**CHEMICAL SAFETY ADVISORY COMMITTEE (CSAC)**
**OPEN MEETING**
**May 24 and 25, 2016**
**CSAC WEB SITE https://www.epa.gov/csac**
**OPPT Docket: EPA-HQ-OPPT-2015-0805**

**Crystal City Marriott**
**1999 Jefferson Davis Highway**
**Arlington VA 22202**
**Hotel Phone #: 703-413-5500**

# Peer Review of the Draft Risk Assessment for TSCA Work Plan Chemical, 1-Bromopropane (CASRN-106-94-5)

## TUESDAY, MAY 24, 2016

**Please note that all times are approximate.**

**9:00 AM** **Meeting Opening and Administrative Procedures** – Steven Knott, M.S., Designated Federal Official, Office of Science Coordination and Policy, EPA

**9:10 AM** **Introduction of Committee Members** - Kenneth Portier, Ph.D., Chair of the CSAC

**9:15 AM** **Welcome and Opening Remarks –** Stan Barone Jr., M.S., Ph.D., Acting Director, Office of Science Coordination and Policy, EPA and Wendy Cleland-Hamnett, J.D., Director, Office of Pollution Prevention and Toxics, EPA

**9:30 AM** **Introduction and Background** – Tala Henry, Ph.D., Director, Risk Assessment Division, Office of Pollution Prevention and Toxics, EPA

**10:00 AM** **Overview of the Draft Risk Assessment for TSCA Work Plan Chemical, 1-Bromopropane (CASRN-106-94-5)** – Katherine Anitole, Ph.D., and Greg Macek, Risk Assessment Division, Office of Pollution Prevention and Toxics, EPA

**10:30 AM** **Break**

**10:45 AM** **Overview of the Draft Risk Assessment for TSCA Work Plan Chemical, 1-Bromopropane (CASRN-106-94-5) Continued** – Katherine Anitole, Ph.D., and Greg Macek, Risk Assessment Division, Office of Pollution Prevention and Toxics, EPA

**12:00 PM** **Lunch**

**1:00 PM** **Public Comments**

**2:00 PM Charge Questions to the Committee**

**General Issues on the Risk Assessment**

**Question 1-1**: Please comment on whether the information provided in Section 1 (Background and Scope) is appropriate and accurately characterizes the fit for purpose nature of this assessment for TSCA related uses? Please provide any specific suggestions for improving the clarity and transparency of the background information that describes scope and limits of the assessment.

**Question 1-2**: Please comment on the scope of the assessment, in particular the conceptual model resulting from EPA/OPPT's problem formulation. Please provide any other significant literature, reports, or data that would be useful to complete this characterization and that may support expansion or refinement of the scope of this assessment.

**2:45 PM Break**

**3:00 PM Charge Questions to the Committee Continued**

**Occupational Exposure Assessment**

**Question 2-1**: Please comment on the approaches used, and provide any specific suggestions or recommendations for alternative approaches, models, or information (references) that could be considered by EPA/OPPT for improving the workplace exposure assessment, including estimations for bystander/non-users (e.g., women of child-bearing age).

**Question 2-2**: Please comment on whether there are any additional occupational exposure scenarios that EPA/OPPT could address that have not already been quantified. Please also provide specific references and/or data to address such additional exposures.

**Question 2-3**: For the exposure assessments based on monitoring data, are you aware of any additional sources of occupational exposure monitoring data that EPA/OPPT could consider in its assessment? If so, please provide specific literature, reports, or data that would help us refine the exposure assessment.

**Question 2-4**: For the exposure assessments based on modeling, are you aware of any additional sources of data that EPA/OPPT could consider in deriving the parameter values used in the modeling? If so, please provide relevant literature, reports, or data that would help us refine the parameters used in the modeling.

**5:00 PM Adjournment**

**WEDNESDAY, MAY 25, 2016**
Crystal City Marriott
1999 Jefferson Davis Highway
Arlington VA 22202
Hotel Phone #: 703-413-5500

**Please note that all times are approximate.**

**9:00 AM** **Meeting Opening and Administrative Procedures** – Steven Knott, M.S., Designated Federal Official, Office of Science Coordination and Policy, EPA

**9:05 AM** **Introduction of Committee Members** – Kenneth Portier, Ph.D., Chair of the CSAC

**9:10 AM** **Follow-up from Previous Day's Discussion (As needed)** – Office of Pollution Prevention and Toxics, EPA

**9:30 AM** **Charge Questions to the Committee Continued**

**Consumer Exposure Assessment**

**Question 3-1**: Please comment on the approach used and provide any specific suggestions or recommendations for alternative approaches, models, or use information (e.g., information on duration, number of user events, amount used) that could be considered by EPA/OPPT in developing and /or refining the exposure assumptions and estimates for spray adhesives, aerosol spot removers and aerosol spray cleaners and degreasers.

