

Office of Research and Development

Health and Environmental Risk Assessment



Health and Environmental Risk Assessment (HERA) National Research Program

Board of Scientific Counselors (BOSC) CSS-HERA Subcommittee

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Health and Environmental Risk Assessment



Introduction



EPA Research

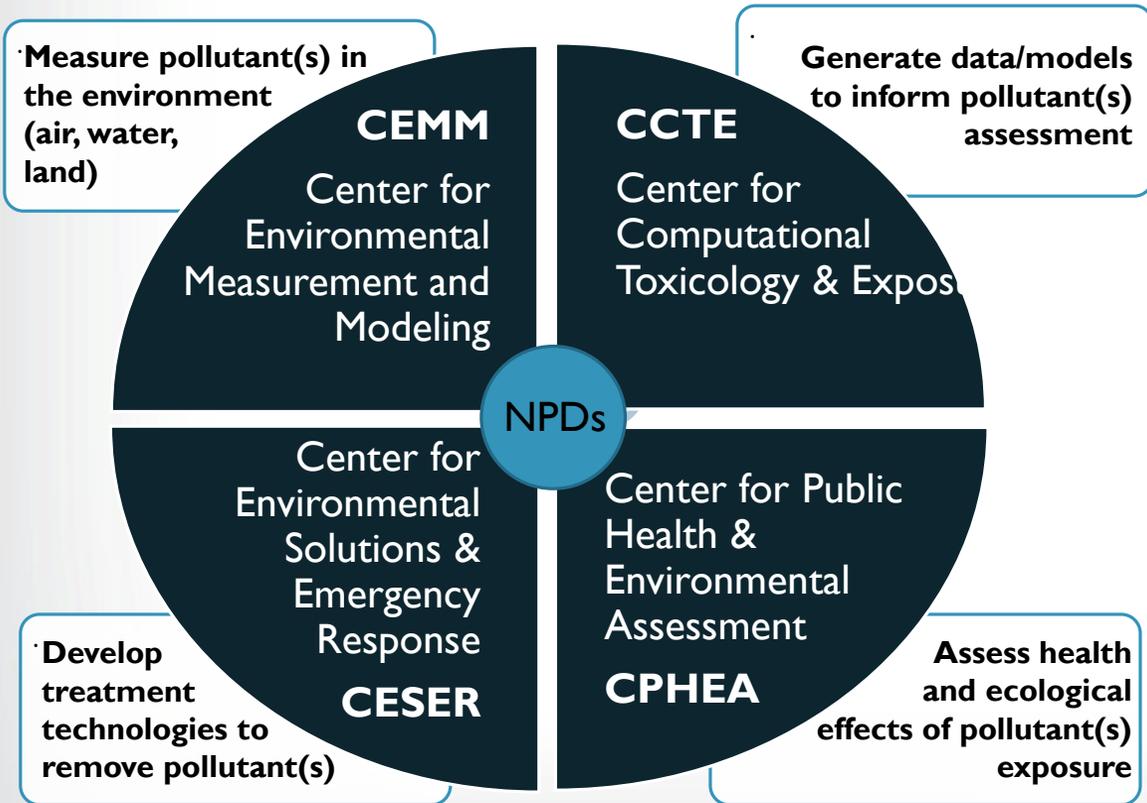
ORD provides the scientific foundation for EPA to execute its mandate to protect human health and the environment.

- **Research to Inform Agency Priorities** – Conduct innovative and anticipatory research to solve longer-term environmental challenges and provide the scientific basis for future environmental protection. This research is applied to the range of EPA program and regional office needs.
- **Targeted Research to Meet Statutory Requirements and Specific Environmental Challenges** – Provide research support to EPA program and regional offices, as well as states, tribes, and local communities, to help them respond to current environmental challenges.
- **Scientific and Technical Support** – Offer unique expertise and translational capacity to assist EPA programs and regions, local, state, and tribal governments, and other Federal agencies as they respond to both emergency and longer-term environmental issues.



Office of Research and Development (ORD)

Organizational structure is designed to enhance our scientific leadership, better integrate scientific approaches to problems, support mission and partner focused solutions, create communities of practice, and align the size and structure to optimize the use of our workforce.



