

U.S. Environmental Protection Agency Board of Scientific Counselors
Ad Hoc Committee to Review Research Plans for: The New Chemicals Collaborative
Research Program

Virtual Meeting Summary

October 24-25, 2022

Dates and Times: October 24-25, 2022, 12:00pm – 6:00pm Eastern time

Location: Virtual

Executive Summary

On October 24-25, the Environmental Protection Agency's (EPA's) Board of Scientific Counselors (BOSC) Ad Hoc Committee to Review Research Plans for The New Chemicals Collaborative Research Program convened in virtual meetings. The goals of the two-day meeting were to discuss planned research activities and challenges associated with modernizing chemical assessment under the New Chemicals Collaborative Research Program. The virtual meeting format allowed for presentations, open dialogue, program feedback, Subcommittee deliberations and questions, and EPA responses to questions.

Day 1 consisted of opening remarks and introductions, and an overview of the New Chemicals Collaborative Research Program. Day 1 also included Session 1: Challenges in New Chemical Assessment Under the Amended Toxic Substances Control Act and Session 2: Overview of the New Chemicals Collaborative Research Program (NCCRP). Day 2 consisted of Subcommittee discussion and deliberations about the Subcommittee's draft strengths, suggestions, and recommendations in response to EPA's charge questions for inclusion in their Subcommittee report.

Mr. Tom Tracy, Designated Federal Officer, Office of Science, Advisor, Policy, and Engagement (OSAPE) welcomed the Subcommittee and thanked members for attending. Dr. Michal Freedhoff, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP), then described the importance and goals of the new research program.

Monday, October 24, 2022

Subcommittee Chair Opening Remarks and Introductions

BOSC Executive Committee Chair Dr. Paul Gilman and Co-Chairs Drs. Richard Becker and Justin Teeguarden introduced panel members and reviewed meeting logistics, explaining how the Subcommittee would review the charge questions and that breakout sessions would correspond directly to each charge question.

Agenda Overview

Dr. Annette Guiseppi-Elie, Acting National Program Director (NPD), Chemical Safety for Sustainability (CSS) Research Program, explained the vision of the CSS Research Program and its eight research areas before reviewing the meeting agenda and introducing the next presenter.

Challenges in New Chemical Assessment Under the Amended Toxic Substances Control Act

Dr. Louis “Gino” Scarano, Senior Science Advisor, Office of Pollution Prevention and Toxics (OPPT), provided an overview of the Toxic Substances Control Act (TSCA) and described challenges in new chemical assessment under the Act. He outlined risk assessment procedures, describing information required from chemical manufacturers, research on associated types of exposures, and evaluations of human health and environmental hazards. He concluded by sharing the vision statement of the New Chemicals Collaborative Research Program and answered questions posed by attendees.

Overview of the New Chemicals Collaborative Research Program (NCCRP)

Dr. Katie Paul Friedman, Toxicologist, Center for Computational Toxicology and Exposure (CCTE), described OPPT’s four-year research plan and the future goals of the Office of Research and Development (ORD) related to evaluating chemicals under the new program. She discussed challenges, such as the lack of detailed information for new chemicals, and New Approach Methods (NAMs) and tools for data curation to help address research gaps and further understanding.

Dr. Paul Friedman introduced five research plan areas included in the NCCRP’s action plan and mentioned collaborations across ORD categories. The first research area is Updating Chemical Categories and involves reviewing existing and new chemicals to determine whether new categories are needed. The second research area is Developing and Expanding Databases Containing TSCA Chemical Information and includes efforts to continue chemical curation while enriching existing databases so they are more accessible and can interact with other applications. The third research area is Developing and Refining QSAR and Predictive Models. Quantitative Structure Activity Relationships (QSAR) mathematical models relate pharmacological or biological activity with physiochemical characteristics of a set of molecules. Dr. Paul Friedman described a proposed standardized workflow for developing new models and improving prediction reports related to hazard exposure pathways. The fourth research area is Exploring Ways to Integrate and Apply in-vitro NAMs in New Chemical Assessments. Dr. Paul Friedman described NAMs for identifying and curating new chemicals, including the potential expansion of bioactivity screening and further incorporation of safety pharmacology, phenotype-altering concentration response modeling, and high output ecological health assays in assessing chemicals. The fifth research area is Developing a TSCA New Chemicals Decision Support Tool to Modernize the Process. Dr. Paul Friedman explained the goal of this research area is to build a proof-of-concept software that integrates all data streams in a new standardized chemical risk assessment context to facilitate decision tracking and workflow evaluation.

Public Comment

Following Dr. Paul Friedman’s presentation, the Subcommittee reviewed one public comment received from the PETA Science Consortium in support of and offering to organize free training opportunities related to standardization of new methods for chemical assessment.

Review BOSC Reports

Dr. Richard Becker, Senior Director, American Chemistry Council, reviewed past BOSC reports and provided guidance to the Subcommittee related to formatting their report. He emphasized the need for including a narrative summary as well as clear, specific key recommendations in response to the charge questions under consideration. Several Subcommittee members asked clarifying questions before Mr. Tom Tracy adjourned the meeting.

Tuesday, October 25, 2022

Opening Remarks from ORD

Maureen Gwinn, Principal Deputy Assistant Administrator for Research and Development, Office of Research and Development, reviewed the goals of the meeting and provided an overview of the previous day's presentations before introducing Dr. Annette Guiseppi-Elie.

Overview of Day 2 by Moderator/Re-state Charge

Dr. Guiseppi-Elie provided procedural direction to the Subcommittee, emphasizing the need to provide actional recommendations in response to the charge questions.

