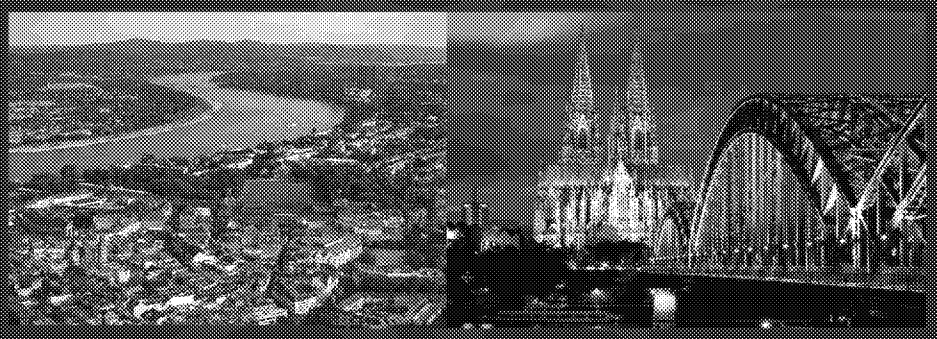
EPA
United States Environmental Protection Agency

US EPA Experiences with Risk Assessment Training Activities



Becki Clark
National Center for Environmental Assessment

Second WHO Meeting on Global Collaboration in Chemical Risk Assessment, Bonn, Germany, March 2012

Office of Research and Development
National Center for Environmental Assessment

0

HSR 101

U.S. Environmental Protection Agency's National Center for Environmental Assessment

EPA
United States Environmental Protection Agency

- EPA's National Center for Environmental Assessment (NCEA) is a leader in the science of human health and ecological risk assessment.
- NCEA develops comprehensive hazard and dose response assessments, ecological risk assessments, innovative risk assessment methods and tools, and risk assessment training.
- NCEA's work is used by EPA's regulatory programs, the U.S. State and local governments, international organizations, and others to make decisions about cleaning up the environment and protecting human health.
- NCEA cooperates with multiple organizations in the U.S. and other countries.

HSR 101

1

NCEA and Risk Assessment at EPA

United States Environmental Protection Agency

NCEA

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

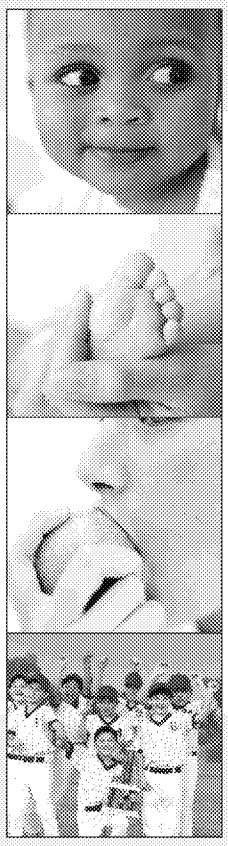
- the researchers in other ORD components who are generating new findings and data

AND

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

United States Environmental Protection Agency

Risk Assessment is Critical to U.S. EPA Regulatory Decision-Making



- U.S. EPA is both a regulatory agency and a science agency
- U.S. EPA operates under many laws that require the assessment of potential risk from exposure to environmental contaminants (*e.g.*, Clean Air Act, Safe Drinking Water Act)
- Risk assessment remains fundamental to major programs in the Agency (water, air, waste)
- Evolving in the face of new understandings about uncertainty, mode of action, metabolism, susceptibility, etc.
- Addressing emerging science and new science challenges

United States Environmental Protection Agency

Challenges Facing the Risk Assessment Community

Risk assessors need:

- Toxicity values; in many cases, if no value is available, we assume zero risk.
- To understand what science an assessment is based on.
- Clear guidance for conducting risk assessments.
- Consistent training in hazard, dose-response, exposure assessments, risk assessment, and risk communication – for this and the next generation of risk assessors.
- To learn about innovations in risk assessment science and methods.