HERA



Wayne Cascio



Kay Holt

HERA



Clean Air Act (CAA)

Safe Drinking Water Act (SDWA)

Clean Water Act (CWA)

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

Superfund Amendments and Reauthorization Act (SARA)

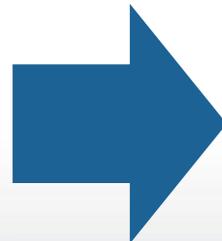
Resource Conservation and Recovery Act (RCRA)

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

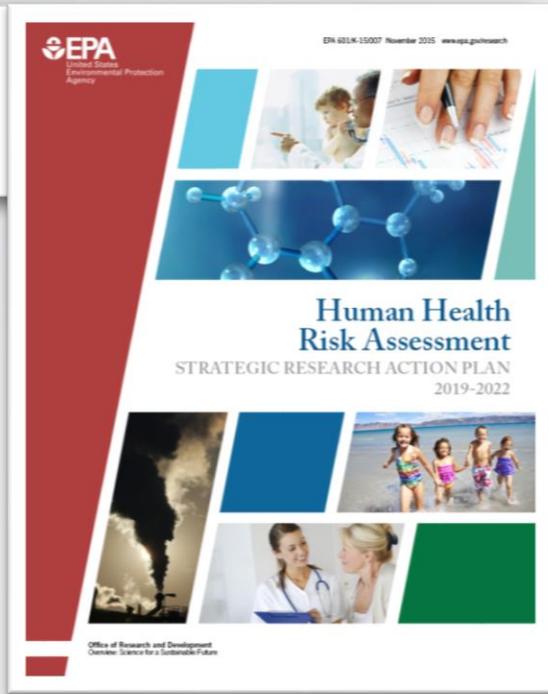
Toxic Substances Control Act (TSCA)



**Broad
Input to
Support**



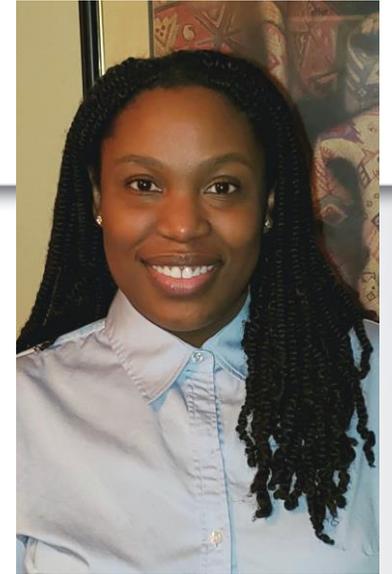
- Agency and ORD Strategic Goals
- Children's Health
- Environmental Justice



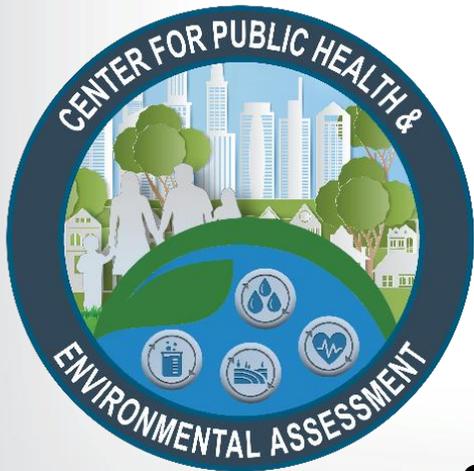
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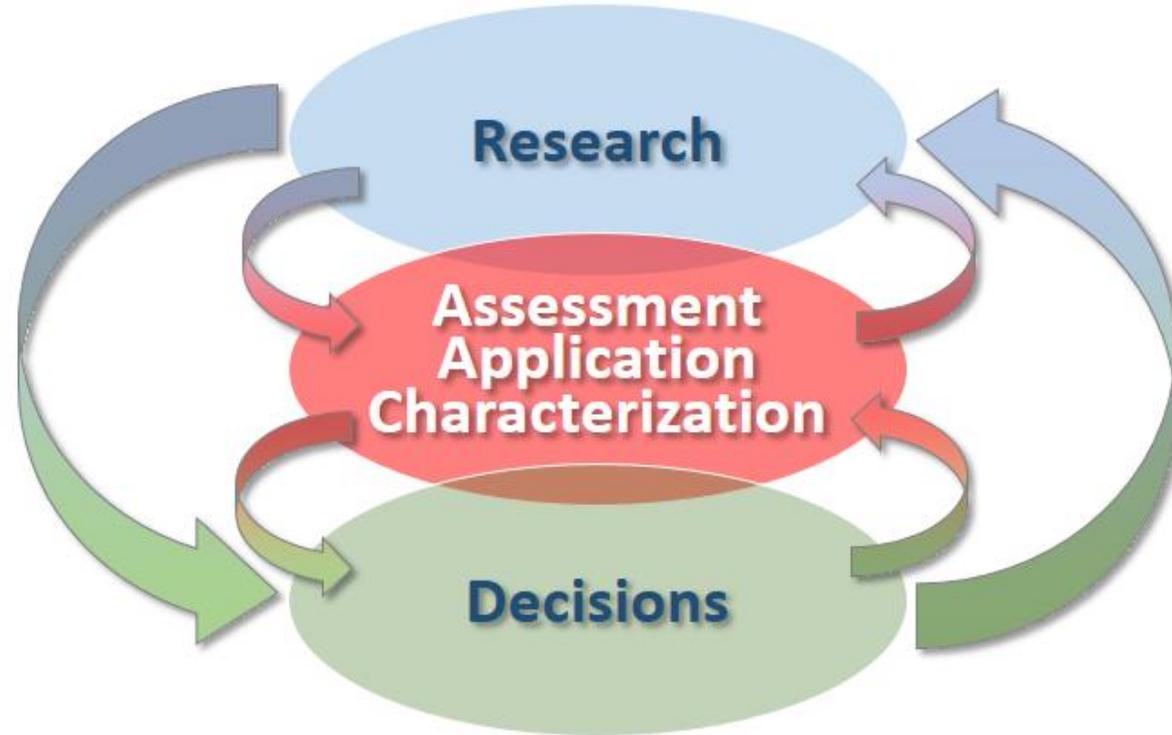
Samantha Jones
NPD



