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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND POLLUTION  
PREVENTION

AUG 10 2016

**MEMORANDUM**

**SUBJECT:** Transmittal of Minutes of the May 11, 2016 Chemical Safety Advisory Committee (CSAC) Meeting Associated with the "Orientation Session on the Toxic Substances Control Act (TSCA)"

**TO:** Wendy Cleland-Hamnett  
Director  
Office of Pollution Prevention and Toxics

**FROM:** Scott Lynn, Ph.D.  
Designated Federal Official CSAC Staff  
Office of Science Coordination and Policy *Steven Smith for*  
*8/10/16*

**THRU:** Laura E. Bailey, M.S.  
Supervisory Physical Scientist/Executive Secretary FIFRA SAP  
Office of Science Coordination and Policy *Steven Smith for*  
*8/10/16*

Stanley Barone, Ph.D.  
Acting Director *Stanley Barone* *8/10/16*  
Office of Science Coordination and Policy

Please find attached the minutes of the May 11, 2016 CSAC open public meeting held in Washington, DC. The minutes represent the material provided to the CSAC, clarifying questions raised by CSAC members, and the Agency responses as discussed during the meeting on the Orientation Session on the Toxic Substances Control Act (TSCA).

Enclosure

cc:

Jim Jones  
Louise Wise  
Jeff Morris, Ph.D.  
Tala Henry, Ph.D.  
Alva Daniels, Ph.D.  
OPPT Docket

## CSAC Members

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**Chemical Safety Advisory Committee Minutes**  
**No. 2016-01**

**A Set of Scientific Issues Being Considered by the  
Environmental Protection Agency Regarding the  
Orientation Session on Toxic Substances Control  
Act (TSCA)**

**May 11, 2016**  
**Chemical Safety Advisory Committee Meeting**  
**Held at the**  
**EPA William Jefferson Clinton Building East**  
**Washington, DC**

The Chemical Safety Advisory Committee (CSAC) is a Federal advisory committee operating in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2 § 9 (c). The CSAC supports the Environmental Protection Agency (EPA) in performing its duties and responsibilities under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., the Pollution Prevention Act, 42 U.S.C. 13101 et seq., and other applicable statutes. The CSAC provides scientific advice, information, and recommendations to the EPA Administrator on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches. The meeting minutes represent the material provided by the Agency to, along with clarifying questions from, the CSAC and do not necessarily represent the views and policies of the EPA or of other agencies in the Executive Branch of the Federal government. Mention of trade names or commercial products does not constitute an endorsement or recommendation for use. The meeting minutes do not create or confer legal rights or impose any legally binding requirements on the EPA or any party.

TABLE OF CONTENTS

COMMITTEE ROSTER .....6

INTRODUCTION .....8

PUBLIC COMMENTERS.....9

EXECUTIVE SUMMARY.....10

ORIENTATION SESSION.....11

COMMITTEE DISCUSSION.....16

## NOTICE

The Chemical Safety Advisory Committee (CSAC) is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2 § 9 (c). The CSAC supports the Environmental Protection Agency (EPA) in performing its duties and responsibilities under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., the Pollution Prevention Act, 42 U.S.C. 13101 et seq., and other applicable statutes. The CSAC provides scientific advice, information, and recommendations to the EPA Administrator on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches. The CSAC serves as the primary scientific peer review mechanism of the Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics (OPPT), and is structured to provide independent and balanced expert assessment of chemical and chemical-related matters facing the Agency. The meeting minutes have been written as part of the activities of the CSAC.

In preparing the meeting minutes, the CSAC carefully considered all information provided by the EPA, as well as information presented in public comment. The meeting minutes represent the material provided by the Agency to, along with clarifying questions from, the CSAC and do not necessarily represent the views and policies of the EPA or of other agencies in the Executive Branch of the Federal government. Mention of trade names or commercial products does not constitute an endorsement or recommendation for use. The meeting minutes do not create or confer legal rights or impose any legally binding requirements on EPA or any party.

