Environmental and Human Health Hazard Summary Peer Review Charge Questions

Section 6(h) of the Toxic Substance Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, directs EPA to take expedited action to propose rules under TSCA with respect to chemicals identified in EPA's 2014 Update of the TSCA Work Plan for Chemical Assessments and meeting criteria relating to persistence, bioaccumulation and toxicity (PBT) and other factors. EPA must issue a proposed rule no later than June 22, 2019, with a final rule to follow no more than 18 months later.

EPA has developed this hazard summary document for five PBT chemical substances it has identified for proposed action under TSCA section 6(h). These documents and the data cited for each PBT will support the development of a proposed rule that addresses the risks of injury to the environment and health that the EPA determines are presented by the subject PBT chemicals.

To create this hazard summary, environmental and human health hazard data were compiled from various primary and secondary sources of both confidential and publicly-available information. The hazard summaries relevant to environmental hazard include acute and chronic toxicological information for both aquatic and terrestrial wildlife. Due to a general lack of data found for 2,4,6-Tris(tert-butyl) phenol (2,4,6 TTBP) and pentachlorothiophenol (PCTP) in the primary and secondary sources initially searched, additional literature searches were conducted for environmental hazard data for these chemicals by searching for the chemical name and CASRN in Web of Science and Science Direct. Generally, more acute than chronic aquatic toxicity data are available for all five PBT chemicals. However, data were available for organisms spanning three trophic levels for all the PBT chemicals, except for PCTP.

The hazard summaries relevant to human health focus on repeated-dose studies given the PBT nature of the chemicals of interest. Available published and unpublished repeated-dose toxicity data are tabulated according to health endpoints and the identified studies are briefly summarized. Human health hazard data are presented in the context of existing toxicological assessments, when available.

Available hazard information is tabulated and briefly summarized within this document. The purpose of the environmental and human health summary is to identify known hazards of the PBT chemicals; the information in this document is not meant to represent an exhaustive literature review nor an analysis of relative importance or comparative dose-response among hazards. EPA leveraged previous data compilations and existing information, wherever possible, as the initial data gathering approach and to survey the environmental and human health hazard data and information.

The document is intended to provide an overview of the nature and extent of hazards for use in making risk-based regulatory decisions. However, some qualitative interpretation is provided in discussing the reported data. Similarly, the document summarizes points of departure (e.g.,

NOAEL/LOAEL) or other hazard benchmarks as reported in the data source, rather than the 'selection' of particular studies for use in conjunction with any particular exposure pathway(s) or risk assessment scenarios, or a dose-response analysis conducted by EPA.

Please focus comments and recommendations on those that are critical to identifying and describing the hazards for each chemical. Please provide a separate response to questions for each of the five PBT chemicals as appropriate:

1. This information, when finalized will inform a technical support document to support EPA's regulatory activities on PBTs. Please comment on the organization and structure of this document to inform this use. Do you have specific recommendations to improve clarity and presentation of this information?

2. Please comment on the methodology for collecting and summarizing information from secondary sources. Was the approach appropriate? Is the description for how and where the literature was obtained clearly described?

3. Please comment on the representativeness and adequacy of the selected literature used in the evidence tables and described in the text to summarize the hazard concerns. Are there additional primary peer-reviewed and publicly available literature that warrant further consideration? If so, please identify or provide these sources and comment on whether acquisition and summarization of this additional information would change the hazard characterization already provided in the existing summaries? Does the information presented clearly and accurately represent the hazards associated with each chemical? Are there any studies that should be removed from the summary and evidence tables due to study quality or data transparency concerns?

4. Has appropriate and sufficient information been obtained from the literature to support the identification of hazards?

5. Please comment on the reliability and relevance of the identified data sets for each chemical and on the strengths and weaknesses of individual data sets that will help to better inform future regulatory actions.