increases in tumors of the liver, kidneys and other tissues have been observed in multiple animal long-term toxicity studies.

In its initial comments, EPN raised objections to EPA scheduling a meeting of the Science Advisory Committee on Chemicals to review the risk evaluations nearly a month before the close of the public comment period. The accelerated timeline prompted EPN to testify at the meeting and submit these additional comments. EPN strongly noted that either the arbitrary deadline for a decision was more important than the integrity of the information going into the decision or this was a mechanism to discourage comments from the stakeholder community, or both.

EPN's additional review of the draft risk evaluations found that:

- **The databases on human health toxicity for 1,4-Dioxane and HBCD and other factors needed to make risk findings are inadequate.** Across all four of the first ten draft TSCA risk evaluations, information quality and quantity is proving not to be a critical component of the agency's decision-making process in determining Benchmark Margins of Exposure used to characterize chemical risks.
- **Long-standing agency-wide consensus guidance should have been used to consider the adequacy of the toxicity database when deriving Benchmark Margins of Exposure in determining risks.** EPN also made this point in its second round of comments on Pigment Violet 29.
- **EPA does not take advantage of "new" TSCA provisions when there is insufficient data to determine unreasonable risk to people or the environment.** Before a risk determination is attempted, EPA should pursue the option of issuing orders or regulations or enter into consent agreements with manufacturers or processors to develop additional data about health, environmental effects and exposure.
- **For 1,4-Dioxane, consumer uses and general population exposures were not included in the draft risk evaluation.** The agency focused its assessment only on the acute, short-term and chronic skin and inhalation exposure of workers in a variety of manufacturing, use and disposal settings.
- **For HBCD, studies are needed to accurately assess the hazards for various groups not considered in the evaluation.** Further studies are needed to evaluate risks related to acute and chronic exposure for adult and female workers of reproductive age, general "background" exposure for all groups from infants to adults, and the same populations exposed by emissions from a nearby facility.

Risk evaluations and related decisions on findings of unreasonable risk are likely to occur once in a lifetime given the many thousands of chemicals to prioritize and assess (or not). Unlike the regulation of pesticides, there is no requirement for EPA to revisit these assessments and decisions. Therefore, EPA has an obligation to get it right the first time; essentially, it's the only time. EPA should consider the recommendations in our comments to be key elements of those obligations.

EPN objects to the process followed and basis on which EPA conducted the risk evaluations for HBCD and 1,4-Dioxane, as it did with the previous risk evaluation for Pigment Violet 29. EPA needs to base its decisions on adequate data and expand its considerations of the populations at risk. EPN urges EPA to discontinue the use of the flawed TSCA systematic review to prevent endangering public health and the environment.