The minutes of the May 11, 2016 CSAC meeting associated with the “Orientation Session on Toxic Substances Control Act” were certified by Kenneth Portier, Ph.D., CSAC Chair, and Scott Lynn, Ph.D., CSAC Designated Federal Official. The minutes were reviewed by Laura E. Bailey, M.S., FIFRA SAP Executive Secretary. The minutes are publicly available on the CSAC website (<https://www.epa.gov/csac>) under the heading of “Meetings” and in the public e-docket, Docket No. EPA-HQ-OPPT-2015-0234, accessible through the docket portal: <http://www.regulations.gov>. Further information about CSAC reports and activities can be obtained from its website at <https://www.epa.gov/csac>. Interested persons are invited to contact Scott Lynn, Ph.D., Designated Federal Official, via e-mail at [lynn.scott@epa.gov](mailto:lynn.scott@epa.gov).

**CSAC Minutes No. 2016-01**

**A Set of Scientific Issues Being Considered by the  
Environmental Protection Agency Regarding:**

**Orientation Session on Toxic Substances Control  
Act (TSCA)**

**May 11, 2016  
Chemical Safety Advisory Committee Meeting  
Held at  
William Jefferson Clinton Building East  
Washington, DC**



**Kenneth Portier, Ph.D.  
CSAC Chair  
Chemical Safety Advisory Committee**



**Scott Lynn, Ph.D.  
Designated Federal Official  
CSAC Staff**

AUG 10 2016

Date: \_\_\_\_\_

AUG 10 2016

Date: \_\_\_\_\_



## COMMITTEE ROSTER

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## INTRODUCTION

On May 11, 2016 the US EPA Chemical Safety Advisory Committee (CSAC) met in an open public meeting via webinar in Washington, DC where the Agency presented scientific issues associated with the “Orientation Session on Toxic Substances Control Act (TSCA).” The US EPA Office of Pollution Prevention and Toxics (OPPT) conducts risk assessments, assesses chemical safety, and manages chemicals under the TSCA Work Plan. The Agency presented to the CSAC a multi-pronged strategy used to ensure the safety of chemicals in commerce. The Agency’s three part strategy for addressing potential risks from existing chemicals includes: 1) identifying chemicals for assessment and taking actions as appropriate; 2) increasing opportunities for industry to move toward using safer chemicals; and 3) increasing public access to data on chemicals that have been developed by EPA and/or provided by industry. The Agency has identified a work plan of chemicals for further assessment under TSCA and the Agency’s TSCA Work Plan helps focus and direct the activities of its Existing Chemicals Program. After gathering input from stakeholders, the Agency developed criteria used for identifying chemicals for further assessment which focused on chemicals which scored high in the screening process based on their combined hazard, exposure, and persistence and bioaccumulation characteristics. Identification of chemicals as Work Plan Chemicals does not mean that the Agency would not consider other chemicals for risk assessment and potential risk management action under TSCA and other statutes. The Agency will consider other chemicals if warranted by available information. If potential risks are indicated in the final TSCA risk assessment following peer review and public comment, the Agency will take necessary risk reduction actions. If no risks are identified in the final assessment, the Agency may conclude its work on the chemical uses being assessed. The CSAC was convened for the Agency to provide an orientation session on TSCA, so the CSAC may, in future meetings, provide advice to the Agency regarding their risk assessments and chemical management under TSCA.

