



# Role of Risk Assessment in Regulatory Decision Making

**Annie M. Jarabek**

Acting Deputy Director

Human Health Risk Assessment (HHRA) national program

Senior Toxicologist

National Center for Environmental Assessment

Office of Research and Development

*Standards Alliance Training on  
Analytical Tools for Regulatory Decision Making*

*Lima, Peru*

*October 30, 2014*

- **Definition of risk assessment**
  - **Risk assessment paradigm: History and evolution**
  - **Role in regulatory decision making**
- **Critical components and terminology**
- **Fit-for-purpose concept**
- **Example applications**
- **Emerging challenges**
- **Resources**
  - **Training and tools**
  - **Collaboration and contacts**

*Disclaimer: These views are those of the author and do not represent US EPA policy.*



# Definition of Risk Assessment is Contextual

Engineering/  
Structural



Environment

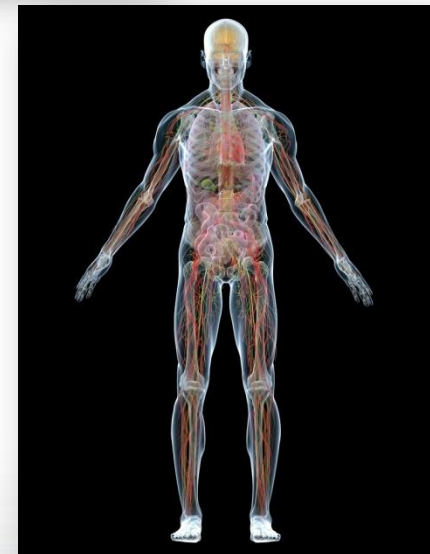


Financial/  
Business

Security:  
Vulnerability  
and Threat

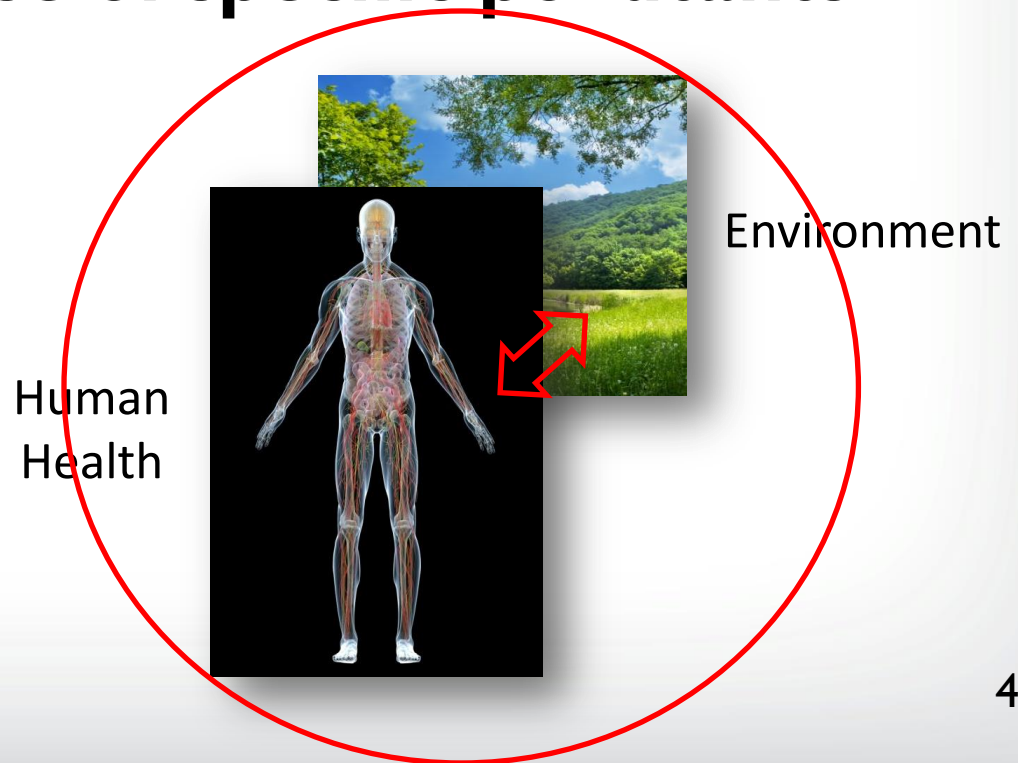


Human  
Health

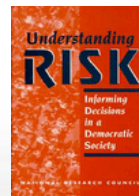


- **Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants**

*From EPA's "Terms of Environment" Glossary*

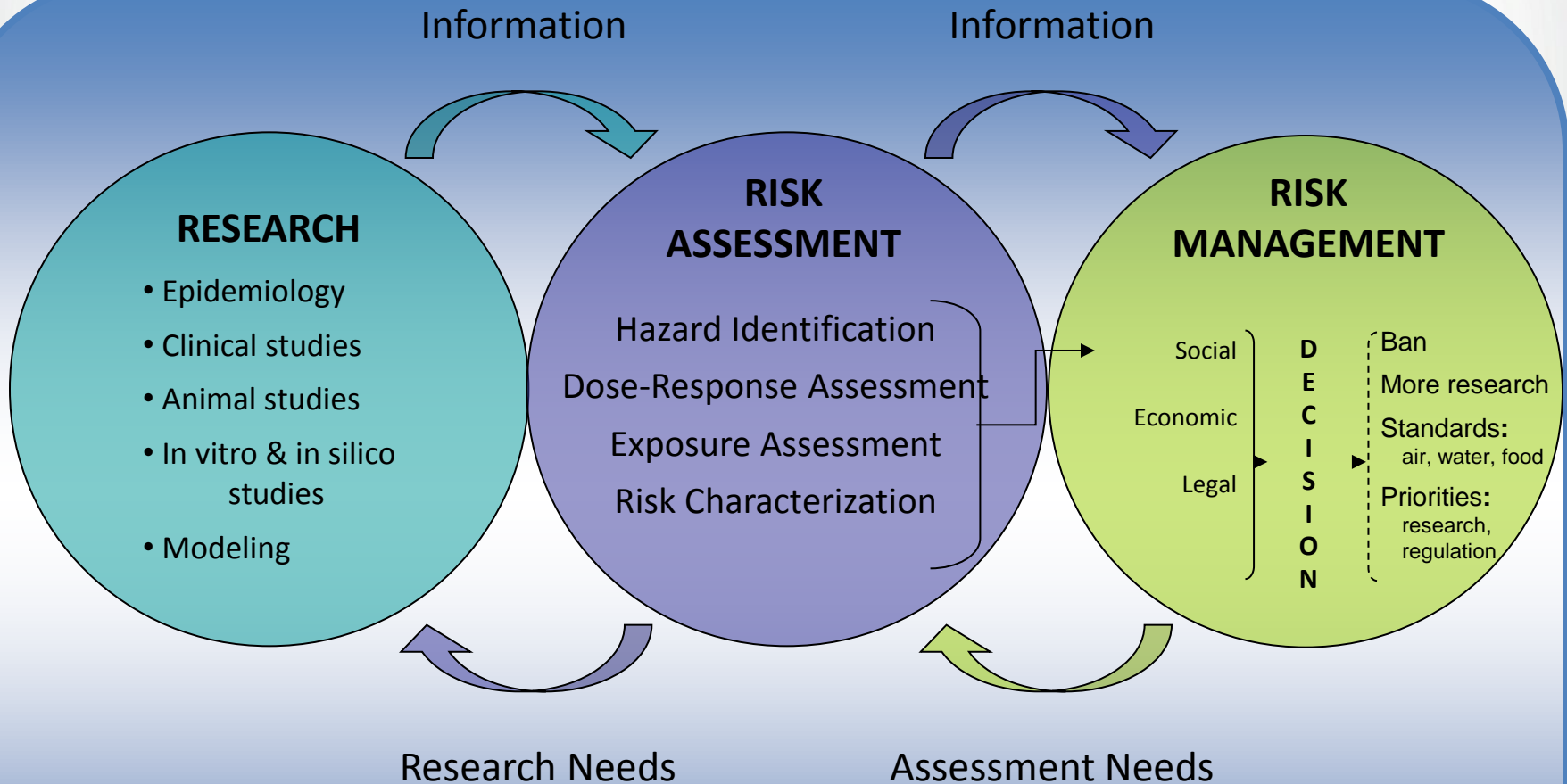


