

Human Health Risk Assessment (HHRA) Program

Science Advisory Board and Board of Scientific Counselors Presentation

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The HHRA Program

PROBLEM STATEMENT

Agency decisions must be based on defensible scientific evaluations of data relevant to assessing human health impacts. Currently, the demand for such assessments is not being fully met, particularly in terms of the number of existing and new chemicals in need of assessment, the types of risk characterization outputs needed to inform decision making, and the tools and data needed to support assessments.

VISION

The Agency will generate timely, credible human health risk assessments to support all priority Agency risk management decisions, thereby enabling the Agency to better predict and prevent risk.

HHRA: Key Themes

- Integrated Risk Information System (IRIS) health hazard and dose response assessments
- Integrated Science Assessments (ISA) of criteria air pollutants
- Community risk and technical support for exposure and health assessments
- Methods, models, and approaches to modernize risk assessment for the 21st century

HHRA Themes:

- Were derived from Agency and partner input
- Target output of high priority assessment needs
- Program/Regional input helps set HHRA Priorities

HHRA Coordinates with Internal and External Partners

- US Environmental Protection Agency, Program Offices and Regions
- National Institutes of Environmental Health Sciences & National Toxicology Program
- Centers for Disease Control and Prevention
- Agency for Toxic Substances and Disease Registry
- NIH Chemical Genomics Center
- California's Environmental Protection Agency, Office of Environmental Health Hazard Assessment
- FDA National Center for Toxicological Research
- Department of Defense
- Environmental Council of the States (ECOS)
- Interstate Technology and Regulatory Council (ITRC)

Key Science Questions

1. What are the important human health effects of chemicals for priority Agency decisions?
2. What are the human health and environmental hazards of criteria air pollutants?
3. What tools and analyses can ORD provide to help EPA programs and communities assess exposure and rapidly scope the risks of emerging issues?
4. How can ORD better meet the needs of decision makers by modernizing risk assessment to incorporate recent scientific innovations, including molecular biology and computational sciences?

Examples of major HHRA efforts informing Agency policies and decisions

Reaching out to Programs and Regions on IRIS priorities

- Set priorities for chemicals on agenda based on many meetings with Programs and Regions
- Solicit new nominations from Programs and Regions for future IRIS assessments

Hexavalent chromium

- Region 7 issue; broad outreach to Program Offices
- Rapid development of draft assessment to meet needs of Programs/Regions

Innovation with Health and Environmental Research Online (HERO) Database

- HERO – a database of scientific studies used to develop EPA risk assessments
 - Created for the Integrated Science Assessment Program
 - Expanded to include IRIS and PPRTV assessments as they are developed
 - Allows the public to readily access
- HERO provides:
 - Citation
 - Abstract
 - Topic areas that describe the reference
 - Assessment(s) that used reference
- HERO is an **EVERGREEN** database – new studies are continuously added



www.epa.gov/hero

Libby asbestos

PCBs in Schools

- PCB exposure estimation tool
- Advisory limits for indoor school air concentrations

Review of the University of Michigan Dioxin Exposure Study

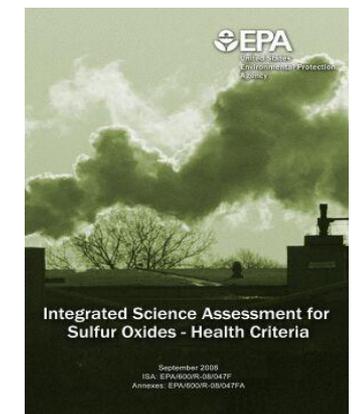
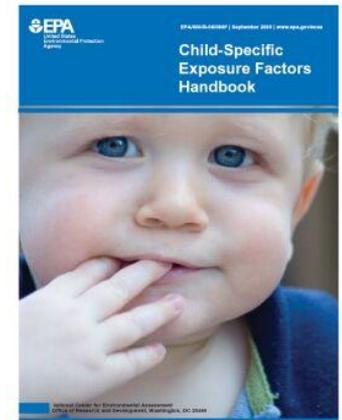
- Support to Region 5 and OSWER
- Evaluation of study results to inform Agency decision-making