US EPA presentations were provided during the CSAC meeting by the following (listed in presentation order):

**Welcome and Opening Remarks** – Laura Bailey, M.S., Supervisory Physical Scientist, Office of Science Coordination and Policy (OSCP), EPA

**Toxic Substances Control Act (TSCA) Overview** – Jeff Morris, Ph.D., Deputy Director, Office of Pollution Prevention and Toxics (OPPT), EPA

**TSCA Work Plan Chemicals** – Tala Henry, Ph.D., Director, Risk Assessment Division (RAD), OPPT

**OPPT’s Risk Assessment Process** – Tala Henry, Ph.D., Director, RAD, OPPT

## PUBLIC COMMENTERS

*Oral statements were provided by (listed in alphabetical order):*

Christina Franz, Senior Director, Regulatory & Technical Affairs, American Chemistry Council

Stephen P. Risotto, Senior Director, Chemicals and Products and Technology Division, American Chemistry Council

Kathleen M. Roberts, Vice President, Bergeson & Campbell PC, N-Methylpyrrolidone (NMP) Producers Group

*Written public comments were provided by (listed in alphabetical order):*

Christina Franz, Senior Director, Regulatory & Technical Affairs, American Chemistry Council

Stephen P. Risotto, Senior Director, Chemicals and Products and Technology Division, American Chemistry Council

Kathleen M. Roberts, Vice President, Bergeson & Campbell PC, N-Methylpyrrolidone (NMP) Producers Group

Michael P. Walls, Vice President, Regulatory & Technical Affairs, American Chemistry Council

## EXECUTIVE SUMMARY

The Chemical Safety Advisory Committee (CSAC) serves as the primary scientific peer review mechanism of the US Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics (OPPT), and is structured to provide independent and balanced expert assessment of chemical and chemical-related matters facing the Agency in performing its duties and responsibilities under the Toxic Substances Control Act (TSCA). The Agency conducts risk assessments, assesses chemical safety, and manages chemicals under TSCA. The CSAC provides scientific advice, information, and recommendations to the EPA Administrator on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches.

The CSAC met in an open public meeting via webinar in Washington, DC where the Agency provided material to CSAC associated with the “Orientation Session on Toxic Substances Control Act (TSCA).” The Agency presented to the CSAC a multi-pronged strategy used to ensure the safety of chemicals in commerce. The Agency’s three part strategy for addressing potential risks from existing chemicals includes: 1) identifying chemicals for assessment and taking actions as appropriate; 2) increasing opportunities for industry to move toward using safer chemicals; and 3) increasing public access to data on chemicals that have been developed by EPA and/or provided by industry. The Agency has identified a work plan of chemicals for further assessment under TSCA and the Agency’s TSCA Work Plan helps focus and direct the activities of its Existing Chemicals Program. After gathering input from stakeholders, the Agency developed criteria used for identifying chemicals for further assessment which focused on chemicals which scored high in the screening process based on their combined hazard, exposure, and persistence and bioaccumulation characteristics. At the end of each Agency presentation, CSAC members had the opportunity to ask clarifying questions and those questions are included in this report.

## **ORIENTATION SESSION**

The CSAC met in an open public meeting via webinar where the Agency presented a multi-pronged strategy used to ensure the safety of chemicals in commerce. Agency senior staff presented the strategy associated with the “Orientation Session on Toxic Substances Control Act (TSCA)” over a four-hour session. Public commenters presented written and oral material to the Committee before and during the webinar. The text that follows summarizes the material provided to the Committee by senior Agency staff, and lists the clarifying questions, and Agency responses, asked by Committee members at the end of each presentation.

### **Introduction**

The USEPA Office of Pollution Prevention and Toxics (OPPT) conducts risk assessments, assesses chemical safety, and manages existing chemicals. The Agency is using a multi-pronged strategy to ensure the safety of chemicals in commerce, recognizing that the current chemicals management law needs to be strengthened. The Agency works under the legislative mandate of the Toxic Substances Control Act (TSCA) passed in 1976 which covers new and existing chemicals and mixtures in commerce in the United States. Food additives, drugs, cosmetic ingredients and pesticide substances are generally excluded from TSCA.

