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


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*

---


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 Simmons
Andrea Bartolotti  Jeff Gift  Carl Mazza  Vicki Soto
Harry Beller  Barbara Glenn  Viktor Morozov  Michele Taylor
Michael Beuthe  Rick Greene  Michelle Muska  Salina Tesfay
David Bussard  Andrew Hotchkiss  Tim O’Farrell  Joe Tietge
Anna Champlin  Bryan Hubbell  Kelly O’Neal  John Vandenberg
Lou D’Amico  Scott Jenkins  Amina Pollard  Kelly Widener
Kacee Deener  Lindsey Jones  Elizabeth Radke  Richard Zepp
Chris Dockins  Dustin Kapraun  Santhini Ramasamy  Ashley Williams
David Dunlap  Stephanie Kim  Bruce Rodan  Todd Zurlinden
Steve Dutton  Andrew Kraft  Mary Ross  Rebecca Dzubow
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