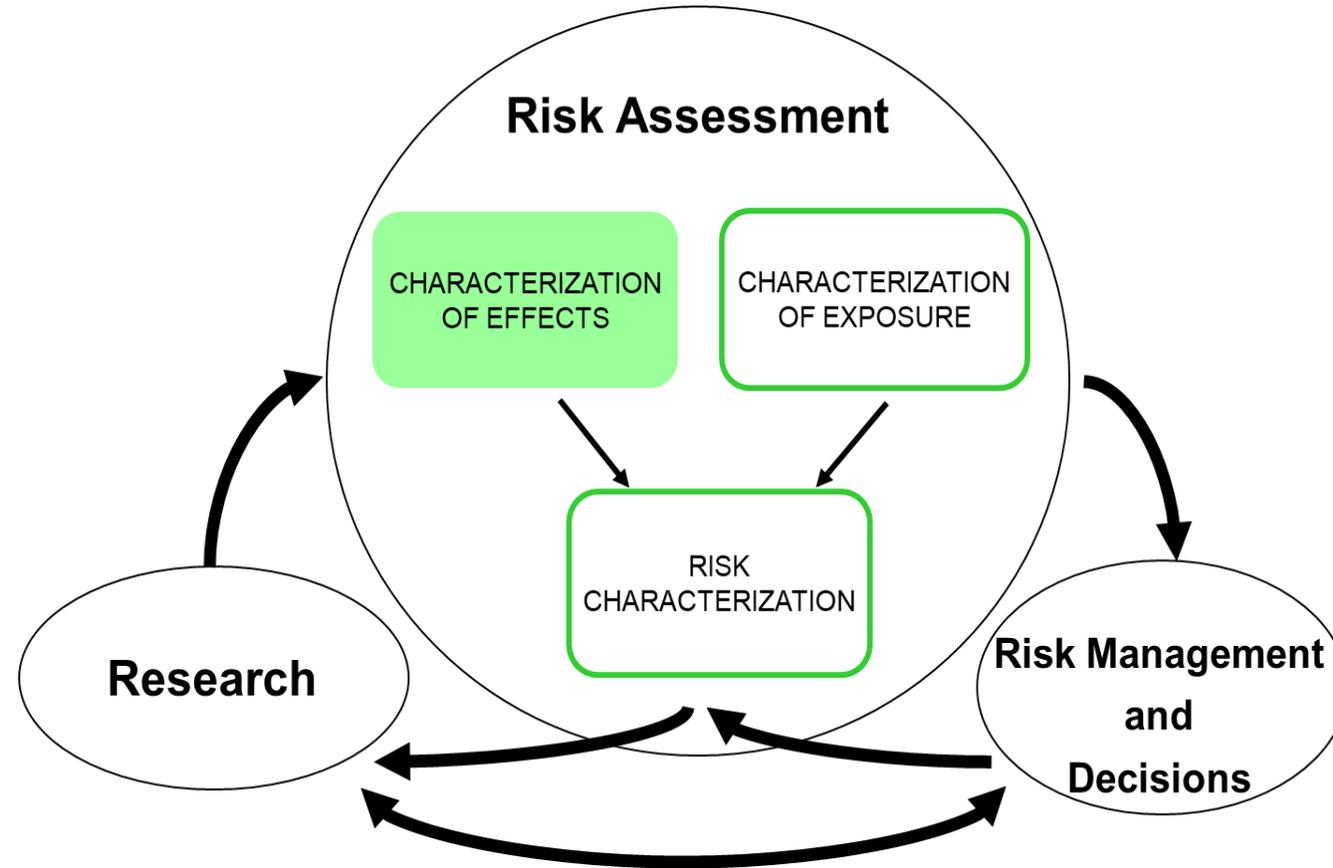
Quinn Weinberger
Associate



Alexa Moore
Associate



Risk-based decisions by the EPA, state/local/tribal agencies and the public to protect public health and the environment are based on reliable, transparent and high-quality assessment methods, models, and data.



