

HUMAN HEALTH RISK ASSESSMENT

Background

Every day, the U.S. Environmental Protection Agency (EPA) must make decisions about environmental pollutants that impact human health and the environment. There are currently more than 80,000 chemicals in commerce, and more are introduced each year. Only a small fraction of these chemicals have been adequately assessed for potential risk, often because of limits in existing data, tools, and resources.

The Human Health Risk Assessment (HHRA) research program helps address this problem by providing state-of-the-science products in support of risk assessment. Examples of HHRA products include independently peer reviewed human health assessments for individual chemicals and chemical mixtures; integrated science assessments for criteria air pollutants; rapid risk assessments and technical support to meet partner and stakeholder needs; and tools to modernize human health risk assessment.

HHRA products provide a critical part of the scientific foundation for much of EPA's decision-making (e.g. site specific cleanups, regulations), enabling the Agency to better predict and prevent risk. The work conducted by the HHRA research program responds directly to the needs of EPA's program and regional offices, as well as to issues of shared concern among the broader risk assessment community.

The HHRA research program is comprised of four complementary and integrated research themes. Within each theme, HHRA scientists work with partners to provide science translation



and technical support for the Program's products.

Theme 1: Integrated Risk Information System Health Hazard and Dose-Response Assessments

The Integrated Risk Information System (IRIS) theme develops peer reviewed, qualitative and quantitative health hazard and dose-response assessments on environmental pollutants of relevance to EPA's regulatory mandates. IRIS assessments are widely used by EPA's programs and regions, as well as by states, international organizations, and the public, to support decision-making.

More than 560 IRIS assessments are available to the public online. EPA and the risk assessment/risk management community consider IRIS the premier source of hazard and dose-response information for environmental pollutants.

In May 2009, EPA revised the IRIS process to streamline and accelerate completion of critical assessments (www.epa.gov/iris/process.htm). In July 2011, EPA announced additional improvements to IRIS to help ensure the continued use of the best and most transparent science as it supports the

EPA's mission of protecting human health and the environment. In response to recommendations made by the National Academy of Sciences, additional changes to further strengthen, streamline, and increases transparency in the development of draft IRIS assessments are being made.

Other key components of this theme include strengthening and improving the IRIS process and database and updating old or outdated IRIS assessments to ensure that they reflect the most currently available peer-reviewed science.

Scientists in the HHRA research program also provide critical technical support to IRIS chemical managers in the areas of statistics, pharmacokinetic modeling, and mode- or mechanism-of-action.

Theme 2: Integrated Science Assessments of Criteria Air Pollutants

Understanding the current science about the health and welfare effects of air pollutants is a critical Agency need to support decisions about the National Ambient Air Quality Standards (NAAQS). To meet this need, scientists in the HHRA research program develop

Integrated Science Assessments (ISAs) that summarize the latest available, relevant science on the health and welfare effects of the six criteria air pollutants—ozone, particulate matter, sulfur dioxide, nitrogen oxides, carbon monoxide, and lead. The HHRA research program is also developing a joint sulfur dioxide and nitrogen oxides ecological ISA and Multipollutant Science Assessments (MSAs) as part of this theme.

ISAs and MSAs are major assessments that undergo rigorous external peer review by the Clean Air Scientific Advisory Committee (CASAC) and provide the scientific-basis for the Administrator's decisions for the NAAQS. Statutory requirements mandate the development of ISAs on a five-year cycle.

The MSAs are an important step in understanding and characterizing the health and welfare impacts of exposure to mixtures of air pollutants. The MSAs are being developed with scientists in EPA's Air, Climate, and Energy research program and EPA's program office partners.

In May 2009, EPA revised the NAAQS process to speed development of these assessments and supporting documents (www.epa.gov/ttn/naaqs/review.html).

The Office of Management and Budget (OMB) and EPA estimate that attainment of the NAAQS offers significant health and environmental benefits to the public, such as fewer adverse health effects, improved visibility, and less damage to agriculture and vegetation.

Theme 3: Community Risk and Technical Support for Exposure and Health Assessments

Communities are often faced with an urgent need for coordinated assistance to assess and address issues of chemical and other environmental contamination. EPA's HHRA research program, in collaboration with the Homeland Security research program, is often called upon to assist in these situations to provide the science to support decision-making at cleanup sites, develop tools to help

understand risks to communities, or supply rapid responses to ensure that decision-makers have the tools they need to address emerging community concerns about environmental chemicals.

Work under this theme includes quick turn-around exposure and risk assessments, crisis-level technical support, the development of Provisional Peer Reviewed Toxicity Values (PPRTVs), tools and guidance for exposure assessments, and methods and tools for conducting cumulative impact and risk assessments. Taken together, this work helps ensure that EPA's regions have the tools and information they need to make timely decisions and address community concerns.

For example, after the BP oil spill and Hurricane Katrina, HHRA scientists provided rapid risk and exposure assessment support to help EPA better understand the potential risk of these environmental emergencies.

The routine development of PPRTVs provides EPA's Office of Solid Waste and Emergency Response (OSWER) with needed toxicity values that provide a scientific basis for decision-making in communities, such as clean up decisions at contaminated Superfund sites.

Scientists in the HHRA research program are also working to better understand how nonchemical stressors – such as socioeconomic status – may impact health effects resulting from exposure to environmental chemicals. This effort will better position the Agency to respond to community environmental justice concerns.

Ultimately, projects conducted under this theme will help EPA meet its mission to protect human health and clean up contaminated communities, including reducing risks for sensitive populations.

Theme 4: Modernizing Risk Assessment Methods

Advances in molecular and systems biology are changing the landscape of human health risk assessment.

Additionally, several recent and important reports from the National Research Council highlighted unmet risk assessment needs and suggested developing new approaches to advance risk assessment using test data emerging from various programs in the United States and internationally.

Work under this theme focuses on the translation of new research in molecular biology and computational sciences, such as that being conducted under EPA's Chemical Safety for Sustainability Program, into practical applications for developing hazard and dose-response assessments – a critically important step for advancing risk assessment. This work impacts not only the development of IRIS, ISA, and PPRTV assessments, but also helps the Agency to quickly assess and address emerging problems.

Key elements of this work include designing and implementing tools to make developing hazard and dose-response assessments more efficient; providing support and training for risk assessment through the Health and Environmental Research Online (HERO) database (<http://hero.epa.gov/>) and the Risk Assessment Training and Experience (RATE) program; and developing innovative approaches to mine databases and link information to users' needs in a more effective fashion. The work in this theme, collectively, will allow EPA to develop hazard and dose-response assessments more quickly and transparently, while providing needed information to risk managers and decision-makers.

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