- **1970: EPA established**
- **1975: First EPA chemical assessment (vinyl chloride)**
- **National Research Council (NRC) publications on risk assessment**
  - 1983: *Managing the Process* – the “Red Book”
  - 1989: *Improving Risk Communication*
  - 1994: *Science and Judgment* – the “Blue Book”
 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



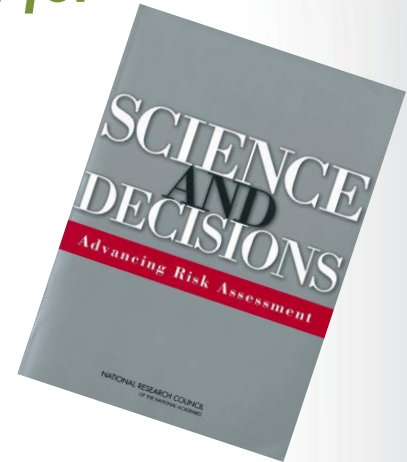


# Risk Assessment Paradigm: Role in Regulatory Decision Making



# Why Do Risk Assessment?

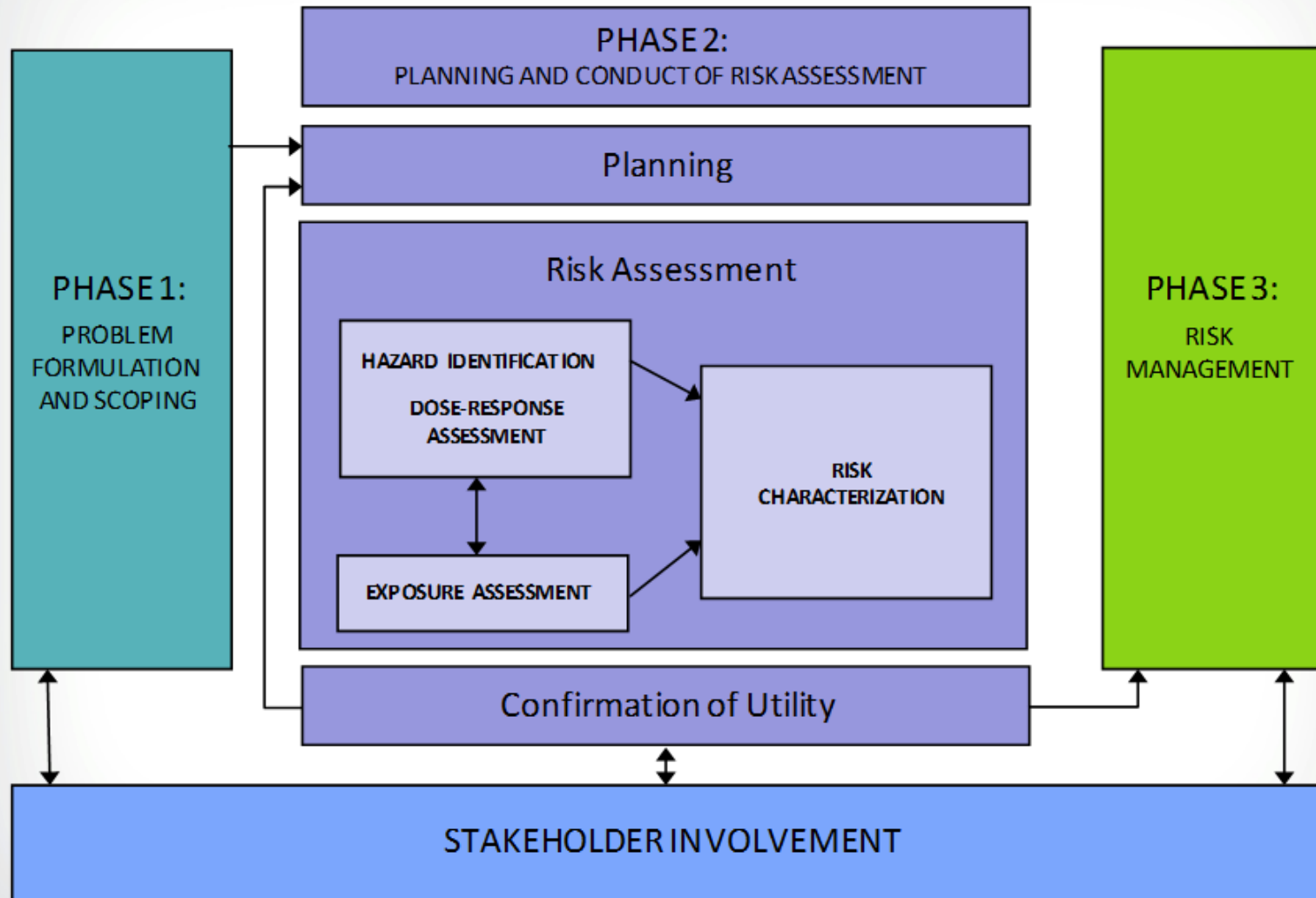
- “... risk assessment should be viewed as *a method for evaluating the relative merits of various options for managing risk ...*” (Science and Decisions, 2009)
- To provide support for decisions to protect public health and the environment.
  - Complex and controversial
  - Risk assessment summarizes the science
- Risk assessment should continue to capture and accurately describe what various research findings do and do not tell us about threats to human health and to the environment, but *only after the risk-management questions that risk assessment should address have been clearly posed, through careful evaluation of the options available to manage the environmental problems at hand.*





