

U.S. Environmental Protection Agency Board of Scientific Counselors

Chemical Safety for Sustainability and Health and Environmental Risk Assessment Subcommittee

Virtual Meeting Summary

May 12-13, 27 and June 24, 2020

Dates and Times: May 12, 2020, 12:30 p.m. to 5:30 p.m.; May 13, 2020, 12:00 p.m. to 6:00 p.m.; May 27, 2020, 1:00 p.m. to 3:00 p.m.; June 24, 2020, 3:00 p.m. to 5:00 p.m. Eastern Time

Location: Virtual

Executive Summary

On May 12–13, 27, and June 24, 2020, the Environmental Protection Agency’s (EPA’s) Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability (CSS) and Health and Environmental Risk Assessment (HERA) Subcommittee (further referred to here as Subcommittee) convened in a virtual meeting. The goals of the two-day meeting and subsequent teleconferences were to hear an overview of the HERA program and research areas, discuss EPA’s response to preliminary Subcommittee comments on the HERA draft Strategic Research Action Plan (StRAP), hear StRAP perspectives from EPA’s program and regional office representatives and the primary Office of Research and Development’s (ORD’s) center director, and the Subcommittee’s review of the draft StRAP. The meeting format allowed for presentations, open dialogue, program feedback, Subcommittee deliberations and questions, and EPA responses to questions.

Day 1 consisted of presentations and discussions outlining the HERA program’s draft StRAP and discussions with EPA program and regional office representatives. Day 2 included presentations and discussion regarding the Center for Public Health and Environmental Assessment’s (CPHEA’s) perspective and various HERA program research areas. The teleconferences on May 27 and June 24 allowed the Subcommittee to draft a report responding to the charge questions.

Dr. Jennifer Orme-Zavaleta, ORD’s Principal Deputy Assistant Administrator for Science, thanked everyone for their flexibility to meet virtually due to Coronavirus Disease 2019 (COVID-19) gathering restrictions. She said ORD looks forward to receiving the Subcommittee’s input as it builds confidence in ORD’s produced research.

Overview of the HERA Research Program StRAP

Dr. Samantha Jones, National Program Director, HERA Research Program, provided an overview of the HERA program and its pivotal role within ORD. She explained that the HERA program purpose is to develop and apply state-of-the-science research to characterize impacts on human and ecological systems, whether they result from exposure to single, complex, or multiple physical, chemical, or biological stressors.

Dr. Jones emphasized how the HERA program aims to be scientifically robust, cohesive, and sufficiently flexible to enable product utilization with consideration to increase the speed, transparency, and access to program research. She then reviewed the HERA program structure

and how it divides into two topics and four research areas. Topic 1, focusing on “Science Assessment and Translation,” divides into Research Areas 1 and 2. Dr. Jones provided examples of ongoing work within Research Area 1 including the Integrated Science Assessments and the Integrated Risk Information System (IRIS).

Dr. Jones outlined how Topic 2, focusing on “Advancing the Science and Practice of Risk Assessment,” includes Research Areas 3 and 4. Specifically, she defined Research Area 3 as focusing on emerging and innovative assessment methodologies, and Research Area 4 as examining the essential assessment and infrastructure tools. She further clarified that the Subcommittee should focus on Research Areas 2, 3, and 4 and associated products.

Dr. Jones discussed the Subcommittees’ comments received during the 2019 consultation and noted that those early comments helped improve the StRAP clarity. One comment conveyed that the research areas and outputs aligned well. Another comment suggested the HERA program prioritize research around methods that could apply to mixtures, cumulative exposure, and epigenomic risk assessment approaches.

Subcommittee members and EPA staff then engaged in discussion on assorted topics, including chemical stressors, chemical prioritization, soil ingestion rates, and characterizing risk assessments.

Review of Charge Questions

Dr. Katrina Waters, chair of the Subcommittee, reiterated the Subcommittee’s task to review the HERA StRAP and the foundational research described in Research Areas 2–4. She reviewed the four Agency-provided charge questions. The Subcommittee formed four member workgroups to develop strengths, suggestions, and recommendations for each charge question. Dr. Waters also welcomed member input for charge questions outside of their workgroup.

Following their discussions in their workgroups, Subcommittee members reconvened and engaged with EPA staff in discussion. Topics discussed included external stakeholders, program vision versus strategic vision, and HERA’s interaction with other agencies.

Discussion with EPA Program and Regional Office Representatives

Representatives from various EPA programs and regional offices provided their perspective on the HERA program’s draft StRAP.

Dr. Kathleen Raffaele discussed the Office of Land and Emergency Management’s (OLEM’s) responsibility for Superfund and hazardous waste management sites and reliance on the HERA program’s technical support centers. She explained the importance of the HERA program’s research to develop toxicity values to aid OLEM’s risk assessment and risk management roles.