The purpose of the HERA program is to develop and apply state-of-the-science research to characterize the impacts on human and ecological systems, whether they result from exposure to single, complex, or multiple physical, chemical, or biological stressors, to support and improve EPA's environmental decisions.

To innovate and advance the science and practice of assessments

By developing a portfolio of fit-for-purpose human health and environmental assessment products and assessment research that meet the needs and priorities of EPA programs and regions, states, tribes, and external stakeholders.

Health and Environmental Risk Assessment



Structure and Approach

Designed to develop and apply state-of-the-science research to characterize the impacts on human and ecological systems whether they result from exposure to single, complex, or multiple physical, chemical, or biological stressors, to support and improve EPA's environmental decisions.

- Designed to no longer be compartmentalized; science and practice of assessment are intentionally interwoven throughout.
- Combines primary assessment products under Research Area I to enable an integrated approach to planning and development instead of a siloed product line perspective.
- More explicitly considers underlying steps of assessment, regardless of the topic(s) or scientific discipline(s).
 - Scoping and problem formulation, identification of evidence (literature search and screening), study evaluation and data extraction, analysis, evidence integration, and presentation of conclusions.
- Program is structured to facilitate efficient construction and production of high quality, scientifically defensible, and contemporary assessments with evolving technologies and science.



HERA Structure

Topic	Research Area
Science Assessments & 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



HERA Program

- Aspires to be nimble to ensure delivery of timely and responsive products.
- Moving away from a ‘one-size-fits-all’ assessment approach.
- Enabling a portfolio of assessment products to better tailor research to meet the needs of decision-makers.
- Providing scientific and technical support throughout the lifecycle of the decision.
- Expanding and improving approaches.
- Facilitating the incorporation of new science in to risk assessment and decision-making.
- Maintaining and improving critical assessment infrastructure and facilitating understanding and engagement.

HERA aims to be scientifically robust, cohesive, and sufficiently flexible to enable utilization of its products with consideration to increase the speed, transparency, and access to program research.



Topic I – Science Assessments and Translation



Science Assessments and Translation

Science Assessment Development		Science Assessment Translation	
Research Area 1	<p>Focused on producing high quality, transparent, consistent, and scientifically defensible assessment products to meet EPA’s diverse statutory and policy needs.</p> <p>*Priorities come from Congress and EPA program offices; peer reviewed by groups such as NAS, SAB, CASAC.</p>	The range of tailored support activities, modules, and applications developed to address the requests from EPA program and regional offices, states, and tribes for technical support and consultations.	Research Area 2

The Integrated Science Assessments



- Concise evaluation and synthesis of the most policy-relevant science supporting the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards.
- ISA provides the scientific foundation for:
 - Risk and Exposure Assessment (REA), if warranted, and Policy Assessment (PA) developed by OAR/OAQPS
 - Agency decisions as reflected in proposed and final NAAQS rulemaking.
- Dig deeper at <https://www.epa.gov/isa>

Integrated Risk Information System



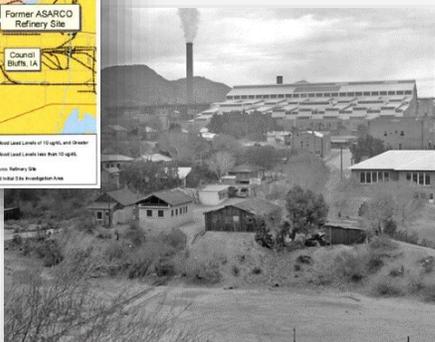
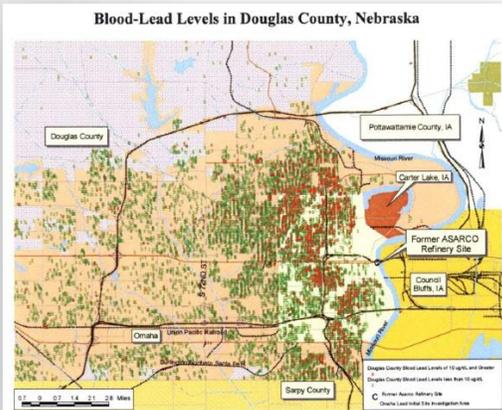
- Provides scientific positions on potential adverse health effects that may result from exposure to substances found in the environment.
- Derives toxicity values
 - Noncancer: Reference Doses (RfDs) and Reference Concentrations (RfCs).
 - Cancer: Oral Slope Factors (OSFs) and Inhalation Unit Risks (IURs).
- Used by:

<ul style="list-style-type: none"> ○ EPA program and regional offices. ○ State and local health agencies. 	<ul style="list-style-type: none"> ○ Other federal agencies. ○ International health agencies.
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- Dig deeper at <https://www.epa.gov/iris>



Research Area 2 – Science Assessment Translation

- Superfund Health Risk Technical Support Center (STSC) is one of the five ORD Technical Support Centers.
- STSC provides scientific technical support in the area of human health risk assessment to OLEM, state, and regional partners.