Open Comment and Question Period from the Panel

Subcommittee members posed several questions related to the previous day's presentations and procedures for developing recommendations in their report. Questions included requests for further clarification about types of chemicals under review, various existing database tools for curation, ability to harmonize data, different NAMs, opportunities for collaboration, and aims of the report.

Break out Group Discussion of Charge Questions (closed sessions)

The Subcommittee discussed the charge questions in closed session groups before reconvening to report back to the full Subcommittee.

Dr. Richard Becker summarized the discussion related to Charge Question 2, which resulted in suggestions rather than full recommendations. Suggestions include using technologies, such as heat maps and spider graphs, to create three-dimensional visualizations, highlighting when no information about a chemical is available, developing a downloadable application to evaluate chemicals, modeling on a set cycle to address the changing chemical landscape, and planning for technology transition.

Dr. Thomas Luechtefeld summarized the discussion of Charge Question 2, which resulted in thirteen suggestions and three recommendations. Recommendations include ensuring there is a programmatic method for easily downloading data to allow for replication by others, clearly defining standard operating and quality control procedures, automating tools as much as possible to reduce the potential for error, and creating standard validation sets for the evaluation of NAMs.

Drs. Justin Teegarden and George Cobb reported on discussion related to Charge Question 3. Their group agrees that a solution integrating machine-readable data and publicly available

modeling platforms is critical. An important consideration is the need to expand tools and approaches for reporting on models' confidence and predictions. Because one of their members was absent, development of recommendations will continue when all members of the group can participate.

Dr. Holger Behrsing summarized discussion of Charge Question 4. The group suggests tying high-throughput cell painting with transcriptomics to ensure they are both sensitive for global predictors of bioactivity. They agree standardization of test systems and new approaches is key, warned that inclusion of toxicity assays might be limited in scope, and highlighted the importance of obtaining stakeholder feedback. Further group discussion will elevate some of the suggestions they considered to full recommendations.

Dr. Marissa Smith shared the suggestions and recommendations discussed by the group reviewing Charge Question 5. Their group suggests including epidemiologic data to increase relevance and ensuring training sets mirror the characteristics of chemicals typically reviewed. The group commends efforts at cross-agency collaboration and the focus on evaluating inhalational effects. They question whether evaluation of geotoxicity is related to Charge Question 4 or 5. Further group discussion is needed about tools and confidence building before they can develop full recommendations.

Committee Questions and Next Steps

Dr. Richard Becker commented he was impressed with the work of the Subcommittee. Dr. Guiseppi-Elie closed the meeting on behalf of Dr. Bruce Rodan. She thanked the group for being engaged and for participating in this first endeavor to obtain feedback related to the new collaborative program.

Meeting Agenda and Other Meeting Materials

The [agenda](#)¹ and other meeting materials can be accessed at [BOSC Review Panel Meeting: October 2022 | US EPA](#).

Meeting Participants

BOSC Ad Hoc Committee to Review Research Plans for: The New Chemicals

Collaborative Research Program Members:

Paul Gilman, *Chair*
Richard Becker, *Co-Chair*
Justin Teeguarden, *Co-Chair*
Hilary Adragna
Holger Behrsing
Rebecca Clewell
George Cobb
Justin Adam Colacino
Annette Guiseppi-Elie
Michal Freedhoff
Thomas Luechtefeld
Sue Marty
Jennifer McPartland
Cheryl Murphy
Mark Nelms
Bruce Rodan*
Marissa Smith
Gina Solomon
Kristie Sullivan

**did not attend any meetings*

EPA Designated Federal Officer (DFO): Tom Tracy, *Office of Science Advisor, Policy, and Engagement*

Presenters:

Annette Guiseppi-Elie, *Acting National Program Director, Chemical Safety for Sustainability (CSS) Research Program*
Maureen Gwinn, *Principal Deputy Assistant Administrator for Research and Development, Office of Research and Development*
Michael Freedhoff, *Assistant Administrator, Office of Chemical Safety and Pollution Prevention*
Katie Paul Friedman, *Toxicologist, Center for Computational Toxicology and Exposure (CCTE)*
Louis “Gino” Scarano, *Senior Science Advisor, Office of Pollution Prevention and Toxics (OPPT)*

¹ [Final Draft NCCRP BOSC Agenda 10-4-22.pdf \(epa.gov\)](#)

Other EPA Attendees:

Stan Barone
Heidi Bethel
Veera Boddu
Mary "Lexie" Burns
Iris Camacho
Kelly Carstens
Jeff Dawson
Chad Deisenroth
Kathie Dionisio
Peter Egeghy
Logan Everett
Madison Feshuk

Maureen Gwinn
Mary Clare Hano
Alison Harrill
Joshua Harrill
Maria Hegstad
Kristin Isaacs
Samantha Jones
John Kenneke
Taylor Lass
David Lattier
Candice Lavelle
Elizabeth Owens

Mary Ross
Kate Saili
Risa Sayre
Raymond Smith
Russell Thomas
Meghan Tierney
Dan Villeneuve
John Wambaugh
Sean Watford
Douglas Young
Richard Zepp

Other Attendees:

Norman Adkins
Amy Clippinger
James Eggenschwiler
Cathy Eylem
Katherine Groff
Levi Howell
Elke Jensen
Lucinda B. Johnson

Richard Judson
Joseph Manuppello
Todd Martin
Andrew Nguyen
Askar Nurassilov
Johnson Nwakamma
Grace Patlewicz
Pat Rizzuto

Bridget Rogers
Amar Singh
Marissa Smith
Emily Sokol
Alexis Temkin
Anna van derZalm
Scarlett VanDyke
Antony Williams

Contractor Support:

Madison Lee
Denyse Marquez Sanchez
Emily Pak
Ashley Peppriell
Sheerin Shirajan
Janielle Vidal
Leah West
Sam Whately
Harry Whately