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. These decisions span a complex regulatory landscape. The Human Health Risk Assessment (HHRA) program informs Agency decisions 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.

The HHRA program is comprised of four integrated topics, which 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 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.

Topic 1: Integrated Risk Information System (IRIS)

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

EPA and the risk assessment/risk management community consider IRIS the premier source of hazard and dose-response information for environmental pollutants. IRIS assessments receive public comment and are subject to rigorous independent peer review.

In May 2009, EPA revised the IRIS process to streamline and accelerate completion of critical assessments. Additional improvements to ensure the continued use of the best and most transparent science were announced in July 2011. In July 2013, in response to recommendations made by the National Research Council, EPA announced additional changes to the IRIS Program to improve the science of assessments, improve the productivity of the Program, and increase transparency so issues are identified and debated early in the process.

Other key components of this topic include continued improvements to the IRIS Program and database and updating old or outdated IRIS assessments to ensure they reflect the most currently available peer-reviewed science.

Scientists in the HHRA program also provide critical technical support to EPA's program and regional offices in the areas of statistics, pharmacokinetic modeling, and mode- or mechanism-of-action.

Topic 2: Integrated Science Assessments (ISAs)

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 program develop Integrated Science Assessments (ISAs) that synthesize 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.

ISAs 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.

This topic area also includes the development of Multipollutant Science Documents (MSDs) that are an important step in understanding and characterizing the health and welfare impacts of exposure to mixtures of air pollutants. The MSDs 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/naaqs). 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.

Topic 3: Community and Site-Specific Risk

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

For example, after the BP oil spill, Hurricane Katrina, and the Freedom Industries chemical spill in West Virginia, 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 Provisional Peer Reviewed Toxicity Values (PPRTV) provide EPA's Office of Land and Emergency Management (OLEM) with needed toxicity values that provide a scientific basis for decision-making in communities, such as clean up decisions at contaminated Superfund sites.

HHRA scientists 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.

Taken together, work under this topic area helps ensure that EPA has the tools and information they need to make timely decisions and address community 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.

Topic 4: Advancing Analyses and Applications

Advances in molecular and systems biology are changing the landscape of human health and ecological 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 alternative technologies and data emerging from various programs in the United States and internationally.

Work under this topic focuses on translating 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 rapidly assess and address emerging problems.

Key elements of this work also 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 the implementation of workshops and public meetings to discuss and evaluate specific scientific issues. Collectively, work in this topic will allow EPA to develop hazard and dose-response assessments more effectively and transparently.

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