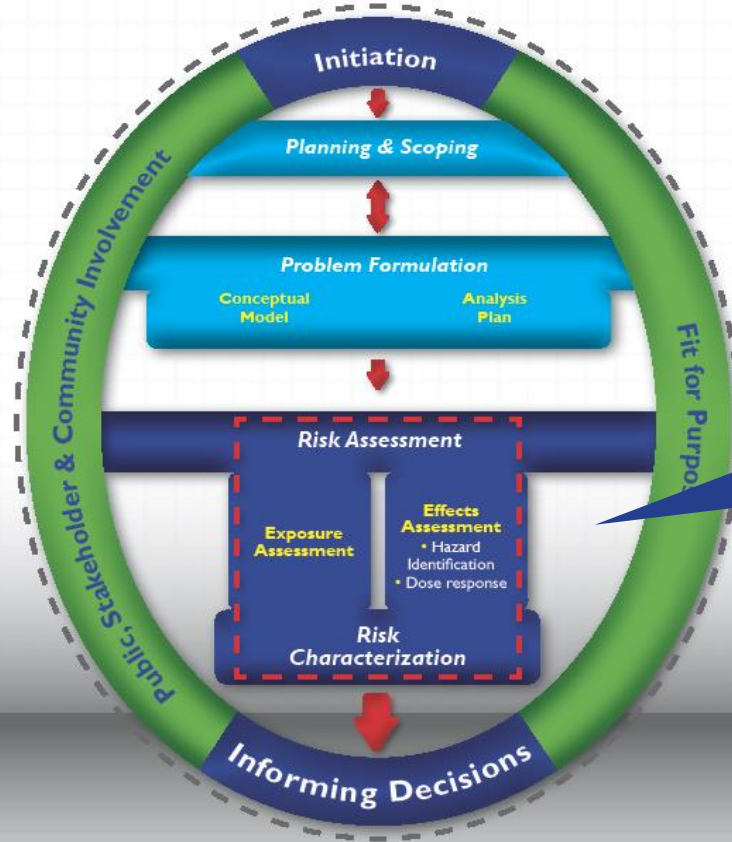


# Updated Risk Assessment Paradigm (2009)





## Framework for Human Health Risk Assessment to Inform Decision Making

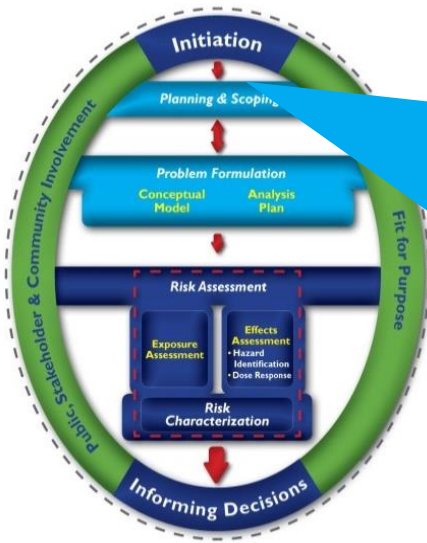


*Risk Assessment in the Federal Government: Managing the Process (NRC 1983)*

The **Red Book Risk Assessment Paradigm** shown by the red dashed lines.

Framework for Human Health Risk Assessment to Inform Decision Making  
EPA/100/R-14/001 April 2014

[www.epa.gov/raf/frameworkhhra.htm](http://www.epa.gov/raf/frameworkhhra.htm)

