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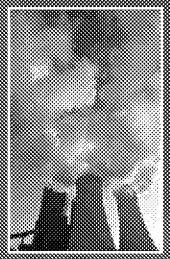
United States
Environmental Protection
Agency

Introduction to Risk Assessment and EPA's Office of Research and Development



RISK ASSESSMENT TRAINING AND EXPERIENCE
Basics of Risk Assessment 101

Office of Research and Development
National Center for Environmental Assessment

EPA
United States
Environmental Protection
Agency

Introduction to Risk Assessment and EPA's Office of Research and Development

- Introduction
- Risk Assessment – Paradigm and Definitions
- How Risk Assessment Informs Risk Management
- EPA's Office of Research and Development (ORD)
  - Mission
  - Risk Assessment at ORD
  - Examples
- Additional Information

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RISK ASSESSMENT PARADIGM

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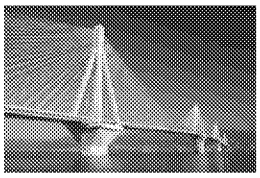
Class Activity

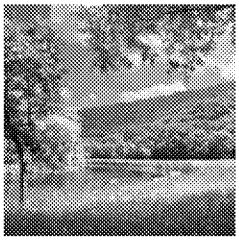
How would you define risk?

How would you define risk assessment?

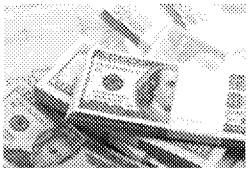
"Risk Assessment" is Contextual

Engineering/ Structural



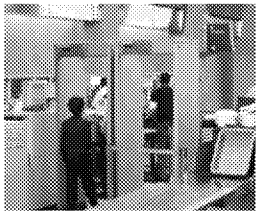


Ecological

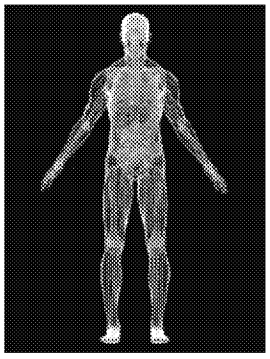


Financial/ Business

Security: Vulnerability and Threat



Human Health



EPA Definition of Risk Assessment

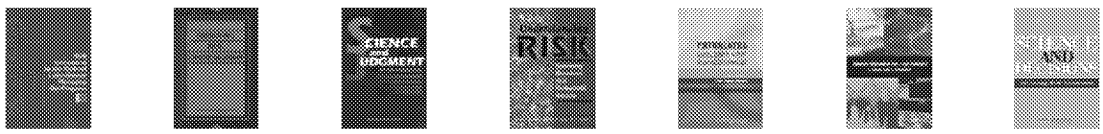
Risk assessment:

Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants

From EPA's "Terms of Environment" Glossary

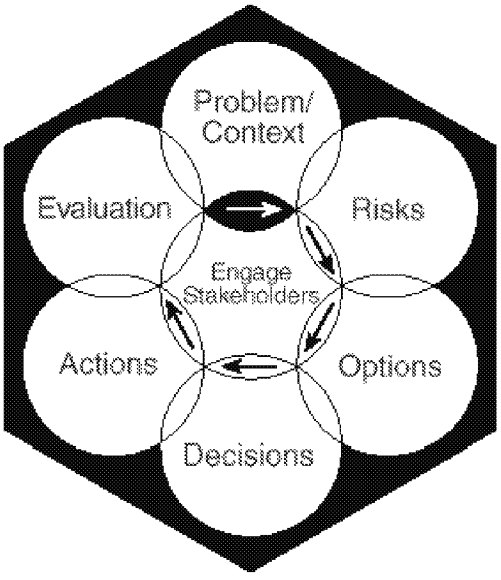
Brief History of Human Health Risk Assessment at EPA