- Long history of responsive and effective technical engagement with programs/regions, states, tribes, other federal agencies, international entities, and the scientific community.
- HERA is building on the existing technical support infrastructure by developing tools and approaches that will increase readiness to respond efficiently when needs are identified.



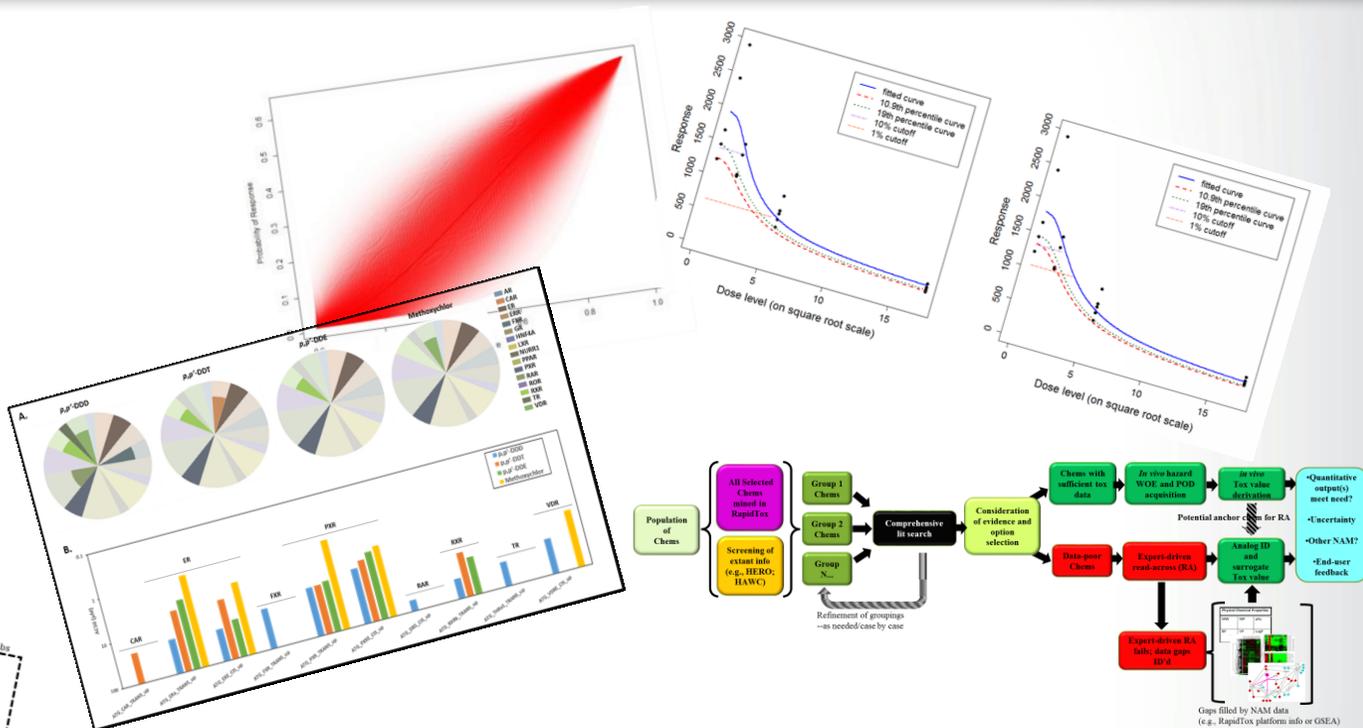
Topic 2 – Advancing the Science and Practice of Risk Assessment



Advancing the Science and Practice of Risk Assessment

Research Area 3	Emerging and Innovative Assessment Methodologies	Essential Assessment and Infrastructure Tools	Research Area 4
	<p>Focused on incorporating new and innovative methodologies in predictive toxicology, rapid evidence evaluation, systematic review, and toxicokinetic and dose-response modeling across a landscape of decision contexts and assessment products</p>	<p>Supports maintenance and development of new and existing tools and databases used in the assessment process and provides training on such tools and resources to stakeholders</p>	

- Focus on evaluating and optimizing the integration of existing, new, and emerging data streams, techniques, models, tools, or other methodologies for practical implementation in assessing human and environmental health.
 - New approach methods (NAMs) and data
 - Rapid assessment methodologies
 - Pharmacokinetics
 - Systematic review
 - Dose-response modeling