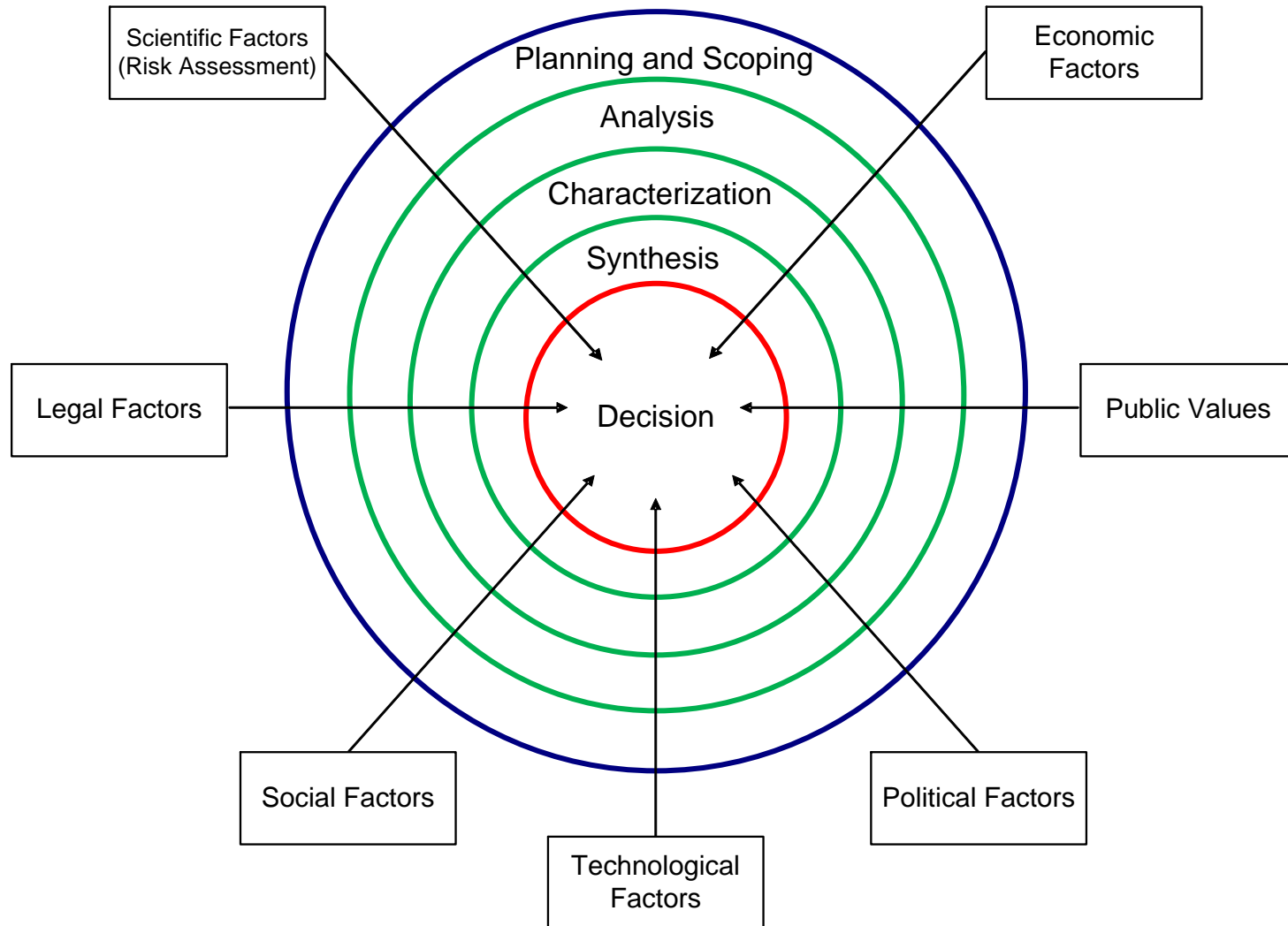


## Key Considerations for Planning and Scoping

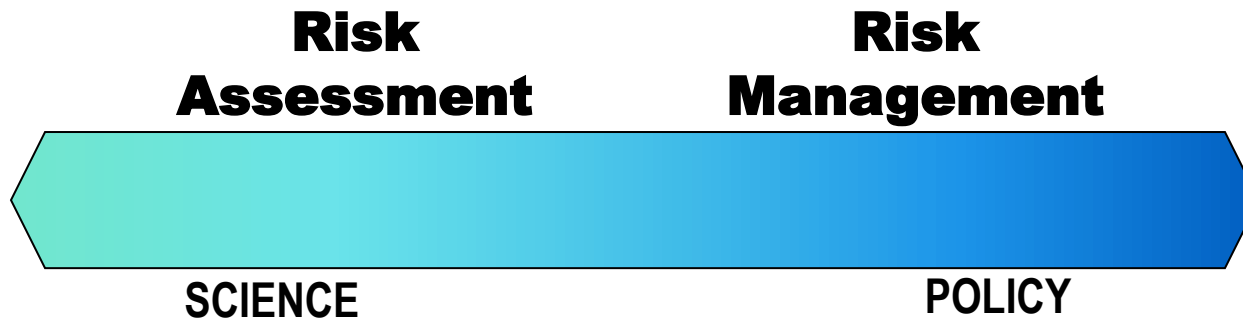
- What decision is to be informed by risk assessment, when is the decision anticipated, and what are the risk management options?
- What legal/statutory requirements affect risk management options and level/type of analysis?
- What other considerations (e.g., environmental justice, life stage, cumulative risk, sustainability) or countervailing risks may influence risk management options and analyses?
- What assessments (e.g., risk, economic) are needed to address decision-making needs?
- What expertise, resources and timelines are available to conduct the assessments(s)?



# Decision Context for Risk Management

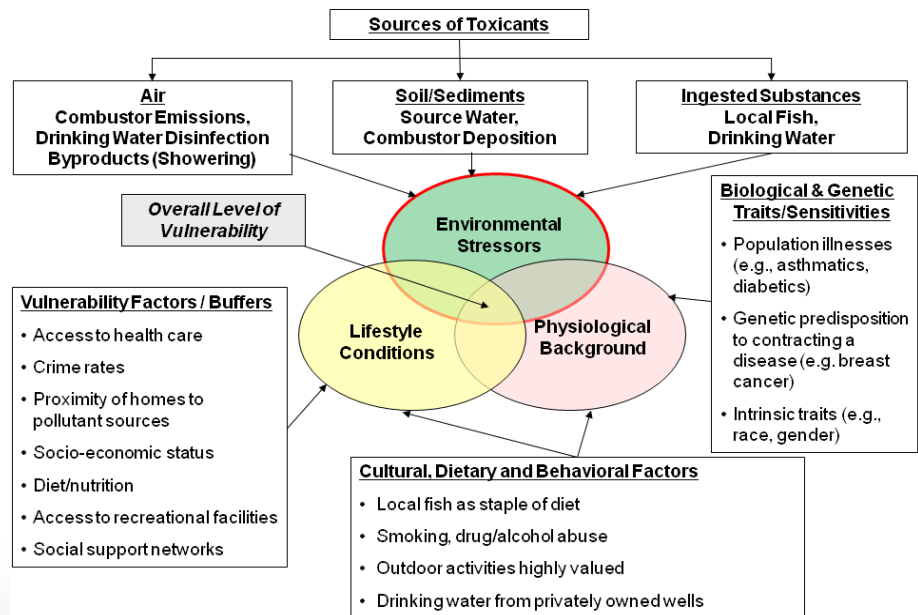
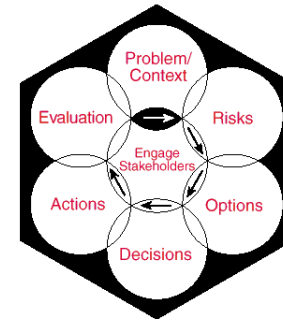


# Risk Assessment and Risk Management are Inter-related



- 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.