Ms. Betsy Behl, Science and Technical Director for the Office of Water (OW), said OW relies on the HERA program’s support under the Safe Drinking Water Act and Clean Water Act. Ms. Behl explained that OW benefits from the HERA program’s development of toxicity values and characterization tools for complex mixtures, specifically under the IRIS program and EPA’s Per- and Polyfluoroalkyl (PFAS) Action Plan.

Dr. Stanley Barone explained that the Office of Chemical Safety and Pollution Prevention (OCSPP) relies on the HERA program for the physiologically based pharmacokinetic (PBPK) and dose-response modeling workgroup. He commented on the HERA program's development of hazard identification and dose-response efforts which help the scoping effort under the Toxic Substances Control Act (TSCA). Dr. Barone explained the HERA program provides valued training to new and existing staff, which is essential as OCSPP increases staff load for TSCA risk evaluations.

Mr. Robert Hetes explained the Office of Air and Radiation's (OAR's) role and described the two offices within OAR (i.e., Office of Air Quality Planning and Standards, or OAQPS, and Office of Transportation and Air Quality, or OTAQ) and their interest in the IRIS program, as well as the Integrated Science Assessments (ISAs) that provide the human health scientific support for OAR's development of the National Ambient Air Quality Standards (NAAQS). Mr. Hetes recognized the HERA program's effort to reduce animal testing and develop a fit-for-purpose approach. He emphasized that OAR looks forward to further collaboration on the decision process to develop these products and continue adverse outcome pathway (AOP) advancements.

Dr. Carole Braverman, EPA Region 5, described her role as ORD's Regional Science Liaison. She discussed the HERA program's long history of regional office engagement. She also emphasized the HERA program's range of expertise and technical support and provided three examples from EPA's regional offices. She acknowledged the importance of training, emphasizing new approach methodologies (NAMs) translation.

Following program and regional office presentations, Subcommittee members engaged with EPA and program and regional office staff in discussion. Topics discussed included metrics, NAMs use, and potential case studies.

Center for Public Health and Environmental Assessment Perspective

Dr. Wayne Cascio, CPHEA Director, thanked the Subcommittee for sharing their time and expertise and noted that the center values their opinions.

CPHEA scientists engage across many programs, and the center handles 40 outputs across those programs. Of their engagement, 29 percent is within the HERA program. Dr. Cascio explained that the HERA program is housed within CPHEA, and CPHEA covers essentially 100 percent of the HERA portfolio. Approximately 80 percent of the HERA program devote resources to partner-driven, fit-for-purpose assessment products and translation and requisite infrastructure (i.e., tools, models, data, and training), and approximately 20 percent of those resources are related to methods development.

CPHEA expertise across all five divisions include exposure, toxicology, epidemiology, and modeling. Dr. Cascio noted that CPHEA can use their expertise through cross talk and collaboration between bench and field researchers and HERA program assessors. Data gaps found in assessment scoping and planning can inform research needs for other parts of the center.

Following the presentation, there were discussions about the integration of the CSS and HERA programs, the specific roles of CPHEA and the HERA program, and stakeholder communication.

Overview of the Research Areas in the Health and Environmental Risk Assessment Strategic Research Action Plan

Dr. Beth Owens, Principal Associate National Program Director, HERA Research Program, provided an overview of the HERA program's research areas. Research Area 1, Science Assessment Development, includes two outputs: a portfolio of interim assessment products to support decision-making (Output 1.1) and a portfolio of final assessment products to support decision-making (Output 1.2).

Dr. Owens explained that the HERA program developed Research Area 2, Science Assessment Translation, in response to the request for technical support in risk assessment. Research Area 2 has two outputs. Output 2.1 is technical support to EPA regions and states through the Superfund Health Risk Technical Support Center and the Ecological Risk Assessment Support Center, and Output 2.2, presented by CPHEA's Dr. Emma Lavoie, is core translational research modules for expert technical support.

Research Area 3 focuses on emerging and innovative assessment methodologies with goals to increase transparency and reduce uncertainty in assessment science and conclusions. Dr. Owens explained these enhancements and research will concentrate on enhancing hazard identification, expanding the repertoire of dose-response methods and models, and characterizing the utility of emerging data and new computational tools applied to risk assessment. CPHEA's Dr. Lucina Lizarraga, Dr. Kris Thayer, and Dr. Amanda Bernstein provided overviews of Research Area 3's outputs.

Research Area 4 enables the new or existing tool and database maintenance and development used in the assessment process. The research area will provide training on those resources and applications. CPHEA's Dr. James Brown and Dr. Jennifer Nichols outlined Research Area 4's outputs.

May 27 and June 24 Teleconferences

Each workgroup identified strengths, suggestions, and preliminary recommendations pertaining to the draft HERA StRAP and the provided charge questions. The Subcommittee discussed the preliminary strengths, suggestions, and recommendations of each workgroup with EPA staff. The recommendations and supporting suggestions would be reviewed and refined by the Subcommittee over the next month and finalized in a draft report to be reviewed at the BOSC Executive Committee meeting in July 2020.