- 1970: EPA established
- 1975: First EPA chemical assessment (vinyl chloride)
- National Research Council (NRC) publications on risk assessment
  - 1983: *Managing the Process* – the "Red Book"
  - 1989: *Improving Risk Communication*
  - 1994: *Science and Judgment* – the "Blue Book"
  - 1996: *Understanding Risk*
  - 2007: *Toxicity Testing in the 21st Century*
  - 2008: *Phthalates and Cumulative Risk Assessment*
  - 2009: *Science and Decisions* – the "Silver Book"



Brief History of Human Health Risk Assessment

- Presidential Commission on Risk Assessment and Risk Management (CRARM)
  - Addressed residual risks from HAPs
  - Developed an integrated risk management approach
- Continued evolution at EPA
  - Multiple chemical (cumulative) risk assessment
  - Community-scale and national-scale assessments



EPA's Integrated Risk Information System (IRIS) Definition of Risk Assessment

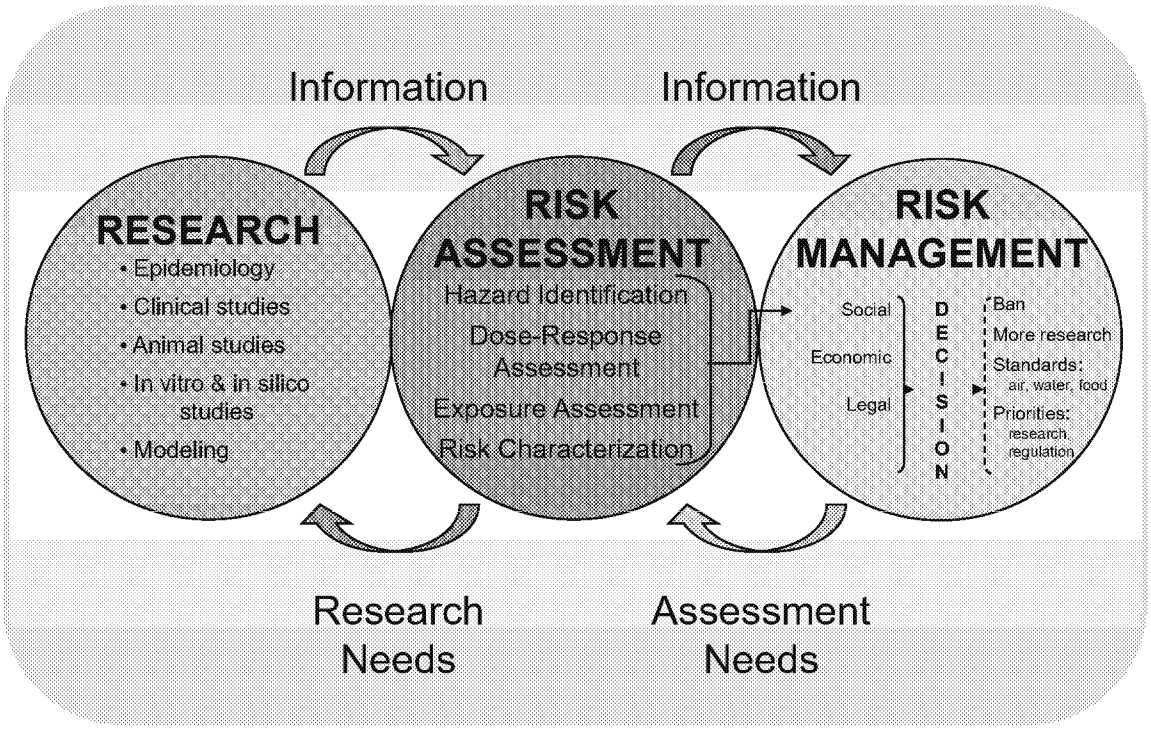
Risk assessment is the evaluation of scientific information on:

- **Hazard Identification** — the hazardous properties of environmental agents,
- **Dose-response Assessment** — the dose-response relationship, and
- **Exposure Assessment** — the extent of human exposure to those agents.