- Presidential Commission on Risk Assessment and Risk Management (CRARM)
  - Addressed residual risks from HAPs
  - Developed an integrated risk management approach
  
- Continued evolution at EPA
  - Integrate multiple chemical (cumulative) and aggregate (all routes) risk
    - Ecological endpoints
    - Wellness
    - Resiliency
  - Community-scale and national-scale assessments



**Risk assessment** is the evaluation of scientific information on:

- the hazardous properties of environmental agents,
- the extent of human exposure to those agents, and
- the dose-response relationship of their toxicity.

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.

*From EPA's Glossary of IRIS Terms*

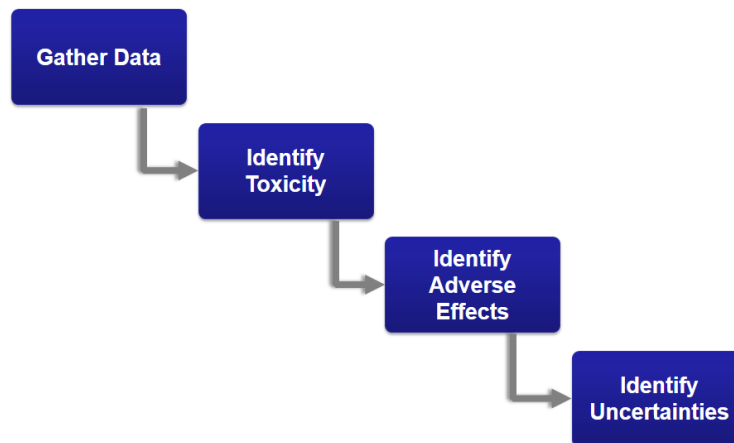
Hazard  
Identification

Exposure  
Assessment

Dose-response  
Assessment

Risk  
Characterization

- 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)





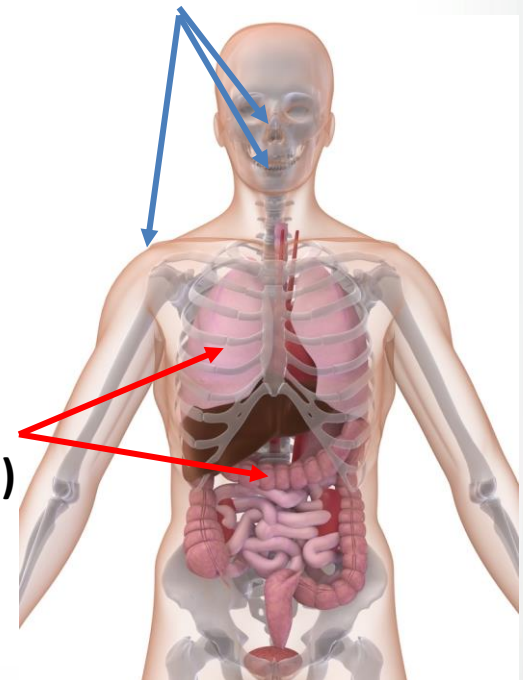
# Key Considerations in Determining Toxicity

- **Effects** – What effects are observed from the data collected?
- **Toxicokinetics** – What does the body do to the chemical?
- **Toxicodynamics** – What does the chemical do to the body?
- **Mode of action** – How does the chemical act to produce an effect?
- **Weight of evidence** – How likely is this chemical to cause non-cancer effects or cancer and under what conditions?
- **Causality Framework** – A way to organize and evaluate toxicity information to assess causality given those data.

- Quantified as the amount of an agent available at the exchange boundaries or portal-of-entries of the organism (e.g., skin, respiratory tract, and GI tract).

**Exposure or Applied Dose**  
Ingested ( $\mu\text{g} / \text{kg}$ )  
Inhaled ( $\mu\text{g} / \text{m}^3$ ),  
or applied to skin

**Internal dose ( $\mu\text{g} / \text{kg}$ )  
or dose rate ( $\mu\text{g} / \text{kg}\text{-day}$ )**  
Amount absorbed  
and available for  
interaction



- 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).



## Exposure Medium and Route

- Inhalation – air
- Oral – water, soil, food
- Dermal – soil, water, food, air



## Exposure Duration

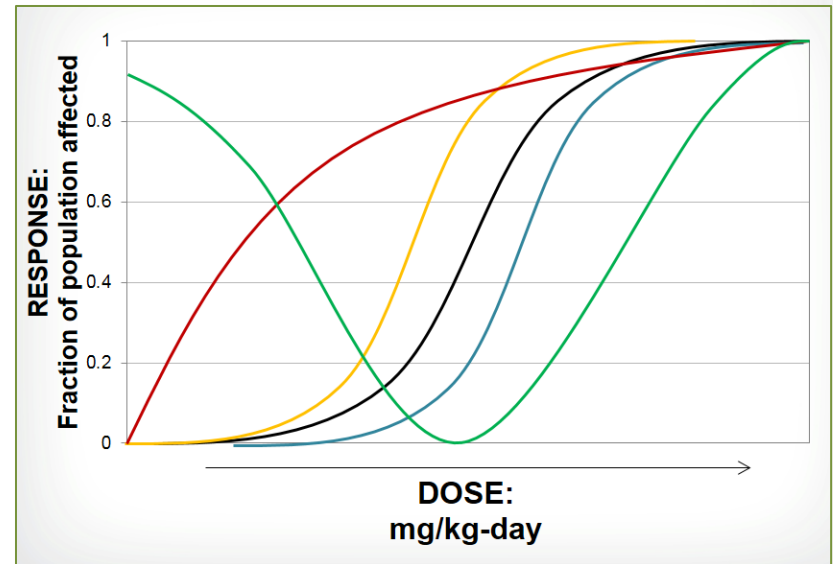
- Acute
- Short-term
- Longer-term
- Chronic (continuous)



## Potentially Exposed Population

- Workers
- Emergency responders or victims
- Pregnant women
- Children or the elderly