ED_012964_00011155-00005

Integrated Risk Information System (IRIS)

United States Environmental Protection Agency

Integrated Risk Information System

IRIS assessments:

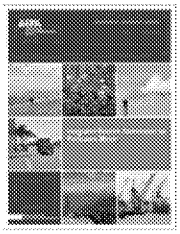
- Provide scientific information on potential adverse health effects that may result from exposure to chemical substances found in the environment; developed according to EPA guidelines for health risk assessment.
- Include oral reference doses and inhalation reference concentrations for non-cancer endpoints.
- Provide a weight of evidence descriptor (e.g., carcinogenic to human) and include oral slope factors and inhalation unit risks for cancer endpoints.
- EPA risk assessors combine IRIS toxicity values with scenario-specific exposure values to estimate risk; used for risk-based decision-making.
- Foster consistent risk assessments across EPA Programs and Regions; available to U.S. States and local communities, international community and private sector
- About 70 assessments are underway, including many high profile chemicals (e.g., high production, in the "news", controversial, vocal stakeholders with good lawyers, Congressional interest)

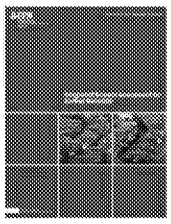
www.epa.gov/iris

Integrated Science Assessments (ISA)

United States Environmental Protection Agency

Integrated Science Assessments:





- Provide the scientific basis for the National Ambient Air Quality Standards (NAAQS) for the six criteria air pollutants.
- Evaluates and integrates evidence from across scientific disciplines – atmospheric sciences, dosimetry, exposure, toxicology, controlled human exposure, epidemiology, ecology or welfare effects.
- Conclusions, causal judgments (e.g., "causal relationship," "likely to be a causal relationship," "suggestive evidence of a causal relationship," "inadequate to infer a causal relationship," and "not likely to be a causal relationship") drawn for health and ecological or environmental effects.
- Are vetted through a rigorous peer review process, including review by the Clean Air Scientific Advisory Council and public comment periods.

EPA
United States
Environmental Protection
Agency

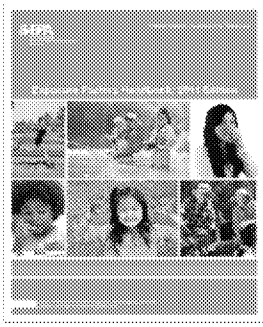
Provisional Peer Reviewed Toxicity Values (PPRTVs)

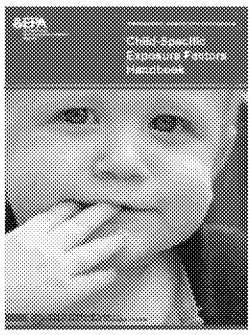
- Provide hazard and dose-response assessments for chemicals of concern at Superfund sites when values are not available in the IRIS database
- Are used to support decisions on acceptable levels of human exposure, establish remediation strategies, and set clean-up goals that are appropriate for protecting human health while not overly conservative and costly.
- May produce up to 6 toxicity values per assessment, including: a subchronic and chronic RfD and RfC, cancer oral slope factor and inhalation unit risk.
- Use the same technical guidance as IRIS assessments and undergo independent external peer review.

http://hhpprtv.ornl.gov

United States Environmental Protection Agency

Exposure Factors Program





Exposure Factors Handbook (2011)

- Summarizes available data on factors used for assessing exposure:
  - Drinking water consumption, soil ingestion, inhalation rates, dermal factors including skin area and soil adherence factors
  - Consumption of fruits and vegetables, fish, meats, dairy products, homegrown foods, human milk
  - Activity patterns, body weight, and consumer products.

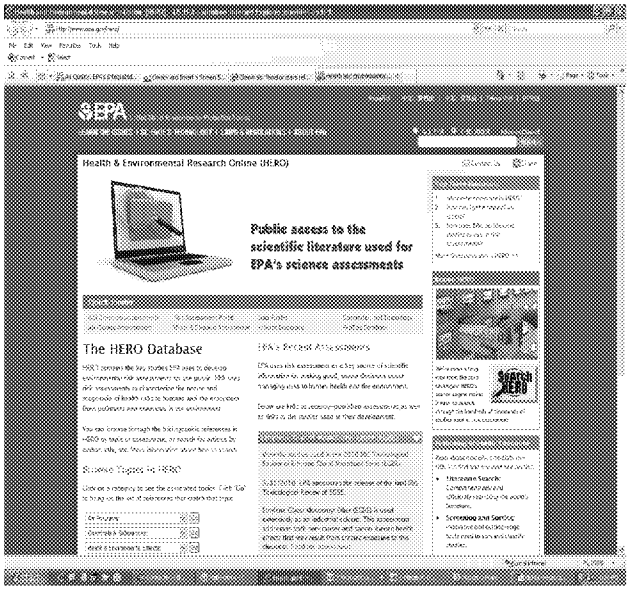
Child-Specific Exposure Factors Handbook (2008)