The product of the risk assessment is a statement regarding the probability that populations or individuals so exposed will be harmed and to what degree. — **Risk Characterization**

From EPA's Glossary of IRIS Terms

Risk Analysis Paradigm



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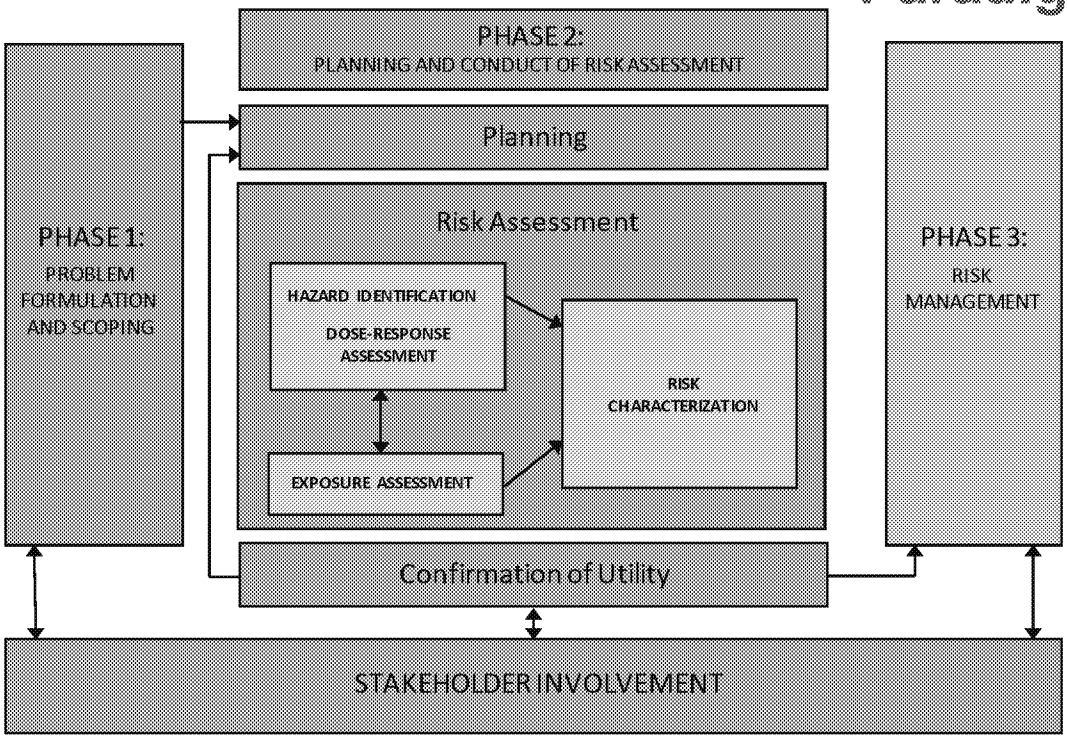
Updated Risk Analysis Paradigm



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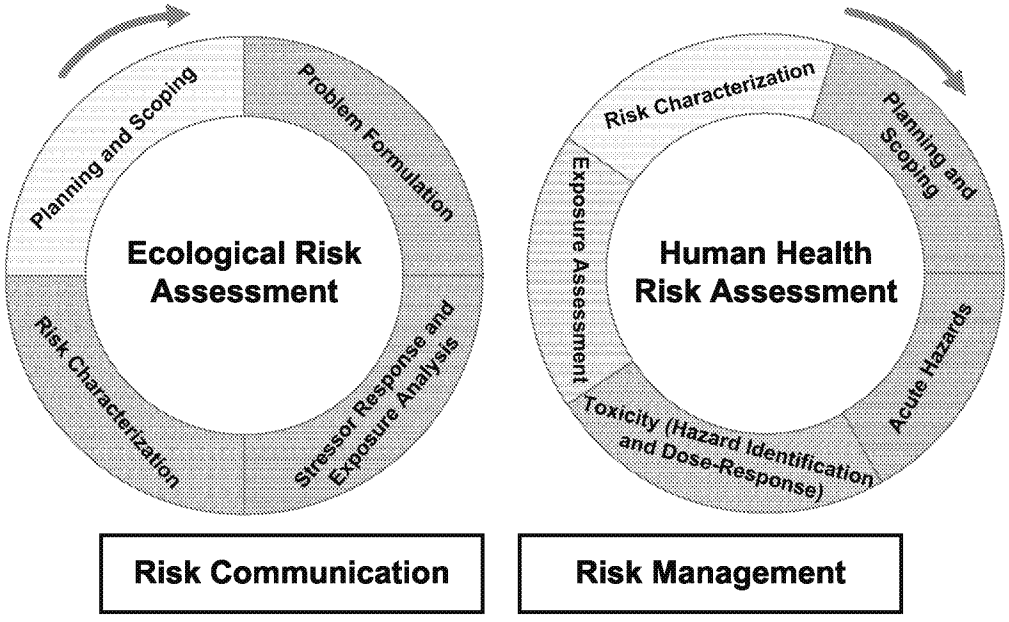
Superfund: An Application of Risk Assessment



