Careers in Regulatory Toxicology: What do I need to know?

Edward V. Ohanian, Ph.D.,
Associate Director for Science, Office of Water,
U.S. Environmental Protection Agency (EPA),
Washington, DC
&
Chair, EPA Risk assessment Forum, Office of
Science Advisor
&
President, SOT/RSESS

GSLC-RSESS Webinar
October 31, 2017
Disclaimer

The views expressed in this presentation are those of Dr. Ohanian and do not necessarily represent the views or policies of the U.S. Environmental Protection Agency.
Environmental Laws and Regulatory Toxicology

- Clean Air Act
- Safe Drinking Water Act
- Food Quality Protection Act
- Comprehensive Environmental Response, Compensation, and Liability Act
- Resource Conservation and Recovery Act
- Toxic Substances Control Act
Risk Assessment/Risk Management

- Dose-Response Assessment
- Hazard Identification
- Exposure Assessment
- Risk Characterization

Risk Management Decisions
- Statutory and Legal Considerations
- Public Health Considerations
- Social Factors
- Economic Factors
- Risk Management Options
- Political Considerations
Risk Characterization

- Summarize all data, strengths and weaknesses
- Integrate information from previous steps
- Discuss uncertainties and assumptions
- Develop estimates of risk for public health and ecological integrity
- Provide tools for risk managers who make decisions.
Risk Management Decision Framework

Planning and Scoping

Analysis

Characterization

Synthesis

Decision

- Scientific Factors
- Economic Factors
- Legal Factors
- Public Values
- Political Factors
- Technological Factors
- Social Factors
Risk Assessment Practices at USEPA

Office of Air and Radiation
Office of Chemical Safety and Pollution Prevention
Office of Land and Emergency Management
Office of Water
EPA Regional Offices
Does the contaminant adversely affect public health?

Is the contaminant known or likely to occur in PWSs with a frequency and at levels posing a threat to public health?

Regulate under Safe Drinking Water Act

Will regulation of the contaminant present a meaningful opportunity for health risk reduction?
• Develop risk assessment guidelines & guidance

• Promote *agency-wide consensus* on risk assessment issues in RAF products

• Ensure that consensus is incorporated into appropriate Agency risk assessment products
Risk Assessment Forum

EPA Administrator

Science and Technology Policy Council

Risk Assessment Forum

Health Effects  Exposure  Ecological Effects

Technical Panels  Special Subcommittees
Past RAF Products
NRC Reports and EPA

Exposure Science in the 21st Century

Phthalates and Cumulative Risk Assessment

Science and Decisions

Toxicity Testing in the 21st Century
More NRC Reports

- Sustainability and the U.S. EPA
- Environmental Decisions in the Face of Uncertainty
- Toxicity-Pathway-Based Risk Assessment
- Review of the Environmental Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response Relationships as They Apply to Endocrine Disruptors
Framework for Human Health Risk Assessment to Inform Decision Making

- Initiation
- Planning & Scoping
- Problem Formulation
  - Conceptual Model
  - Analysis Plan
- Risk Assessment
  - Exposure Assessment
  - Effects Assessment
    - Hazard Identification
    - Dose Response
- Risk Characterization
- Informing Decisions
Uncertainty Factor Selection (Historically 10x)

- Interspecies extrapolation
- Intraspecies extrapolation
- Study duration
- LOAEL to NOAEL
- Database deficiencies

Key concepts include identification/measurement of TK and TD dose metrics associated with the critical effect

- Data-derived Evaluation Factors (US EPA, 2014)
- Chemical-specific Adjustment Factors (WHO/IPCS, 2005)
Toxicity Pathway

Biologic Inputs

Exposure
Tissue Dose
Biologic Interaction
Perturbation

Biologic Inputs

MOA

Early Cellular Changes
Adaptive Stress Responses
Cell Injury

Normal Biologic Function

Morbidity and Mortality

Higher yet
Adverse Outcome Pathway - Regulatory Application?
Promoting Technology and Innovation in Water Sector
National Water Program Research Needs
EPA National Research Programs

See: http://www.epa.gov/research
Making decisions with sound science requires:

- Relevant, high quality, cutting-edge research in human health, ecology, pollution control and prevention, economics and decision sciences
- Proper characterization of scientific findings
- Appropriate use of science in the decision process

Research and development contribute uniquely to:

- Health and ecological research, as well as research in pollution prevention and new technology
- In-house research and an external grants program
- Problem-driven and core research
More Information on USEPA Careers

http://www.epa.gov

http://www.epa.gov/careers/benefits.html

http://www.epa.gov/epahome/grants.htm

http://www.epa.gov/epahrist/opm.htm

http://www.epa.gov/ncer

http://www.epa.gov/ezhire/

http://www.epa.gov/ow

http://www.epa.gov/ord

http://www.epa.gov/ocspp
Explore Agency websites for programs; Consult with national and international experts through SOT; Identify and weigh several options; ask for feedback