

**EPA BOSC CSS/HERA Subcommittee
HERA Draft Report
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CSS/HERA Subcommittee

Health and Environmental Risk Assessment Subcommittee

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Review Focus and Logistics

- The CSS StRAP was reviewed last year, so this review was focused only on the HERA StRAP.
- Provide input on the draft 2019–2022 HERA StRAP document and the foundational research that underpins HERA’s vision to advance the science and practices of risk assessment to support EPA programs and regions, states and tribes.
- Meeting was held virtually on May 12-13, 2020
- Given the complementary nature of the CSS and HERA missions, the review considered potential areas of intersection and synergy in research activities.

HERA Mission and Vision

- **Renamed:** The name was changed from Human Health Risk Assessment (HHRA) to HERA to better reflect the breadth of the program, which includes environmental assessments such as those presented in the Integrated Science Assessments for secondary National Ambient Air Quality Standards.
- **Mission:** The HERA National Research Program is designed to develop and apply state-of-the-science research to characterize the impacts on human and ecological systems from exposure to single, complex, or multiple physical, chemical, or biological stressors. The program provides science assessments and research advancing the science and practice of risk assessment.
- **Vision:** HERA will provide priority assessment products, identify critical science issues as they arise, and facilitate advances in approaches to address emerging challenges, incorporate innovations, and continuously refine applications. The goal of the HERA research program is to ensure that decisions by EPA are based on reliable, transparent, and high-quality risk assessment methods, models, and data.

HERA StRAP 2019–2022 Research Objectives

- **The Science Assessments and Translation topic** provides scientific and technical support from development to application of assessment products, throughout the lifecycle of the Agency decision. Emphasis is placed on providing high quality, state-of-the-science, transparent, consistent, and scientifically defensible assessment products to meet EPA's diverse statutory and policy needs, and to address requests from EPA programs and regions, states, and tribes for technical support and consultation.
- **The Advancing the Science and Practice of Risk Assessment topic** focuses on scientific innovations to advance analytic approaches and applications for assessments to improve the accuracy, efficiency, flexibility, and utility of assessment activities served by the HERA program. Emphasis is placed on enhancing hazard characterization, expanding the repertoire of dose-response methods and models, and characterizing the utility of emerging data and new computational tools as applied to risk assessment. It also enhances and maintains critical assessment infrastructure, including databases, models, and software support.

HERA's Research Program is organized around 2 topics with 4 research areas

Topics	Research Areas
Science Assessments and Translation	1. Science Assessment Development
	2. Science Assessment Translation
Advancing the Science and Practice of Risk Assessment	3. Emerging and Innovative Assessment Methodologies
	4. Essential Assessment and Infrastructure Tools

Derived from Table 2, HERA Draft StRAP

Charge Questions

- **Question 1a.** Please comment on the extent to which the research outlined for the 2019-2022 timeframe supports the relevant Agency priorities as described in the EPA and ORD Strategic Plans?
- **Question 1b.** Each ORD research program undertook a rigorous engagement process to provide additional detail on specific EPA program and region, state, and tribal needs, the results of which are summarized in introductory sections, descriptions of specific research topics, and appendices. How well does the proposed foundational research program respond to these identified needs?
- **Question 1c:** Does the StRAP, including the topics, research areas, and proposed outputs, clearly describe the strategic vision of the program? Please comment on the extent to which the StRAP provides a coherent structure toward making progress on the strategic vision in the 2019-2022 timeframe.
- **Question 1d:** Recognizing ORD's focus on addressing identified Agency, state, and tribal research needs, are there any prioritization considerations, other critical emerging foundational research needs, or fields of expertise and/or new research methods, where this program should consider investing resources?

General Observations

- HERA's research topics clearly support the goals of the EPA and ORD strategic plans and close coordination with EPA programs was evident.
- The overall structure of the research areas, and outputs will advance the science and practice of hazard and risk assessment, however there was insufficient detail on the implementation plan.
- A consistent theme was the lack of metrics to define progress toward specific research outputs and a process for developing performance measurements and self-assessments.
- Coordination of common research areas with CSS was not evident.
- Despite previous review comments to develop a coherent strategy to assess the cumulative risk of mixtures, it was surprisingly absent.

Q.1a: Please comment on the extent to which the research outlined for the 2019-2022 timeframe supports the relevant Agency priorities as described in the EPA and ORD Strategic Plans?

The Subcommittee considered the HERA research program well-aligned with goals of EPA and ORD strategic plans. The Subcommittee offers the following recommendations to support relevant Agency priorities.