Extensive support for regulatory actions

- National Ambient Air Quality Standards (NAAQS)
- Risk and Technology Review actions
- Utility Maximum Achievable Control Technology (MACT)
- Dioxin Preliminary Remediation Goals (PRGs)
- Perchlorate

Partnerships and Connections with other ORD Programs

1. **ORD research products are integrated into assessments performed under HHRA**
2. **Assessment needs inform National Research Programs**
 - Exposure Factors Handbook and Child-Specific Exposure Factors Handbook – *Sustainable and Healthy Communities (SHC); Safe and Sustainable Water Resources (SSWR)*
 - IRIS health assessments – *SSWR; SHC; Air, Climate and Energy (ACE); Chemical Safety and Sustainability (CSS)*
 - Provisional Peer Reviewed Toxicity Values (PPRTVs) – *SHC, CSS*
 - Integrated Science Assessments – *ACE, SHC*
 - Cumulative Risk Assessment – *ACE, SHC, SSWR, CSS, and Homeland Security Research (HSR)*
 - New Methods, Models and Approaches in Risk Assessment – *CSS, ACE, SSWR, SHC, and HSR*



Coordination and Collaboration between HHRA and CSS

Hazard Identification

- Expand use of CSS data for hazard characterization
- Import NCCT tools (ToxCast etc.); train staff in use
- Redesign MOA section of NCEA assessments to start with knowledge maps and link to phenotypes
- Utilize knowledge maps to characterize, as feasible:
 - Human susceptibility and variability
 - Mixtures
 - Low-dose response
 - Relevance of non-human test species
- Begin to evaluate use in multiple stressors/community-level assessments

Dose-Response

- Transition comparative potency tools from NCCT into:
 - PPRTVs and special projects, especially for data limited chemicals
 - Mixture evaluations
 - New risk assessment models that account for background of response, human variability, and defined mixtures exposures

Outcomes and Impacts of HHRA Products

Risk assessments are required for risk-based decisions which provide metrics for Risk/Risk evaluation of trade offs and cost benefits analysis. Risk-based metrics will be critical to the development of sustainable solutions.

Examples of anticipated impacts of HHRA products:

- (Dioxin, TCE, PERC) decisions on numerous sites
- ISAs improvement in air quality
- Chromium 6 – improvements in DW quality
- Cumulative Assessment effects on communities

APPENDIX

Why is EPA investing in this area?

Statutory authority for EPA's HHRA program

The **Clean Air Act** (CAA, Section 103) mandates that EPA conduct a national research and development program for the prevention and control of air pollution. This program includes assessment of risks, development of methods and tools for analysis of data, and development of Integrated Science Assessments (ISAs) to serve as the basis for review of the National Ambient Air Quality Standards (NAAQS) on a 5-year cycle. The 1990 CAA Amendments further mandate determination of risks from mobile, area, and major sources of air toxics.

The **Safe Drinking Water Act** (1974 amended in 1996) authorizes research and assessments focusing on microbes (e.g., *Cryptosporidium*), disinfection byproducts, arsenic, sulfate, and radon, including effects on sensitive subpopulations. Other research provisions address risks associated with waterborne disease, complex mixtures, and unregulated contaminants.

The **Food Quality Protection Act** (1996) mandates research and assessment of risk from exposures to pesticides, including aggregate exposures and cumulative risk and risk to sensitive subpopulations.

The **Comprehensive Environmental Response, Compensation, and Liability Act** (CERCLA; Superfund, 1980) requires research, development, and training to improve EPA's scientific capability to assess and evaluate effects on, and risk to, human health from hazardous substances.