### **TSCA Inventory**

The Agency is required by TSCA section 8(b) to compile, keep current and publish a list of each chemical substance that is manufactured or processed, including imports, in the US for uses under TSCA. This list is called the TSCA Inventory and is based on chemical manufacturer and processor reporting. The TSCA Inventory was initially published in 1979, and second version, containing about 62,000 chemical substances was published in 1982. The TSCA Inventory now lists about 85,000 chemical substances.

### **TSCA New Chemicals Program**

The Agency’s New Chemicals Program assesses chemical safety of chemicals in the premanufacturing phase that are not yet on the TSCA Inventory. Manufacturers, including importers, of new chemicals are required under TSCA section 5(a) to submit a premanufacture notice (PMN) to the Agency 90 days prior to manufacture/import. This information includes: chemical identity; use; anticipated production volume; exposure and release information; and existing test data. Unless the Agency takes action to require additional data, restrict or regulate based on concerns, chemicals enter commerce without further consideration. Since 1976, the Agency has reviewed more than 38,000 new chemicals.

## **TSCA Existing Chemicals Program**

The Agency's three part strategy for addressing potential risks from existing chemicals includes: 1) Identifying chemicals for assessment and taking actions as appropriate; 2) Increasing opportunities for industry to move toward using safer chemicals; and 3) Increasing public access to data on chemicals that have been developed by EPA and/or provided by industry. The Agency has identified a work plan of chemicals for further assessment under TSCA and the Agency's TSCA Work Plan helps focus and direct the activities of its Existing Chemicals Program. After gathering input from stakeholders, The Agency developed criteria used for identifying chemicals for further assessment which focused on chemicals which scored high in the screening process based on their combined hazard, exposure, and persistence and bioaccumulation characteristics. Identification of chemicals as Work Plan Chemicals does not mean that the Agency would not consider other chemicals for risk assessment and potential risk management action under TSCA and other statutes.

The Agency develops TSCA Work Plan Chemical assessments using the best available information and approaches. Assessments focus on those TSCA uses of the chemical with significant potential for exposure to humans and/or the environment. In some cases, the Agency's TSCA Work Plan Chemical assessments will address chemicals that are not on the TSCA Work Plan when it is advantageous to group and review related/similar chemicals together. For example, the Agency may assess groups of structurally similar chemicals in order to support more informed decisions about alternative substances with similar properties and potential uses.

## **TSCA Work Plan Chemical Assessment Process**

### *Problem Formulation and Initial Assessment*

As a first step in evaluating TSCA Work Plan Chemicals, the Agency performs problem formulation to determine if available data and current assessment approaches and tools will support the assessments. Problem formulation is the analytical phase of the assessment in which the purpose for the assessment is articulated, the problem defined and a plan for analyzing and characterizing risk is determined. Problem formulation draws from regulatory, decision-making and policy context of the assessment, informs the technical approach to the assessment and systematically identifies the major factors to be considered in risk assessment. Outcomes of a problem formulation are:

- Conceptual Model – including a visual representation and written description of actual or predicted relationships between chemicals and human or wildlife, and
- Analysis Plan – describing the intentions regarding the technical aspects of the risk assessment

Based on on-going experience in conducting TSCA Work Plan Chemical assessments and stakeholder feedback, starting in 2015 the Agency is publishing a problem formulation for each TSCA Work Plan assessment as a stand-alone document to facilitate



public and stakeholder comment and input prior to conducting further risk analysis. Commensurate with release of a problem formulation document, the Agency will open a public docket for receiving comments, data or information from interested stakeholders. The Agency believes publishing problem formulations for TSCA Work Plan assessments will increase transparency of the thinking and analysis process, provide opportunity for public/stakeholders to comment on the approach and provide additional information/data to supplement or refine assessment approach prior to conducting detailed risk analysis and risk characterization. If problem formulation indicates the need to conduct a risk assessment, and there are enough data to do so, the Agency will initiate a risk assessment which is the process to estimate the nature and probability of adverse health and environmental effects in humans and ecological receptors from chemical contaminants that may be present in the environment.