- **Recommendation 1a.1:** The BOSC recommends including specific actions for enhancing opportunities for public participation and transparency in (a) the development, performance assessment, and applications of new and improved methods, and (b) the development of HERA strategic plans.
- **Recommendation 1a.2:** The BOSC recommends that a work force development and training program strategy connected with research mission should be further articulated in the StRAP. Particular emphasis should describe the integration of advanced and emerging bioactivity profiling methods using weight of evidence assessment methodologies for hazard characterization and risk evaluation.
- **Recommendation 1a.3:** The BOSC recommends that HERA should provide yearly updates on progress made in, and challenges arising from, collaborations with CSS, including impacts on deliverables. The BOSC also recommends that HERA more clearly delineate the roles and responsibilities within and outside HERA that are necessary to deliver projects and how these inter-Agency collaborations and resources are integrated.

Q.1b. Each ORD research program undertook a rigorous engagement process to provide additional detail on specific EPA program and region, state, and tribal needs, the results of which are summarized in introductory sections, descriptions of specific research topics, and appendices. How well does the proposed foundational research program respond to these identified needs?

The Subcommittee considered the engagement of EPA Program offices to be very strong as evidenced by presentations during the meeting, however there was little evidence of engagement with States and tribes. The Subcommittee offers the following recommendations to identify and respond to partner and stakeholder research needs.

- **Recommendation 1b.1:** For future StRAPs, the BOSC recommends developing a deliberate partner and stakeholder engagement plan that details the process that will be undertaken to identify needs, recognizing that priorities and needs may shift over time. HERA should seek guidance from partners as to how they would like to be included in the research planning process and then tailor the plan as needed to specific partner groups. This will be critical for the implementation process.
- **Recommendation 1b.2:** For the current StRAP, the BOSC recommends developing a deliberate partner engagement plan for the purpose of soliciting feedback from partners regarding implementation of the HERA StRAP. This will help to ensure that the implementation is meeting the identified needs and will help to enable mid-course corrections, if necessary.

Q.1c. Does the StRAP, including the topics, research areas, and proposed outputs, clearly describe the strategic vision of the program? Please comment on the extent to which the StRAP provides a coherent structure toward making progress on the strategic vision in the 2019-2022 timeframe.

The Subcommittee offers the following recommendations to more clearly and coherently describe the research agenda of HERA in the current StRAP and future StRAPs.

- **Recommendation 1c.1:** The BOSC recommends significant improvements to the StRAP documents to provide additional clarity on the specific projects and deliverables associated with its various research outputs as well as metrics for benchmarking progress and success.
- **Recommendation 1c.2:** The BOSC has previously recommended that HERA develop methods to evaluate mixtures. Given the complexity of the topic, the BOSC recommends that HERA develop a coherent strategy for evaluating co-exposures to chemical mixtures, specifically going beyond homogeneous mixtures (e.g. PAHs) and including cumulative risk assessment.
- **Recommendation 1c.3:** The BOSC recommends that HERA consider implications relating to exposures to susceptible populations in its research activities, including factors such as genetic variability, cumulative stressors, and variability related to age, health status, pregnancy, and other population-level factors.
- **Recommendation 1c.4:** The BOSC recommends that HERA should define how exposure science will be incorporated into risk assessment, and its role in advancing this aspect of exposure science including specific HERA roles and responsibilities and collaborations within ORD and with EPA Program Offices, EPA regions, states, and tribes.

Q.1d: Recognizing ORD's focus on addressing identified Agency, state, and tribal research needs, are there any prioritization considerations, other critical emerging foundational research needs, or fields of expertise and/or new research methods, where this program should consider investing resources?

The Subcommittee felt that HERA should consider implementing a process for identifying emerging environmental issues, such as microplastics, for timely integration with research programs. The Subcommittee offers these recommendations to address emerging issues and technologies.

- **Recommendation 1d.1:** The BOSC recommends that HERA increase training opportunities for the development and use of new approach methodologies in order to better understand the concerns in replacing current approaches with new data and communicate their utility and uncertainties.
- **Recommendation 1d.2:** The BOSC recommends that HERA incorporate considerations relevant to combined exposures to chemical mixtures and other stressors (non-chemical, physical and/or biological agents) consistently throughout their research and assessment activities, including a specific initiative to achieve this objective, as stated in the StRAP.
- **Recommendation 1d.3:** If HERA has constraints on internal research personnel and/or resources to address new research needs or methods, the BOSC recommends that HERA should consider other funding mechanisms, e.g., STAR grants, to be able to access the capabilities of collaborators.

Conclusions

- The Subcommittee believes that the HERA StRAP articulates research areas and outputs that are appropriate and advance the science and practice of hazard and risk assessment. These activities could be enhanced by development of metrics for evaluating their success.
- The technical support offered to EPA programs and regions are well connected with EPA's goals to protect and enhance health and the environment.
- The Subcommittee looks forward to hearing more details of the implementation strategy and continuing to serve as a resource to HERA for improvements to the scientific and strategic topics related to the research program.