http://www.epa.gov/oswer/riskassessment/risk_superfund.htm

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RISK ASSESSMENT TERMINOLOGY

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Important Risk Assessment Definitions:

Hazard

The inherent toxicity of a compound. Hazard identification of a given substance is an informed judgment based on verifiable toxicity data from animal models or human studies.

(EPA's Glossary of Terms of the Environment)

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Important Risk Assessment Definitions:

Exposure

Quantified as the amount of an agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut).

From EPA's IRIS Glossary

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Important Risk Assessment Definitions:

Exposure Assessment

- Identifying the pathways by which toxicants may reach individuals, estimating how much of a chemical an individual is likely to be exposed to, and estimating the number likely to be exposed (EPA's Terms of Environment).
- The determination or estimation (qualitative or quantitative) of the magnitude, frequency, or duration, and route of exposure (EPA's Exposure Factors Handbook).

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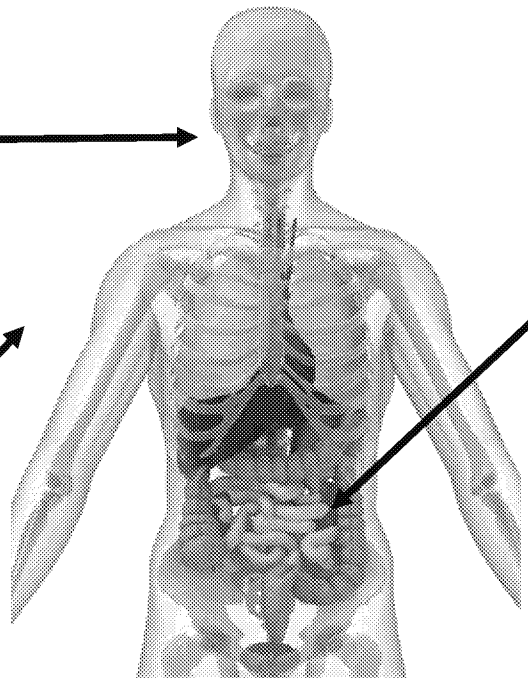
Important Risk Assessment Definitions:
Dose

Potential dose:
Ingested, inhaled, applied to skin
(µg / kg–day)

Applied dose:
Available for absorption
(µg / m^3)



Internal dose:
Amount absorbed and available for interaction
(µg / kg)