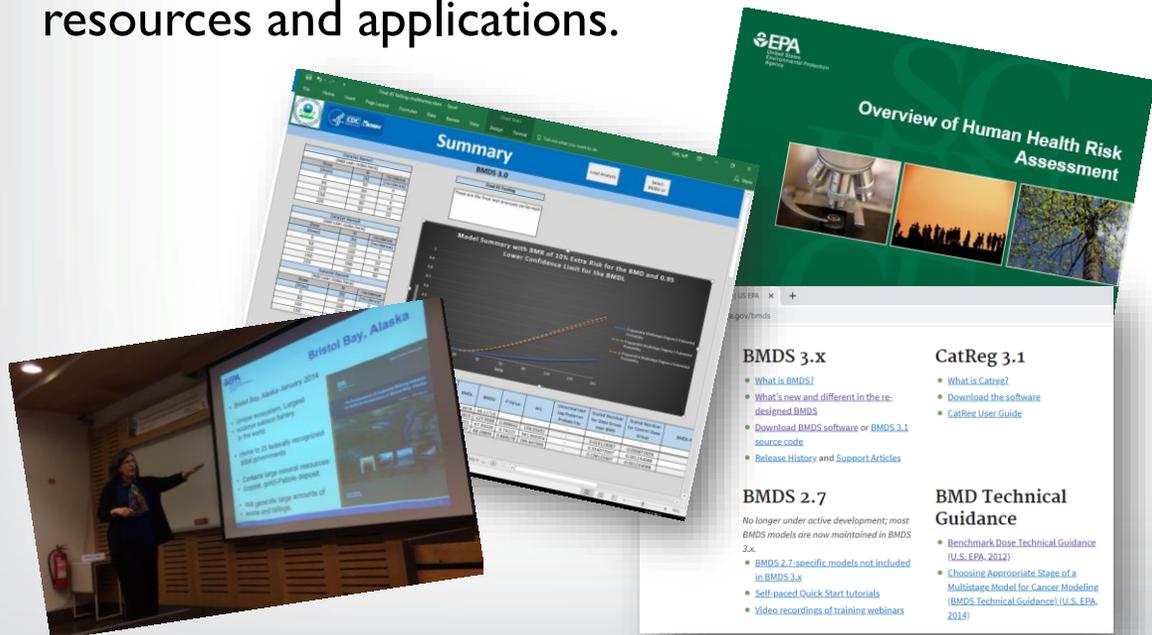
	acute single dose	single dose	short-term 7 d 10 doses	
Developmental				
Gastrointestinal	1	1		
Hematologic		1		
Hepatic			1	
Immune		1		
Metabolic		1		
Nervous			1	
Renal	1	1	1	
Reproductive				1
Respiratory	1			1
Systemic/Whole Body	1	1	1	1
Grand Total	1	1	1	4

- Anchored in assessment development.
- Improve the accuracy, efficiency, flexibility, and utility of applications across the large landscape of assessment activities served by the HERA program.



Research Area 4 – Essential Assessment and Infrastructure Tools

- Delivering state-of-the-science assessment products requires the use of software and database tools to provide the necessary infrastructure.
- Enables the maintenance and development of new or existing tools and databases used in the assessment process and provides training on these resources and applications.



- Allows for:
 - efficient and transparent assessment development under systematic review methodologies.
 - broader sharing of assessment materials, products, and practices with others with common interests in assessments.
 - transparent engagement by increasing and accelerating end-user understanding of HERA tools and concepts.
 - integrate HERA products with the CSS program dashboards and computational tools.

Health and Environmental Risk Assessment



BOSC Comments - 2019 Consultation



BOSC Comments related to Overarching Program

- Research Areas and Outputs align well.
- Prioritize research on methods that could apply to mixtures or cumulative exposure and toxicity as well as epigenomic risk assessment approaches.
- Continue to develop and institutionalize workflows that are problem-formulation driven and fit-for-purpose for strong alignment of HERA applied research with specific decision contexts.
- Clarify the scope of HERA research as it relates to risk assessment and the exposure and toxicity data that informs such assessments.
- Describe how integration of health and ecological assessments will occur.

- Research Area 1
 - Portfolio approach of tailoring product to question rather than one-size-fits-all assessments is a step forward.
 - Interagency coordination on evaluation of individual and groups of chemicals that fall across agency purviews.

- Research Area 2
 - Value of expertise and products to EPA partners and stakeholders is tangible evidence (SF technical support centers and other tech support) of HERA serving needs.
 - Recommend analyzing requests that come in to identify areas of need in furtherance of science challenges.

- Research Area 3
 - Continue increasing efficiency and transparency with systematic review advancements (machine learning, open source software).
 - Progress on developing systematic review methods is impressive and recommend continuing with some focus on assessing risk of bias and mechanistic studies.