- Evaluating the quantitative **relationship** between **dose** and toxicological **responses**.
- 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 severity level of response
  - Percent response in a group of subjects (or populations)
  - Probability of occurrence or change in severity level of response within a population



- 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)



# U.S. Regulatory Acts

## Air

Clean Air Act

CAA Amendments  
of 1990

## Water

Safe Drinking  
Water Act

Clean Water Act

Oil Pollution Act

## Hazardous Waste

Resource  
Conservation and  
Recovery Act

Comprehensive,  
Environmental  
Response, Recovery,  
and Liability Act

Toxic Substances  
Control Act

Superfund  
Amendments  
Reauthorization Act

## Toxics & Pesticides

Federal Insecticide,  
Fungicide, and  
Rodenticide Act

Food Quality  
Protection Act

Toxic Substances  
Control Act

Pesticide  
Registration  
Improvement Act





## EPA Role in U.S. Environmental Regulation

### EPA

- Conduct research
- Perform risk assessments
- Set national standards
- Monitor compliance
- Enforce national standards

### States

- Develop state-level standards
- Monitor compliance
- Enforce state and national standards
- Issue permits



# Ambient and General Public Reference Values: Characteristics

- **Exposure Type:** Ambient
- **Duration:** Generally long-term
- **Medium:** Developed for air, water, and food
- **Enforceability:** Some are legally enforceable
- **Applicability:** Prevent harm from chemical exposures over the course of a lifetime; must protect sensitive subgroups
- **Adaptability:** Frequently developed for protection of human health and the environment





# Reference Values: Levels of Enforceability

## Exposure Standards

Relatively few

Mandated by statute and legally enforceable

Rigid development process

Developed by government agencies specified in statutes

Intended to protect health and the environment, but balances other considerations

## Exposure Guidelines

Numerous

Not legally enforceable

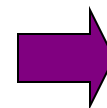
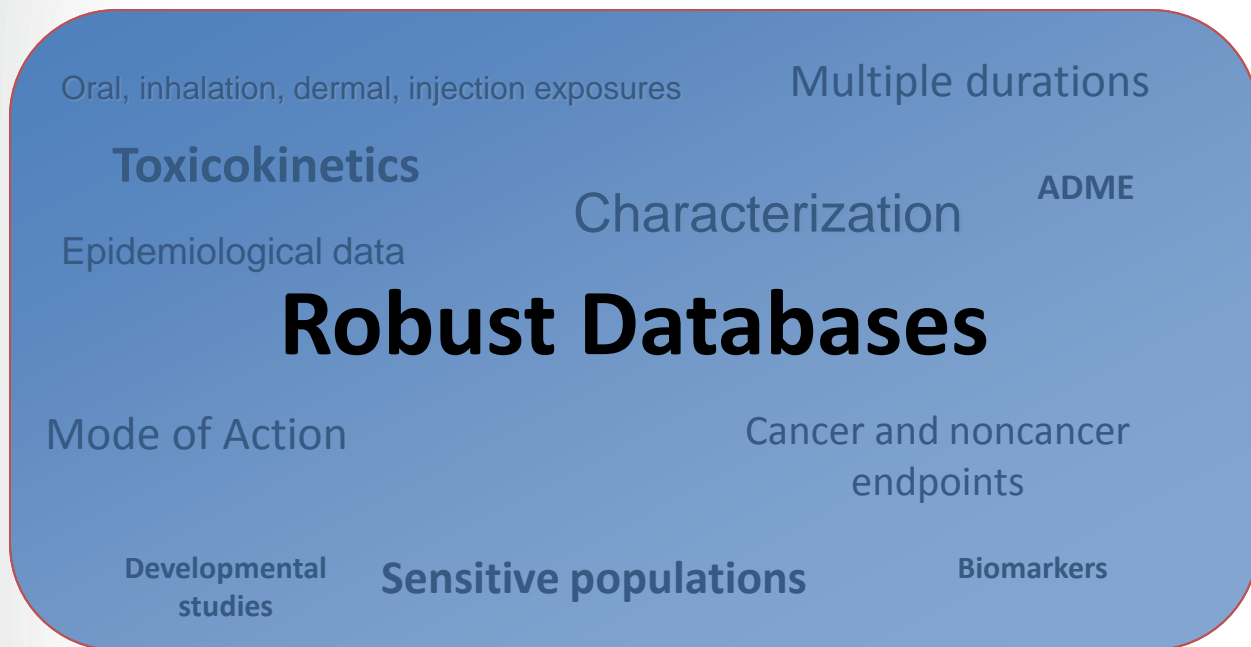
Flexible development process

Developed by many types of entity

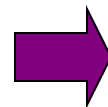
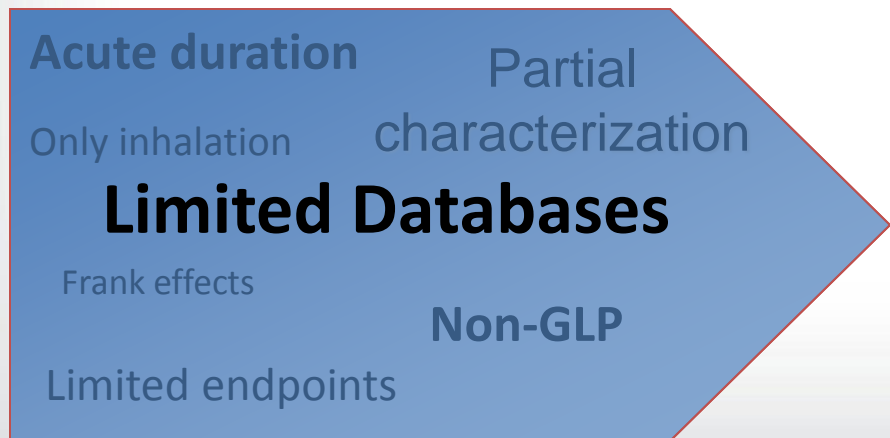
Intended to protect human health and the environment