Final Assessments Posted in 2010

- Hydrogen cyanide and cyanide salts
- cis-1,2-dichloroethylene
- trans-1,2-dichloroethylene
- Pentachlorophenol
- Chloroprene
- Acrylamide
- Carbon tetrachloride
- EGBE
- 1,4-dioxane
- 1,1,2,2-tetrachloroethane

Selected Major Upcoming Assessment Products

Chemical	Step in IRIS Process	Target Date for Posting
Arsenic (cancer)	Focused 2 nd external peer review (SAB) report received Feb 2011	Aug 2011
Chromium VI	External peer review (independent panel meets May 2011)	Sep 2011
Dioxin	External peer review (SAB)	Dec 2011
Formaldehyde	External peer review (NAS)	TBD
Halogenated Platinum Salts	Agency/interagency review	Sep 2011
Libby amphibole asbestos	Interagency review	Sep 2012
PCBs (noncancer)	Agency review	Sep 2012
Phthalates cumulative assessment	Draft development	Sep 2012
Polycyclic aromatic hydrocarbon (PAH) mixtures	External peer review (SAB) report received Mar 2011	Dec 2011
Tetrachloroethylene (perc)	External peer review (NAS)	Jul 2011
Trichloroethylene (TCE)	External peer review (SAB)	Sep 2011

Ensuring Transparency in HHRA

IRIS Assessments:

- EPA directs Interagency review; comments from Federal Agencies are publicly available
- IRIS listening sessions for public and stakeholder input
- Public Comments from docket included in materials for external peer review panel
- Briefings for other Agencies (e.g, USDA, FDA) on high profile chemicals
- Increased transparency in adding chemicals to IRIS agenda; nomination form asks for information on potential public health impacts of nominated chemicals
- FRN for new chemicals on IRIS agenda being developed to provide advanced notice of development of IRIS assessments

Integrated Science Assessments (ISA)

- Restructured ISA with concise summary and integrative synthesis of key findings
 - Focus on key policy-relevant findings
 - Development of causality framework used in ISAs; provides transparency and consistency in drawing conclusions and causal judgments
- Health and Environmental Research Online (HERO) database - Allows the public to easily access studies on which decisions are based

Program/Regional Input Helps Set HHRA IRIS Priorities

In 2010, NCEA reached out to the Programs and Regions to help set priorities for IRIS:

- Better understanding of need and timing for toxicity values
- Set priorities for chemicals on agenda – many meetings with Programs and Regions
- Solicit new nominations – revised process adds feedback loop to Programs and Regions

Chemical Name	High Priority for Office?	Time Needs	Regulatory Needs	Additional Considerations
Already on Table 1				
uranium	5	2012	CERCLA 108(b)	Needed as basis for NPL listing and site cleanup; Common contaminant at waste and cleanup sites.
ETBE	1			Potential for leaking underground storage tank
platinum	1	2010		High priority for OTAQ in evaluating emissions of diesel retrofit applications
urea	0			Used in selective catalytic reduction systems to meet NOX standards
High Priority Group				
ethylbenzene	6	2012	CERCLA 108(b); RQ List; DW Std. Update	Mobile sources; Used for hydraulic fracturing; High priority for several regions because of site considerations
PCBs (noncancer)	7	2011	CERCLA 108(b); OPPT reg on PCB use reauthorization	Concern for children's health; High priority for 3 regions (PCB in schools and buildings; NPL sites)
cadmium	5	2014	CERCLA 108(b); DW Std update	Found at 103 Superfund sites.
cobalt	5	2012	Coal Ash Rule; UCMR3/RegDet4	common contaminant at cleanup sites
antimony	3	2012	CERCLA 108(b); DW Std update	Found at 72 Superfund sites
ethylene dichloride	4	2012	CERCLA 108(b)	Needed as basis for NPL listing and site cleanup
manganese	4		CERCLA 108(b)	Concern for children's health; chemical of concern in numerous RODs
ammonia	2		CERCLA 108(b); RQ List	Used in selective catalytic reduction systems to meet Nox standards
chloroethane	3		CERCLA 108(b)	Needed as basis for NPL listing and site cleanup.
diethyl phthalate	3	2012	CERCLA 108(b)	Concern for children's health. Duwamish NPL site.
ethanol	3			Concern because of biofuels (OTAQ and OEM); EISA; used for hydraulic fracturing
RDX	3			Needed as basis for NPL listing and site cleanup; Common contaminant for emergency removal actions.
Medium Priority Group				
nickel	3		CERCLA 108(b)	Found at 94 Superfund sites.
naphthalene	4			Mobile sources; Used for hydraulic fracturing; site considerations in regions.
acetaldehyde	2	2012	CERCLA 108(b)	Ambient air increased in acetaldehyde are expected with increased use of ethanol in fuel.
hexachlorobutadiene	2	2012	CERCLA 108(b)	Needed as basis for NPL listing and site cleanup
styrene	2		CERCLA 108(b)	Would be used for NATA