- Research Area 4
 - Education on application of systematic review (SR) in environmental health is commendable and should be continued and further strengthened.
 - Training and engagement further develop to build up vision.

Health and Environmental Risk Assessment

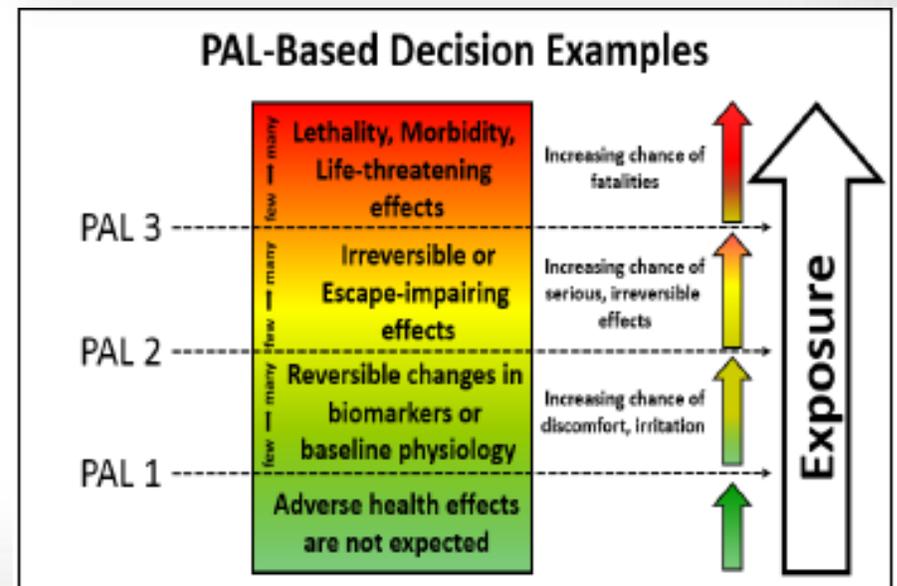


**Collaboration across ORD
and Connections to CSS**

- Ranges from formal integration to collaboration among EPA scientists working on related issues.
- Cross-ORD Strategic areas allow for coordinated efforts across Programs.
 - PFAS
 - Lead
- Engagement across Agency allows for coordination with other offices
 - Children's health
 - Environmental justice



- Share responsibility for providing reliable and timely chemical hazard information to ensure communities can respond to emergency threats.
- Provisional Advisory Levels
 - emerging fit-for-purpose assessment product
 - support risk-based site-specific decisions during emergency response incidents that can aid in making critical decisions on site access



Continuum of research and assessment to inform Agency activities related to chemicals

- Use and population of chemicals information to and from the Chemicals Dashboard throughout assessment product development (HERA Outputs 1.1/1.2 and 3.2).
- Coordinated and collaborative research to advance, translate, and build confidence in the application of new approach methods (NAMs) and data in risk assessment (HERA Output 3.1).

Perfluorobutanesulfonic acid
375-73-5 | DTXSID5030030
Searched by DSSTox Substance Id.

Quantitative Risk Assessment Values

- No IRIS values
- PPRTV values available
- EPA RSL values available
- Minimum RID: 0.020 mg/kg-day (chronic, PPRTV (ORNL), oral, 8)
- No RIC calculated
- IVIVE POD not calculated

Quantitative Hazard Values

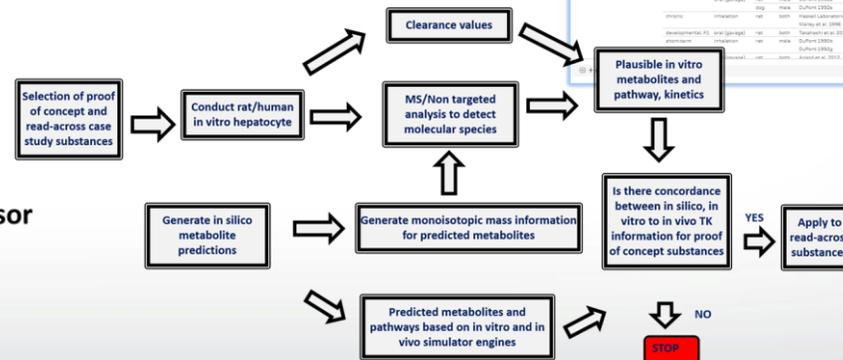
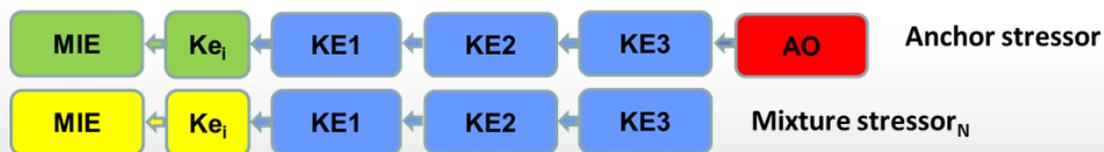
- Minimum oral POD: 19 mg/kg-day (subchronic, PPRTV (ORNL), oral, 8)
- No inhalation POD values
- No ToxCast data

