ORD Human Health Risk Assessment (HHRA) Program

Science Advisory Board Presentation

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March 3, 2011

Risk Assessment at EPA

HHRA

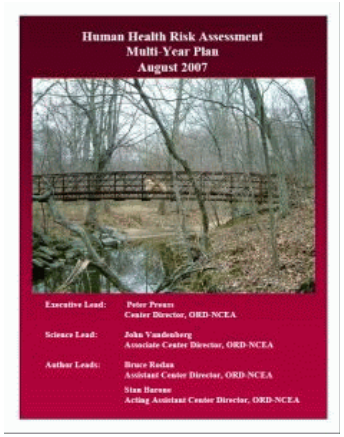
occupies a critical position in EPA's Office of Research and Development between:

- the researchers in other ORD components who are generating new findings and data

AND

- the regulators in the EPA program offices and regions who must make regulatory, enforcement, and remedial action decisions

HHRA Framework: Timely, Relevant and Responsive Research



IRIS and other priority health hazard assessments:

- Develop IRIS human health assessments
- Provisional Peer Reviewed Toxicity Values (PPRTVs) for EPA's waste site clean-up program (Superfund)
- Incidence Response Assessments

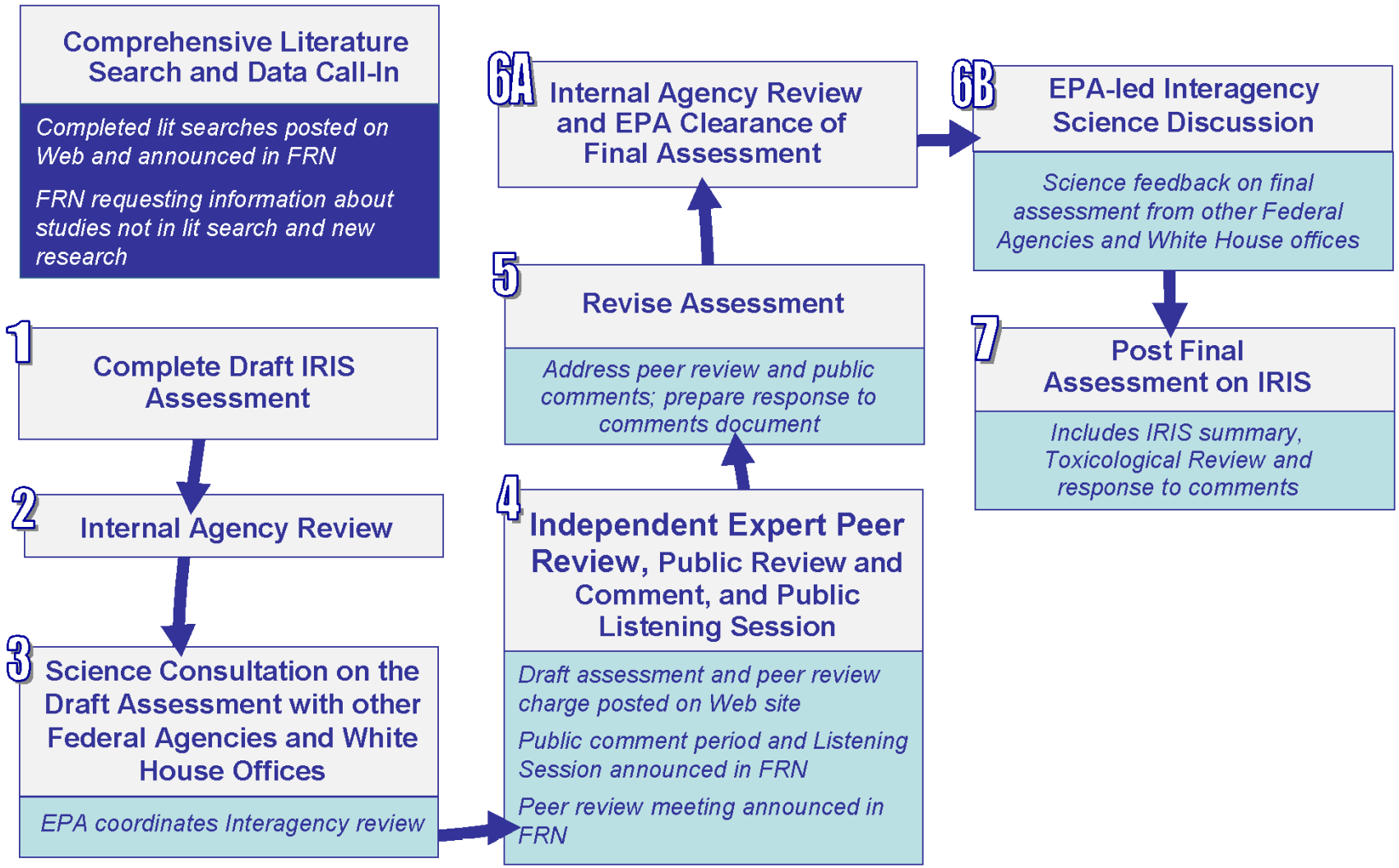
State-of-the-science risk assessment models, methods, and guidance:

- Uncertainty analysis
- Identification of possible modes of action
- Physiologically-Based Pharmacokinetics (PBPK) Modeling
- Approaches to quantification
- Approaches for Assessing Risk of Environmental Exposures to Susceptible Populations
- Approaches for cumulative risk assessment

Air Quality Integrated Science Assessments (ISA):

- Producing ISAs which provide the scientific bases for EPA's air quality decision-making
  - *Ozone – underway – 1st draft March 2011- Final expected completion 2012*
  - *Lead – Lead ISA Information Call-in – 2010– Post ERD in 2011*
  - *Particulate Matter – Completed 2009*
  - *Nitrogen Oxides – ISA – Health and Environmental Criteria – final in 2008*
  - *Sulfur dioxide – ISA – Health and Environmental Criteria – final in 2008*
  - *Hold multi pollutant assessment workshop – Feb 2011*

Current IRIS Assessment Development Process



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 2nd round external peer review (SAB)	Jun 2011
Chromium VI	External peer review (independent panel)	Dec 2011
Dioxin	External peer review (SAB)	Dec 2011
Formaldehyde	External peer review (NAS)	Sep 2011
Libby amphibole asbestos	Draft development	Sep 2012
PCBs (noncancer)	Draft development	Sep 2012
Polycyclic aromatic hydrocarbon (PAH) mixtures	External peer review (SAB)	Dec 2011
Phthalates cumulative assessment	Draft development	Sep 2012
Tetrachloroethylene (perc)	External peer review (NAS)	Jun 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

Scientific and Technical Support

- 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 provided perspective on how study results could inform Agency decision-making
- Extensive support for regulatory actions
  - NAAQS
  - RTR actions
  - Utility MACT - appropriate & necessary analysis
  - Dioxin PRGs
  - Perchlorate

Example of major HHRA effort that informs Agency policy and decision making in IRIS

Reaching out to Programs and Regions on IRIS priorities

- Better understand 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

Hexavalent chromium

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

Example of major HHRA effort that informs 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, and
- Novel research and analytical approaches to better characterize the health effects of multi-pollutant exposures.

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

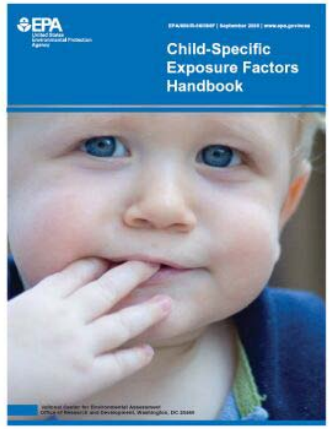
- **Dioxin Formation and Risk Assessment**
- **Fish Consumption Rates Assessment**
- **Risk Assessment for Gulf Swimmers**
- **Toxicity of Chemicals in the Gulf**

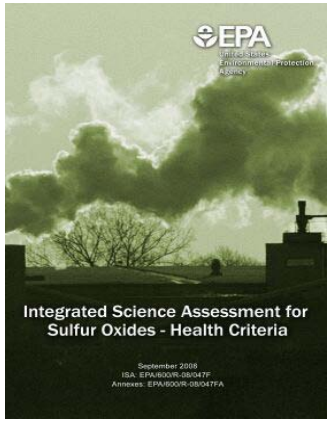
Chronicle / Kurt Rogers

Partnerships and Connections with other ORD Programs

ORD research products are integrated into assessments performed under HHRA and 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 (SSW)*
- IRIS health assessments – *SSW; 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 – *SHC, SSW and CSS*
- NexGen Risk Assessment – *CSS, ACE, SSW, SHC, and Homeland Security Research (HSR),*





ORD 2012 Budget Increases and Decreases for HHRA

FY2010 Enacted $46.3M,

FY2012 President's Budget $45.7M,

Net Change -$0.6M

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.

United States Environmental Protection Agency

APPENDIX

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
  - Has been expanded to include IRIS assessments as they are developed
  - Allows the public to readily access studies on which decisions are based.

- HERO provides:
  - Citation
  - Abstract
  - Topic areas that describe the reference
  - Assessment for which reference was used

- HERO is an ***EVERGREEN*** database – new studies are continuously added

www.epa.gov/hero

Program/Regional Input Helps Set IRIS Priorities

United States Environmental Protection Agency

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

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

- Better understand 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