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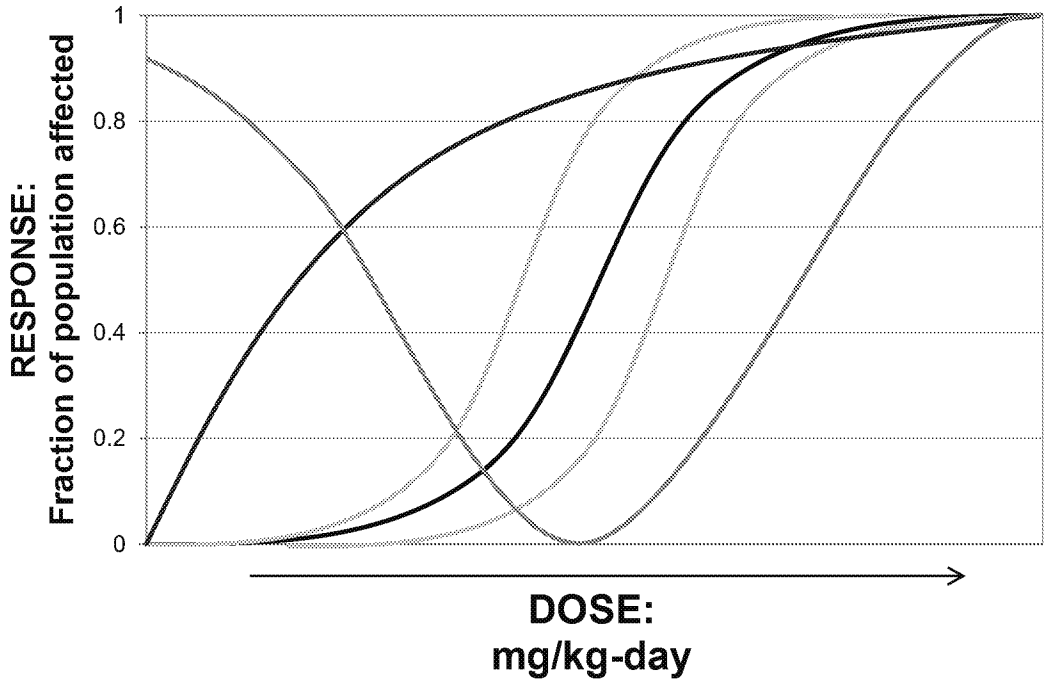
Important Risk Assessment Definitions:
Dose-Response Assessment

- Evaluating the quantitative relationship between dose and toxicological responses. (EPA's Terms of the Environment)
- A determination of the relationship between the magnitude of an administered, applied, or internal dose and a specific biological response.

  Response can be expressed as:
  - Measured or observed incidence or change in level of response
  - Percent response in a group of subjects (or populations)
  - Probability of occurrence or change in level of response within a population. (EPA's IRIS Glossary)

Example Dose-Response Curves



Important Risk Assessment Definitions:

Risk Characterization

- The last phase of the risk assessment process that estimates the potential for adverse health or ecological effects to occur from exposure to a stressor and evaluates the uncertainty involved.

(EPA's Terms of Environment)

- The integration of information on hazard, exposure, and dose-response to provide an estimate of the likelihood that any of the identified adverse effects will occur in exposed people.

(*EPA's IRIS Glossary*)

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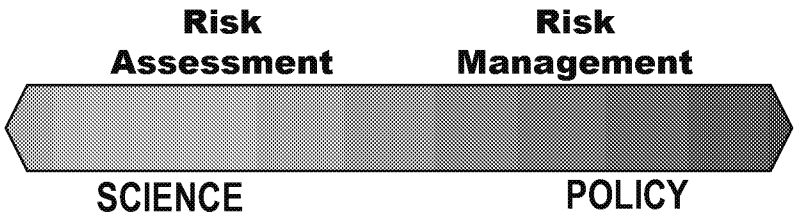
Risk Assessment and Risk Management Are Interrelated



- Risk assessors and risk managers need to have a good sense of when a decision is scientific judgment versus when it is a policy decision informed by science.
- Opinions vary on how separated risk assessment and risk management should be.
- The most current frameworks recommend an iterative process.
- Transparency is key.