#### *Data Needs Assessment*

In some instances, as a result of problem formulation, the Agency identifies data gaps (uses, exposure pathways, toxicity data) so significant as to prevent conducting meaningful risk assessment. In these cases, the Agency will publish a Data Needs Assessment document and provide opportunity for public/stakeholders to comment or identify/provide data or information that may fill identified data gaps prior to pursuing data collection via TSCA authorities.

#### *Opportunities for Public Input*

The Agency issues draft risk assessments for public review and comment followed by independent peer review in accordance with Agency peer review guidelines. The Agency considers all public and peer review comments as it revises and finalizes the risk assessment. There are multiple opportunities for public input on peer review plans, chemical assessments, and opportunities to submit relevant data on assessments to the federal docket. Opportunities for public input on chemicals may include when the Agency:

- lists a chemical on the annual work plan list
- publishes a problem formulation or data needs assessment
- publishes a data needs assessment
- announces a peer review plan
- releases a draft risk assessment for public comment and peer review

#### *Draft Assessments for Peer Review and Public Comment*

The Agency has released a draft assessment for the TSCA Work Plan Chemical listed below for peer review and public comment.

- 1-Bromopropane (1-BP)

#### *Completed Chemical Assessments*

The Agency completed assessments for the TSCA Work Plan Chemicals listed below:

- N-Methylpyrrolidone (NMP)



- Antimony Trioxide (ATO)
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[ $\gamma$ ]-2-benzopyran (HHCB)
- Methylene Chloride
- Trichloroethylene (TCE)

#### *Completed Problem Formulation and Initial Assessments*

The Agency has released Problem Formulation and Initial Assessments for the TSCA Work Plan Chemicals listed below.

- Chlorinated Phosphate Esters Cluster
- Cyclic Aliphatic Bromides Cluster
- Tetrabromobisphenol A and Related Chemicals Cluster
- Brominated Phthalate Cluster
- 1,4-Dioxane

#### *Ongoing Chemical Assessments*

The Agency has initiated assessments for the TSCA Work Plan Chemicals listed below.

- Long-chained Chlorinated Paraffins (LCCPs; C<sub>18-20</sub>)
- Medium-chained Chlorinated Paraffins (MCCPs; C<sub>14-17</sub>)
- Octamethylcyclotetrasiloxane (D4)

The Agency will consider other chemicals if warranted by available information. If potential risks are indicated in the final TSCA risk assessment following peer review and public comment, the Agency will take necessary risk reduction actions. If no risks are identified in the final assessment, the Agency may conclude its work on the chemical uses being assessed.

#### **Conclusion**

The Agency follows the TSCA Work Plan, which is currently 85 chemicals, to prioritize chemicals for risk assessment. These risk assessments determine if there is the potential for risk through the uses of these chemicals. If there is the potential for risk this could lead to regulatory action or voluntary measures on behalf of the manufacturer to reduce or mitigate the risk. If there is no potential for risk, the risk assessment on that chemical is concluded. The following documents are utilized as guidance with relevance to Work Plan Risk Assessments:

- 2014 Framework for Human Health Risk Assessment to Inform Decision Making
  - 2011 Recommended Use of Body Weight 3/4 as the Default Method in Derivation of the Oral Reference Dose
  - 2006 A Framework for Assessing Health Risk of Environmental Exposures to Children
  - 2005 Guidelines for Carcinogen Risk Assessment

- 2005 Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens
  - 2002 A Review of the Reference Dose and Reference Concentration Processes
  - 1998 Guidelines for Neurotoxicity Risk Assessment
  - 1996 Guidelines for Reproductive Toxicity Risk Assessment
  - 1991 Guidelines for Developmental Toxicity Risk Assessment
- 1992 Guidelines for Exposure Assessment
  - 2011 Exposure Factors Handbook
  - 2009 Guidance Document on the Development, Evaluation and Application of Environmental Models
  - 2001 Summary Report of the Technical Workshop on Issues Associated with Considering Developmental Changes in Behavior and Anatomy When Assessing Exposure to Children
- 1998 Guidelines for Ecological Risk Assessment
- 2000 Risk Characterization Handbook
- 2015 Peer Review Handbook -4th Edition

## COMMITTEE DISCUSSION

At the end of each Agency presentation, CSAC members had the opportunity to ask clarifying questions. For each Agency presentation, the clarifying questions (Q) are listed in the chronological order asked and each is followed by the Agency response (R).