- Consolidates all child exposure data into single document

Health and Environmental Research Online (HERO) Database – Making Risk Assessments Transparent

United States Environmental Protection Agency

- **HERO** is a database of scientific studies used to develop EPA risk assessments.
  - Is used for IRIS, ISAs and PPRTVs
  - 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

9

HSR 101

9

Risk Assessment -- Maturing and Evolving

EPA United States Environmental Protection Agency

1970s

- Beginnings of the field of risk assessment
- Emphasis on oral route
- General acceptance of Safety Factors (10x10)
- Beginnings of cancer guidelines

1980s

- Adopt National Academy of Sciences' Risk Assessment/Risk Management paradigm
- EPA publishes five risk assessment guidelines
- First paper on Reference Dose (RfD)
- Integrated Risk Information System (IRIS)

1990s

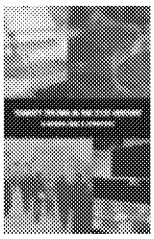
- Inhalation Reference Concentration (RfC)
- Oral RfD methodology
- Applications of PBPK models
- BBDR models developed
- BMD models developed and applied

2000s

- Examination of non-cancer methods
- Revised cancer guidelines, including MOA
- Susceptible populations
- Cumulative assessment approaches
- Probabilistic approaches
- Uncertainty analysis
- ***Emerging issues: biofuels, nanoparticles, "omics"…Next Generation Risk Assessment***

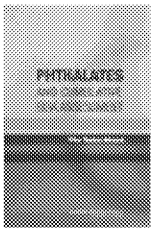
EPA
United States
Environmental Protection
Agency

Recent Influences on the Future of Risk Assessment



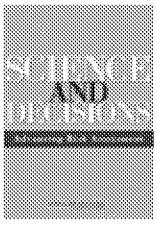
Toxicity Testing in the 21st Century:

- Risk assessment should take advantage of advances in toxicogenomics, bioinformatics, systems biology, epigenetics, and computational toxicology.
- The use of emerging methods will generate more data on potential risks and expand capabilities to test chemicals more efficiently.



Phthalates and Cumulative Risk Assessment:

- Group chemicals that cause common adverse outcomes and do not focus exclusively on structural similarity or similar mechanisms of action.
- Phthalates and other agents that cause androgen insufficiency or block androgen-receptor signaling should be considered in a cumulative risk assessment.



Science and Decisions: Advancing Risk Assessment:

- Design risk assessments to meet needs of risk managers.
- Need for consistent approaches to determine level of analysis, attention to variability in human susceptibility, quantify population variability in dose response assessment.
- Unify dose-response analysis for cancer and noncancer effects; noncancer effects do not necessarily have a threshold; background exposures and underlying disease can lead to linearity at population doses of concern.
- Consider nonchemical stressors and background risk when conducting cumulative assessments.

EPA United States Environmental Protection Agency

Risk Assessment Training and Experience (RATE)

The Challenge: The risk assessment community needs up to date information and training on principles and practices of risk assessment, especially in an era of scarce resources and evolving scientific knowledge.

The Solution: EPA is partnering with a coalition of states, federal agencies, industry and other stakeholders to develop the Risk Assessment Training and Experience (RATE) program.

The RATE program:

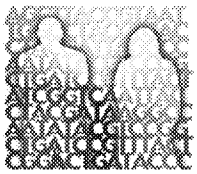
- Provides comprehensive risk assessment instruction in a classroom setting; will eventually include a web-based platform.
- Includes modules on the fundamentals of risk assessment; hazard identification; dose-response; exposure assessment; and risk characterization, communication and management.

This innovative program will:

- Help ensure that state-of-the-art methods are incorporated into risk assessment practice.
- Train the next generation of risk assessors and environmental leaders, ensuring that decisions are based on sound science and the most current risk assessment practices.