Cancer Information

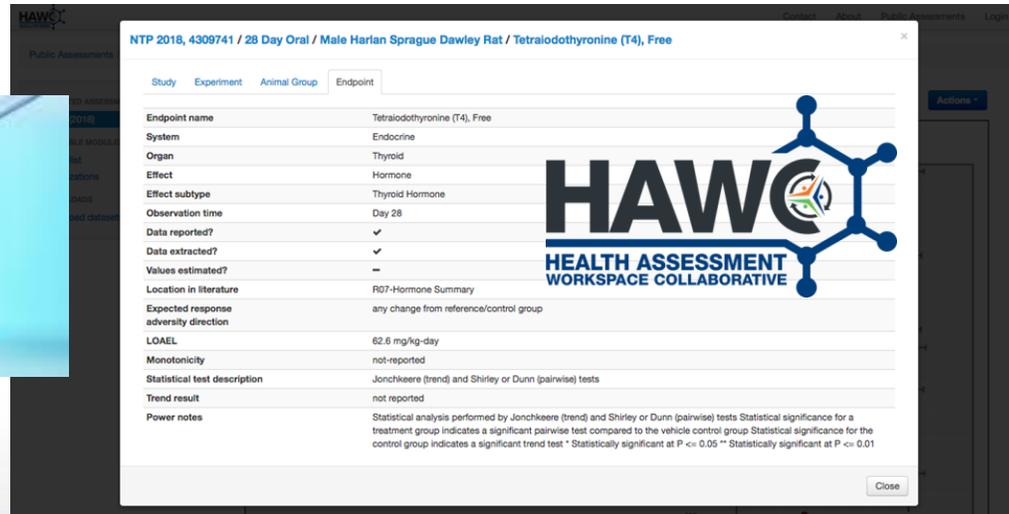
- No cancer slope factor
- No inhalation unit risk value
- No cancer findings reported
- No genotoxicity findings reported

Reproductive Toxicology

- No reproductive toxicity data available.



- Joint development of the RapidTox Dashboard, including the underlying workflows and application considerations (HERA Output 3.2).
- Evaluate application and appropriate uncertainty associated with the range of pharmacokinetic models and data (including HTTK and IVIVE) (HERA Output 3.3).
- Harmonize HERA infrastructure with the CSS dashboards and computational tools (HERA Output 4.1).



NTP 2018, 4309741 / 28 Day Oral / Male Harlan Sprague Dawley Rat / Tetraiodothyronine (T4), Free

Study	Experiment	Animal Group	Endpoint
Endpoint name: Tetraiodothyronine (T4), Free			
System: Endocrine			
Organ: Thyroid			
Effect: Hormone			
Effect subtype: Thyroid Hormone			
Observation time: Day 28			
Data reported?: <input checked="" type="checkbox"/>			
Data extracted?: <input checked="" type="checkbox"/>			
Values estimated?: <input type="checkbox"/>			
Location in literature: R07-Hormone Summary			
Expected response adversity direction: any change from reference/control group			
LOAEL: 62.6 mg/kg-day			
Monotonicity: not-reported			
Statistical test description: Jonckheere (trend) and Shirley or Dunn (pairwise) tests			
Trend result: not reported			
Power notes: Statistical analysis performed by Jonckheere (trend) and Shirley or Dunn (pairwise) tests. Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group. Statistical significance for the control group indicates a significant trend test. * Statistically significant at $P <= 0.05$ ** Statistically significant at $P <= 0.01$			

HAWC
HEALTH ASSESSMENT
WORKSPACE COLLABORATIVE



HERA is committed to advancing risk assessment by:

- Streamlining program to focus on key overarching research areas.
- Increasing alignment with priorities of the Agency to provide the tailored assessment products and scientific and technical support needed.
- Enhancing the application of best practices and automation and computational tools to promote greater throughput and higher productivity overall.
- Investing in advancements in the science and practice of risk assessment that are anchored in assessment development.
- Continuing to ensure that the research remains solutions-focused and driven by the priority needs.
- Producing fit-for-purpose assessment products that are reliable, decision-relevant, state-of-the-science, transparent, and high-quality to advance risk assessment methods and increase confidence in the application of science to support critical decisions to characterize potential impacts to human health and the environment.



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- OEJ – Matthew Tejada, Onyemaechi Nweke

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THANK YOU!