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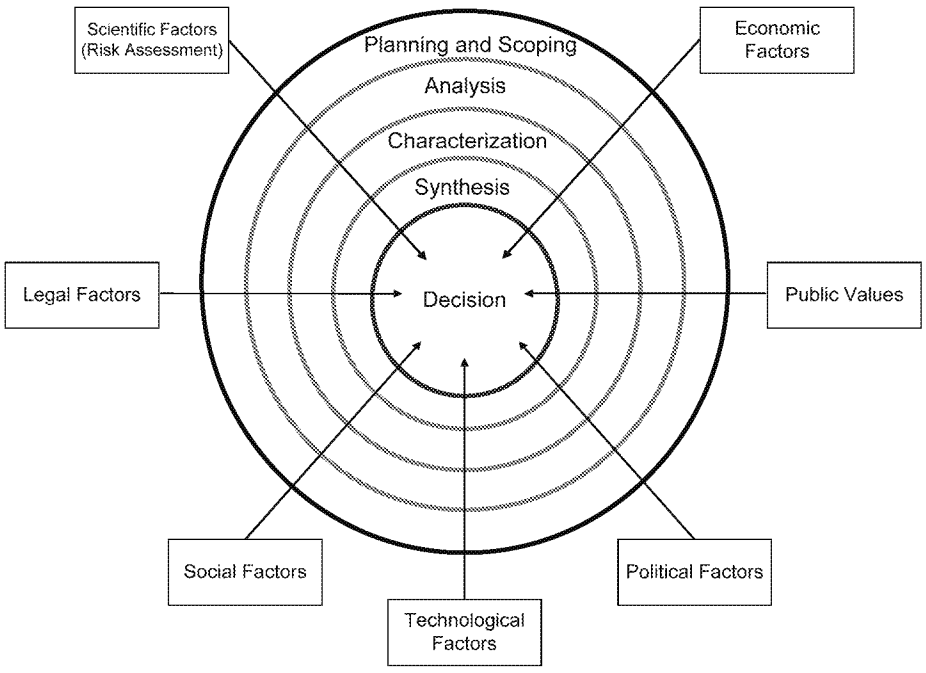
Risk Management Decision Framework



Source: EPA's Risk Characterization Handbook (2000)

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Risk Assessment to Support Risk Management at EPA, the ORD Role

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EPA Offices

EPA
ADMINISTRATOR and DEPUTY ADMINISTRATOR

- Administration and Resources Management
- Air and Radiation
- Chemical Safety and Pollution Prevention
- Chief Financial Officer
- Enforcement and Compliance Assurance
- Environmental Information
- General Counsel
- Inspector General
- International and Tribal Affairs
- Research and Development
- Solid Waste and Emergency Response
- Water

REGIONAL OFFICES

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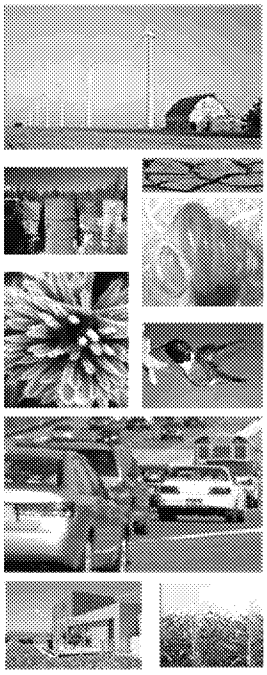
ORD Mission Statement



- Perform research and development
- Provide technical support
- Integrate the work of ORD's scientific partners
- Provide leadership in addressing emerging issues and in advancing the science of risk assessment