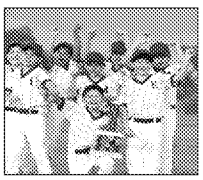
RATE Courses

United States Environmental Protection Agency



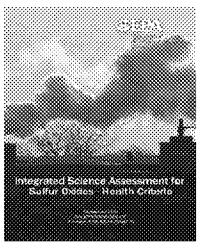
Basics of Risk Assessment (BRA)

- BRA101: Introduction: Risk Assessment and EPA's Office of Research and Development
- BRA102: Laws and Regulatory Foundations for Risk Assessment
- BRA103: Development and Overview of Current Regulatory and Advisory Values



Basics of Human Health Risk Assessment (HBA)

- HBA201: Overview of Human Health Risk Assessment
- HBA202: Overview of Human Health Toxicity Values
- HBA203R: Overview of the Development of IRIS Toxicity Assessments

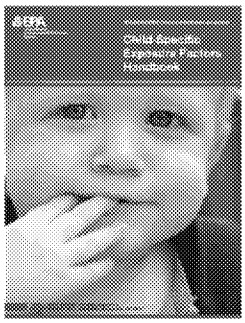


Science Behind Human Health Hazard Assessment (HSR)

- HSR301: Animal Toxicology: Study Designs and Selected Organ Toxicity
- HSR302: Epidemiology and Human Studies
- HSR303: Incorporation of Mode of Action into Risk Assessment
- HSR304: Uncertainty and Variability
- HSR305: Quantitative Methods and Models: Dosimetry Adjustments and PBPK Concepts
- HSR306: Quantitative Methods and Models: Benchmark Dose Approach
- HSR309: Case study—Development of a human health risk assessment

RATE Courses

United States Environmental Protection Agency



Exposure Assessment (EXA)

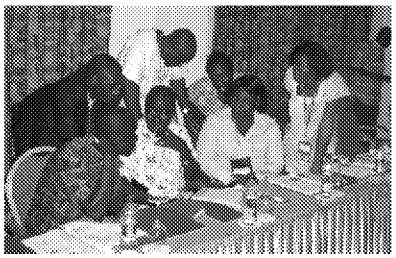
- EXA401: General Concepts in Exposure Assessment
- EXA402: Approaches for Quantifying Exposure
- EXA403: Developing Exposure Scenarios
- EXA404: Monitoring and Modeling Strategies
- EXA405: Fate and Transport
- EXA406: Obtaining and Using Exposure Factor Data
- EXA407: Calculating Doses and Assessing Uncertainty and Variability
- EXA408: Interpreting Biomonitoring Data and the Use of Simple Pharmacokinetic Models
- EXA409 Case study— Lead Contamination and Local Exposure
- EXA410: Case study— The Columbus Municipal Solid Waste Incinerator

Additional Courses

- Option 1: Chemical Mixtures (1/2 day)
- Option 2: Aggregate and Cumulative Risk (1/2 day)
- Option 2: Exposure Models (1 day)
- Option 3: Risk Characterization/Communication (3 days)

Risk Assessment Training and Experience (RATE)

United States Environmental Protection Agency



Ghana (2011)

- International Conference on Occupational Health and Safety for Small and Medium-scale Enterprises
- Comprehensive risk assessment training using RATE modules

South Africa (2009)

- Risk Analysis 101: Introduction to Risk Analysis
- 7th Congress of the Toxicology in Developing Countries

Egypt (2008)

- The Middle East Partnership Initiative Food Defense Workshop
- Training on use of risk assessment in food defense and to protect water infrastructure
- Basic risk assessment session to graduate students and scientists at Beni Suef University, Egypt

EPA's risk assessment training was well-received and in some cases provided the first risk assessment training the scientists had received.

THANK YOU!!

Becki Clark, Acting Director
National Center for Environmental Assessment (8601P)
Office of Research and Development
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

clark.becki@epa.gov

U. S. Environmental Protection Agency	www.epa.gov
Office of Research and Development	www.epa.gov/ORD
National Center for Environmental Assessment	www.epa.gov/NCEA
EPA's Integrated Risk Information System	www.epa.gov/iris/
Risk Assessment	www.epa.gov/risk/
Integrated Science Assessments	www.epa.gov/ncea/isa
Exposure Factors Program	www.epa.gov/ncea/efh