### Toxic Substances Control Act (TSCA) Overview

Q1: The Agency mentioned about half of the PMN submissions go to the market and a Committee member wondered what happens to the other half. The Committee member inquired if it is more on the manufacturers side, where they choose not to pursue a particular PMN chemical submission, or if it is something about the PMN process that sets it aside.

R1: The Agency indicated that it is both. In many cases, the Agency informs the company that more data need to be generated to support a decision and in many cases the company will decide not to go forward with commercializing due to business reasons.

Q2: The Agency mentioned that health data wasn't required in the PMN submissions, but a Committee member questioned how often the Agency receives health data in PMN submissions, or what percentage of applications have no data versus those that have some data.

R2: Data are not required to be generated to support the PMN, but if there are existing data then submitters are encouraged to submit it. About 10-15% of PMN submissions are submitted with data and the majority of the data submitted is acute aquatic toxicity data.

Q3: A Committee member noted 'the regrettable substitution problem' (*i.e.*, when a chemical is removed from the market and the replacement chemical is worse or equally as bad), and requested clarification where this was addressed.

R3: The Agency referenced two aspects: 1) to the extent that substitutes come from the New Chemicals Program, those chemicals haven't been documented to cause problems; and 2) in the larger existing chemical space it is a real issue. The Agency is trying to group chemicals together in classes to assess them, e.g., flame retardants, in an effort to address the issue of regrettable substitution. In addition, the Agency also has a Safer Chemicals Program which tries to identify chemicals that are lower hazard to give the marketplace information on choices.

Q4: The overview presentation included the terminology "will present an unreasonable risk" indicates that there must be evidence of unreasonable risk. A Committee member asked how EPA operationalized "unreasonable".

R4: The Agency stated that there are two components: 1) the actual health or ecological risk associated with the chemical including the severity of the endpoints; and 2) the cost-

society component which takes into account both the severity of the health and ecological impact and the societal cost of taking action to mitigate or reduce those risks.

Q5: A Committee member asked if the Agency envisions the Committee advising on the prioritization process for chemical reviews under TSCA. Specific mention was made to the uncertainties in high-throughput screening that might fold into that prioritization process.

R5: The Agency noted there was an expectation of TSCA reform, which would create a need for the Agency to revisit science issues associated with prioritization.

### **TSCA Work Plan Chemicals**

Q6: A Committee member commented that the process outlined is very similar to NTP's public outreach steps, which while adding time, has proved very valuable during problem formulation. The Committee member asked if public review, feedback and input provided more clarity on the problem formulation. The Committee member also asked about processes or guidance documents that explained the methodologies utilized for "read across".

R6: The Agency stated that public review of problem formulations absolutely helps them ask sharper questions and the Agency has gained new information during the peer review process. The Agency also stated that they have met with industry stakeholders on problem formulations and the industry stakeholders have been able to provide additional data or information that refines the use scenario.

The Agency has been identifying analogs and conducting "read across" for a very long time. This process is described in the new chemical guidance called Sustainable Futures which was published about 15 years ago. The Agency was also a major player in the Organization for Economic and Cooperative Development (OECD) development of the Guidance on Grouping of Chemicals which outlines how to make categories and articulates the various kinds of "read of across" and the confidence necessary for supporting each one.

Q7: A Committee member inquired how neurotoxicity was decided to be described as a hazard parameter for screening level prioritization.