**Question 3-2**: Exposure estimates were developed for three consumer uses: spray adhesives, aerosol spot removers and aerosol spray cleaners and degreasers. All products are aerosol sprays and appear to be available for sale and use by consumers in the U.S. There were no current reliable data regarding the consumer exposure scenarios. Please comment on the consumer uses selected for this assessment and provide any specific suggestions or recommendations for additional uses (including information on duration, number of user events, amount used) that could be considered for evaluation.

**10:30 AM** **Break**

**10:45 AM** **Charge Questions to the Committee Continued**

**Hazard and Dose-Response Assessments**

**Question 4-1**: EPA/OPPT concluded in the risk assessment that 1-BP carcinogenesis occurs through a probable mutagenic mode of action based on the totality of the available data/information and the WOE. Please comment whether the cancer hazard assessment has adequately described the WOE regarding the mutagenic mode of action.

**Question 4-2**: EPA/OPPT identified liver toxicity, kidney toxicity, reproductive/developmental toxicity, and neurotoxicity in the risk assessment as adverse human health effects for risk

characterization. EPA/OPPT used these endpoints to calculate PODs to assess non-cancer risks associated with chronic inhalation exposures. As part of the review, please comment on the choice of these endpoints as PODs for assessing risks in humans associated with acute and chronic inhalation exposures to 1-BP. Are there other data that EPA/OPPT could have considered for the hazard identification and dose response associated with chronic inhalation exposures? If so, please provide specific data and references.

**12:00 PM Lunch**

**1:00 PM Charge Questions to the Committee Continued**

**Question 4-3**: Please comment on the WOE analysis for the choices of non-cancer endpoints for the acute and chronic risk scenarios. Please provide additional data, data interpretation or information that would have informed the WOE analysis and selection of critical studies for the PODs.

**Question 4-4**: Typically, EPA uses the benchmark dose modeling software (BMDS) with a benchmark response (BMR) of 10% and the models are restricted to multistage models or the broader suite of dichotomous models in BMDS and a single best model is chosen for the POD. EPA/OPPT used an alternative approach to calculate the cancer POD versus the standard approach of choosing best fit model. Briefly, EPA/OPPT used a model averaging approach considering multiple benchmark dose models to calculate the POD at a benchmark response (BMR) level of 0.1%. Please comment on the assumptions, strengths and weaknesses of the model averaging approach for determining the POD in the cancer assessment.

**2:30 PM Break**

**2:45 PM Charge Questions to the Committee Continued**

**Risk Characterization**

**Question 5-1**: EPA/OPPT interpreted the endpoint of decreases in live litter size following exposure to 1-BP before and during gestation, as a surrogate for frank developmental effects relevant to humans per EPA's Guidelines for Developmental Toxicity Risk Assessment. EPA/OPPT used this endpoint to calculate a point of departure (POD) to assess non-cancer risks associated with acute inhalation exposures to 1-BP. Please comment on the assumptions, strengths and weaknesses of the MOE approaches used to estimate the non-cancer risks to workers and occupational non-users following acute inhalation exposures to 1-BP, including the MOEs presented in the document. Please comment on the assumptions, strengths and weaknesses of the MOE approaches used to estimate risks to consumers following acute inhalation exposures; including non-users (e.g., bystanders who may be children, or women of childbearing age). Specifically, please comment on the decision to limit the analysis to acute exposures without residual concerns between events and what data could critically inform modifying this approach for consumers. Please comment on the selection of uncertainty factor values in deriving the benchmark MOE for acute inhalation exposures.

**Question 5-2**: Please comment on the assumptions, strengths and weaknesses of the MOE approaches used to estimate the non-cancer risks to workers and occupational non-users

following chronic inhalation exposures to 1-BP, including the MOEs presented in the document. Please comment on the selection of uncertainty factor values in deriving the benchmark MOE for chronic inhalation exposures.

**Question 5-3**: Please comment on the assumptions, strengths and weaknesses of the approach used to estimate added lifetime cancer risks to workers which EPA/OPPT-derived from an inhalation unit risk based on lung tumors in female mice for estimating incremental or added individual lifetime cancer risk.

**Question 5-4**: Please comment on whether the risk characterization has adequately described the assumptions, uncertainties and data limitations in the methodology used to assess risks from 1-BP. Please comment on whether this information and risk conclusions are presented in a logical, transparent manner and provide suggestions that could increase clarity in the risk characterization.

**5:00 PM Adjournment**

*As noted above, please be advised that agenda times are approximate. For further information, please contact the Designated Federal Official for this meeting, Mr. Steven Knott, via telephone: (202) 564-0103 or email:knott.steven@epa.gov*.