Dr. Waters outlined the topics to include in the executive summary of the subcommittee report:

- Defining metrics for success and performing self-assessments
- Providing more detail on stakeholder and partner engagement
- Detailing the lack of clarity around the role of exposure science
- Providing clear connections between the CSS program, the HERA program, and their roles in NAMs development
- Prioritizing research on mixtures and cumulative risk assessment

Meeting Agenda and Other Meeting Materials

The [agenda](#)¹, [charge questions](#)², and other meeting materials can be accessed at <https://www.epa.gov/bosc/chemical-safety-sustainability-health-and-environmental-risk-assessment-subcommittee-may-2020>.

Meeting Participants

BOSC Chemical Safety for Sustainability and Health and Environmental Risk Assessment Subcommittee Members:

Katrina Waters, *Chair*
James Stevens, *Vice Chair***
Anthony Bahinski***
Richard Becker
Juan Colberg
Paul Gilman*
Richard Di Giulio
Chris Gennings
Dale Johnson
Daland Juberg
Juleen Lam
Timothy Malloy
Jennifer McPartland
Jane Rose
Gina Solomon
Ponisseril Somasundaran
Donna Vorhees
Clifford Weisel
Mark Wiesner**

**BOSC Executive Committee Chair*

*** did not attend June 24*

****did not attend May 27 or June 24*

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

EPA Presenters:

Stan Barone, *Office of Chemical Safety and Pollution Prevention*
Betsy Behl, *Office of Water*

¹ https://www.epa.gov/sites/production/files/2020-05/documents/agenda_bosc_review_of_hera_strap_may_2020_3.pdf

² https://www.epa.gov/sites/production/files/2020-06/documents/hera_strap_charge_questions_for_bosc_review_may2020.pdf

Amanda Bernstein, *Post-Doctoral Fellow, Oak Ridge Institute for Science and Education, Center for Public Health and Environmental Assessment*
 Carole Braverman, *EPA Region 5*
 James Brown, *Senior Health Scientist, Center for Public Health and Environmental Assessment/Health and Environmental Effects Assessment Division*
 Wayne Cascio, *Director, Center for Public Health and Environmental Assessment*
 Robert Hetes, *Office of Air and Radiation*
 Samantha Jones, *National Program Director, Health and Environmental Risk Assessment Research Program*
 Emma Lavoie, *Senior Advisor, Center for Public Health and Environmental Assessment*
 Lucina Lizarraga, *Center for Public Health and Environmental Assessment/Chemical and Pollutant Assessment Division*
 Jennifer Nichols, *Senior Advisor for Program Management and Coordination, Center for Public Health and Environmental Assessment/Health and Environmental Effects Assessment Division*
 Jennifer Orme-Zavaleta, *Principal Deputy Assistant Administrator for Science, Office of Research and Development*
 Beth Owens, *Principal Associate National Program Director, Health and Environmental Risk Assessment Research Program*
 Kathleen Raffaele, *Office of Land and Emergency Management*
 Kris Thayer, *Director, Center for Public Health and Environmental Assessment/Chemical and Pollutant Assessment Division*

Other EPA Attendees:

James Avery	Megan Fleming	Xiaoyu Liu	Kathryn Saterson
Tina Bahadori	Stiven Foster	Christine Lloyd	Paul Schlosser
Cal Baier-Anderson	Jeff Frithsen	Mario Mangino	Jane Ellen
Andrea Bartolotti	Jeff Gift	Carl Mazza	Simmons
Harry Beller	Barbara Glenn	Viktor Morozov	Vicki Soto
Michael Beuthe	Rick Greene	Michelle Muska	Michele Taylor
David Bussard	Andrew Hotchkiss	Tim O'Farrell	Salina Tesfay
Anna Champlin	Bryan Hubbell	Kelly O'Neal	Joe Tietge
Lou D'Amico	Scott Jenkins	Amina Pollard	John Vandenberg
Kacee Deener	Lindsey Jones	Elizabeth Radke	Kelly Widener
Chris Dockins	Dustin Kapraun	Santhini Ramasamy	Ashlei Williams
David Dunlap	Stephanie Kim	Bruce Rodan	Richard Zepp
Steve Dutton	Andrew Kraft	Mary Ross	Todd Zurlinden
Rebecca Dzubow	David Kryak	William Russo	

Other Attendees:

Erik Anderson	Robert Janssen	Mangala Nanthakumar	Nathan Smith
David Bottimore	Michelle Le	Rebecca Shoji	Boyce Wofford
Steve Covell	David Lipsky	Tom Sim	Linda Wilson

Yvonne Gray

Chris Moody

David Smith

Contractor Support (ICF):

Canden Byrd

Blake Riley

Amy Scheuer

Catherine Smith