# Continuum of Confidence in Data and Concept of Fit-for-Purpose



**Preferred Values**



**Less-Preferred Values**



# Exposure Standards

Medium	Standard	Regulated Contaminants	Regulatory Authority
Air	<b>National Ambient Air Quality Standards (NAAQS)</b>	<b>6 Criteria Pollutants in ambient air</b>	<b>EPA, as mandated by the Clean Air Act</b>
	Permissible Exposure Limits ( <b>PELs</b> )	~500 contaminants in workplace air	OSHA, as mandated by the Occupational Safety and Health Act
Water	Maximum Contaminant Levels ( <b>MCLs</b> )	90 chemical, microbiological, radiological, and physical contaminants in drinking water	EPA, as mandated by the Safe Drinking Water Act
Food	Maximum Residue Limits ( <b>MRLs</b> )	Hundreds of pesticide chemicals in food and feed commodities	EPA, as mandated by the Federal Food, Drug, and Cosmetics Act, as amended by the Food Quality Protection Act



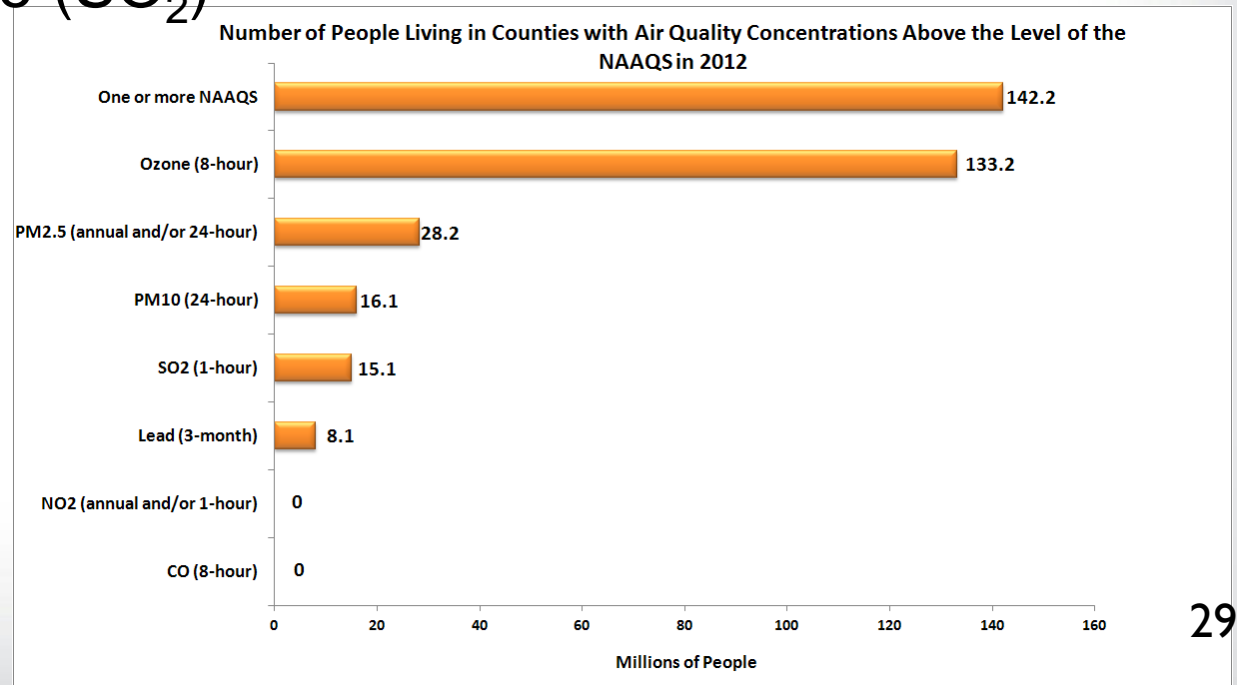
# Criteria Pollutants Characteristics

- **"Numerous and diverse mobile and stationary sources"**
- **Widespread exposure: millions of people, ecosystems**
- **Typically non-cancer health endpoints**
- **Typically human health data available**
- **Some produce ecological effects**
  
- ***Different considerations apply to setting NAAQS versus to achieving them***
  - **Setting NAAQS: Health and environmental effects**
  - **Achieving NAAQS: Account for cost, technical feasibility, time needed to attain**



# Current Criteria Pollutants

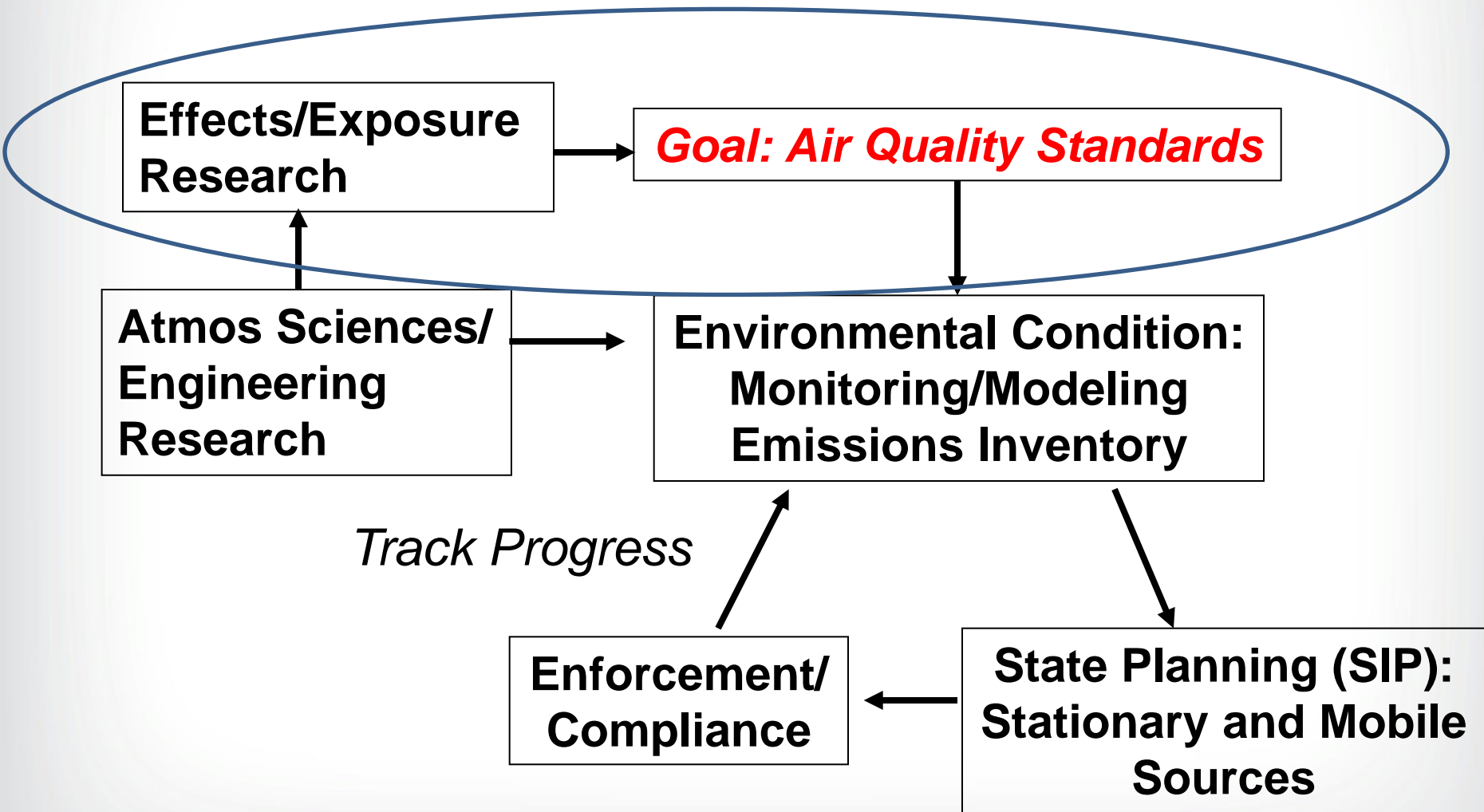
- 6 criteria pollutants (EPA can modify list):
  - Ground-level (tropospheric ozone ( $O_3$ ))
  - Particulate matter ( $PM_{2.5}$  and  $PM_{10}$ )
  - Carbon monoxide (CO)
  - Sulfur dioxide ( $SO_2$ )
  - Nitrogen