Examples of major HHRA efforts that inform Agency policy and decision making in ISAs

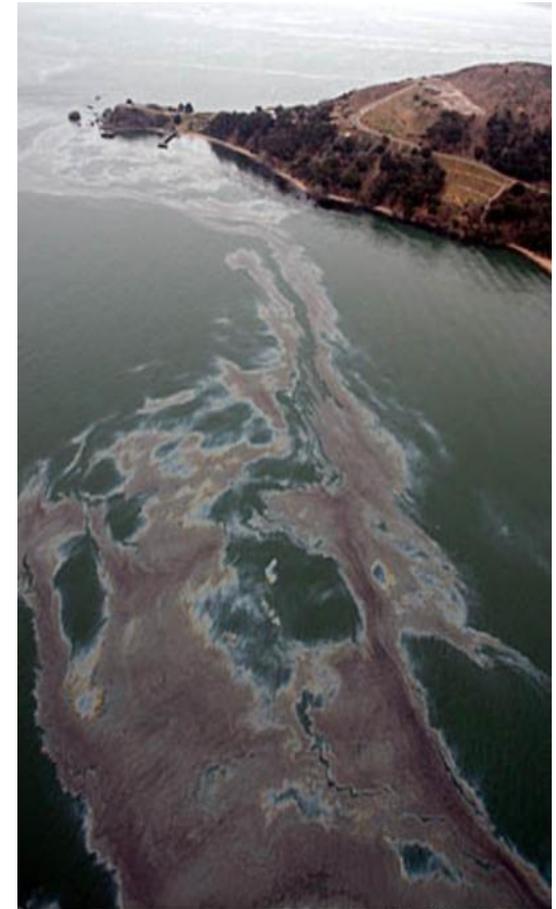
Extensive support for regulatory actions on primary and secondary standards for NAAQS

Development of Multi-pollutant Assessment strategy in collaboration with Agency Partners

- The use of scientific information and statistical approaches in conducting air pollution risk analyses in multi-pollutant exposure environments
- Interpretation and integration of information across scientific disciplines in developing a multi-pollutant science assessment to support the NAAQS reviews
- Novel research and analytical approaches to better characterize the health effects of multi-pollutant exposures

Examples of HHRA effort that informs Agency policy and decisions – Emergency Response for Gulf Oil Spill

- Dioxin Formation and Risk Assessment
- Fish Consumption Rates Assessment
- Risk Assessment for Gulf Swimmers
- Toxicity of Chemicals in the Gulf



Chronicle / Kurt Rogers

ORD 2012 President's Budget for HHRA

FY2012 President's Budget \$45.7M, FTE 165.5

In FY 2012, ORD will continue to support EPA's Integrated Risk Information System (IRIS).

The new process has helped EPA accelerate progress on the IRIS agenda for 58 assessments:

- 10 of these were complete in 2010
- 19 are undergoing external peer review or final agency and interagency review
- 3 are in interagency science consultation
- 36 are in draft development or Agency review
- which reflects recent addition of 21 chemicals in 2011

Completion of 10 assessments in 2010 is more than the average of the 3 previous years.