R7: Neurotoxicity was not an endpoint identified in the original methodology, but it was added in response to a point raised in a stakeholder public comment process.

Q8: A Committee member pointed out that the prioritization criteria did not list hormonal action that is not reproductive or developmental.

R8: The Agency considers endocrine disruption as a mode of action that potentially leads to an adverse outcome.

Q9: A Committee member asked if the Agency can go back and do another risk assessment on a chemical for a specific different use.

R9: The Agency can absolutely do that.

Q10: A Committee member inquired where in the process would a review of the current state of the literature be considered in assessing work plan chemicals. The Committee member indicated that the USEPA Integrated Risk Information System (IRIS) program recently received positive feedback from an advisory panel on their literature review process.

R10: The Agency indicated that the process has been evolving and literature review now occurs before and during the problem formulation step of risk assessments. The Agency is working across offices to adopt process and infrastructure on systematic literature review.

### **OPPT's Risk Assessment Process**

Q11: A Committee member inquired if special populations at risk (*e.g.*, elderly, ill, pregnant women, *etc.*) are considered as receptors/populations as defined for Chemical-Specific Uses.

R11: The Agency indicated that if data and information are available it is incorporated into the problem formulation. The Agency also noted that several occupational scenarios associated with recent risk assessments were specifically focused on pregnant women. The Agency further noted that it is a part of the Agency's charge to consider sensitive and vulnerable populations.

Q12: A Committee member questioned whether the exposure characterization of the exposure assessment assumed safety equipment as a factor in occupational exposure characterization or if a worst case pattern would be utilized.

R12: The Agency indicated that they perform a baseline exposure assessment with no engineering controls or personal protective equipment (PPE) but also try to develop occupational exposure assessment scenarios which would be fit for purpose to help define and determine the level of risk should risk reduction or mitigation actions be needed. Thus, both exposure assessment scenarios (with and without PPE) are performed for occupational use of chemicals.

Q13: A Committee member questioned whether the Agency planned to incorporate Adverse Outcome Pathways (AOPs) in the Weight of Evidence approach.

R13: The Agency will use AOPs to the extent that they are available and fit for purpose for the chemicals regulated under TSCA. That kind of evidence is used in selection of toxicity endpoints and mode of action discussion. AOPs are good evidence if they are

available and the Agency is incorporating those and high-throughput data into risk assessments.

Q14: A Committee member noted the use of deterministic risk assessments for ecological risk assessments and the controversy of the use of No Observed Effect Concentrations. The question was raised, if data were available, would the Agency utilize a probabilistic risk assessment approach. The Committee member further suggested that a few of the chemicals on the TSCA work plan might have enough data to do a probabilistic risk assessment.

R14: The Agency replied that, data permitting, they would utilize a probabilistic risk assessment approach including species sensitivity distributions, but under the current TSCA there are few work plan chemicals for which there would be enough data. If a TSCA work plan chemical has ambient water quality criteria, the Agency would coordinate between offices on a risk assessment.

Q15: A Committee member questioned the extent that the Agency has examined their exposure assessments to determine if they are comparable to or in agreement with other platforms (*e.g.*, SHEDS, European EASE, *etc.*). This Committee member suggested running several models on a set of chemicals in parallel and comparing the results via a systematic analysis to determine the extent of agreement to inform on improving each model. Two other Committee members agreed with the usefulness of an exposure model comparison or consensus exercise.

R15: The Agency uses a number of models in conducting exposure assessments. Some of these models have been developed by OPPT and others have been developed by the USEPA Office of Research and Development including high throughput exposure models. However, most models do not consider occupational exposures which are of importance for work plan chemicals.

Q16: One Committee member supported the movement towards a systematic literature review process and encouraged the Agency to explore automated tools to facilitate the process (*e.g.*, machine learning approaches to reduce the time spent screening studies for relevance).

R16: The Agency is moving in that direction and OPPT is collaborating with a number of other USEPA offices on adopting existing and developing new tools and strategies.