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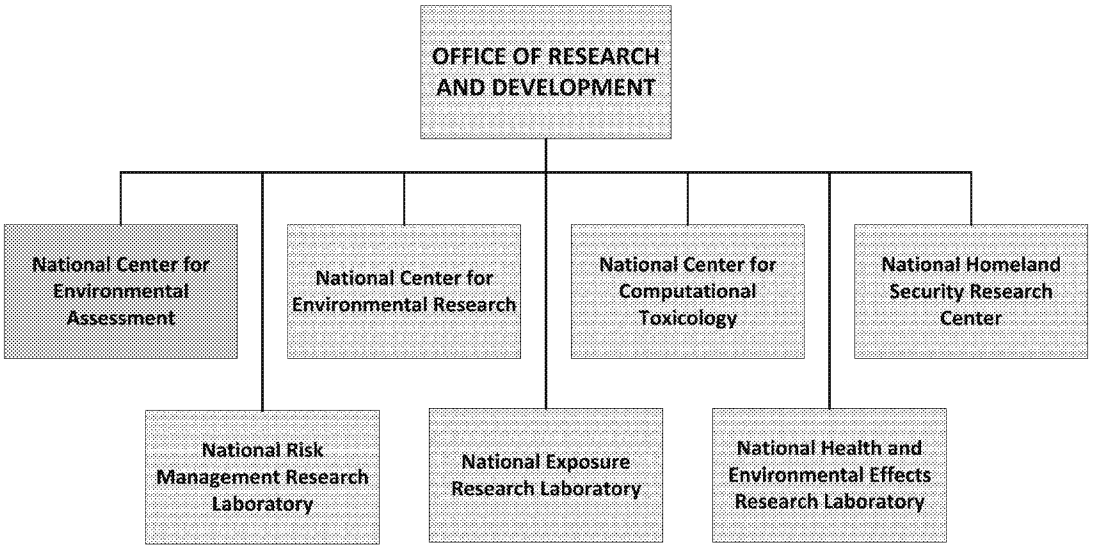
ORD Labs and Centers



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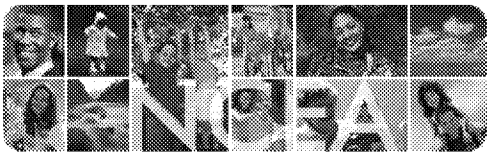
National Center for Environmental Assessment

Resource center for human health and ecological risk assessment

NCEA:

- Develops guidelines, methodologies, and training
- Creates tools and databases
- Integrates and applies ORD- and extramural-generated research
- Performs risk assessments
- Consults with EPA programs, regions, and decision makers



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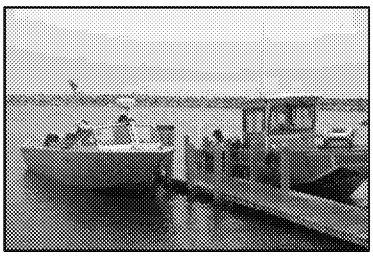
EXAMPLES OF NCEA PRODUCTS USED IN RISK ASSESSMENT

IRIS Values Used in Generation of Fish Advisories

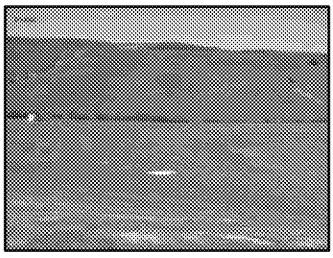


- IRIS includes an RfD for methylmercury
- RfD combined with exposure factors and contaminant concentrations
- Result is general advice about fish consumption and location-specific advisories

IRIS Values for Superfund

Casmalia Resources in Santa Barbara County, CA

- Former hazardous waste management facility
- Chemicals of concern include pesticides, solvents, acids (including hydrogen sulfide), PCBs, and heavy metals
- IRIS values support decisions about remedial actions including landfill covers, groundwater monitoring, and site improvements

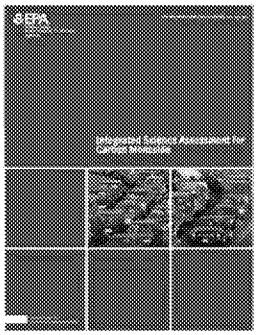


Integrated Science Assessments

The ISA accurately reflects "the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health which may be expected from the presence of [a] pollutant in ambient air." (Clean Air Act, Section 108, 2003)

ISA for Carbon Monoxide – January 2010

ISA states "that a causal relationship is likely to exist between relevant short-term CO exposures and cardiovascular morbidity."



Wrap Up

- EPA has been a leader in the environmental risk assessment field since the 1970s
- A basic paradigm (with associated terminology and concepts) guides the application of risk assessment principles
  - Terms can vary by context
  - Processes continue to evolve
- ORD products and guidance are crucial for EPA risk assessments