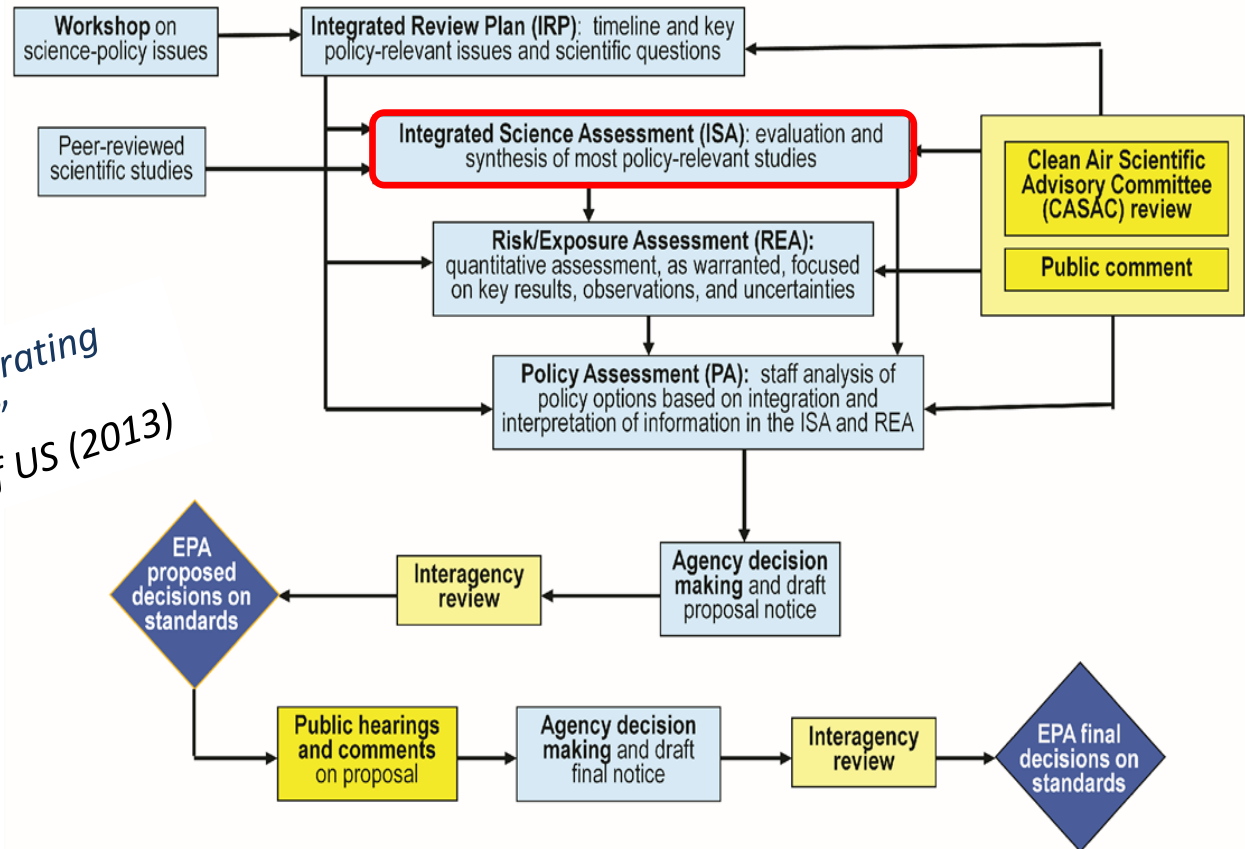


# Framework for Air Quality Management



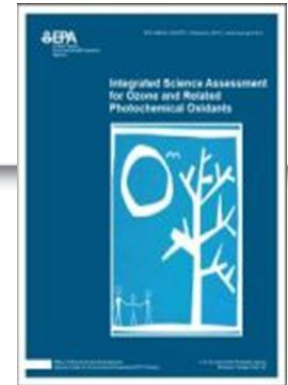


# Integrated Science Assessments (ISA)



*"A five-star process for incorporating science into regulatory policy." Administrative Conference of US (2013)*

- Provide a concise review, synthesis, and evaluation of the most policy-relevant science to serve as the scientific foundation for review of the National Ambient Air Quality Standards (NAAQS) for criteria pollutants
- Prepared in close coordination with EPA office of air quality planning and standards

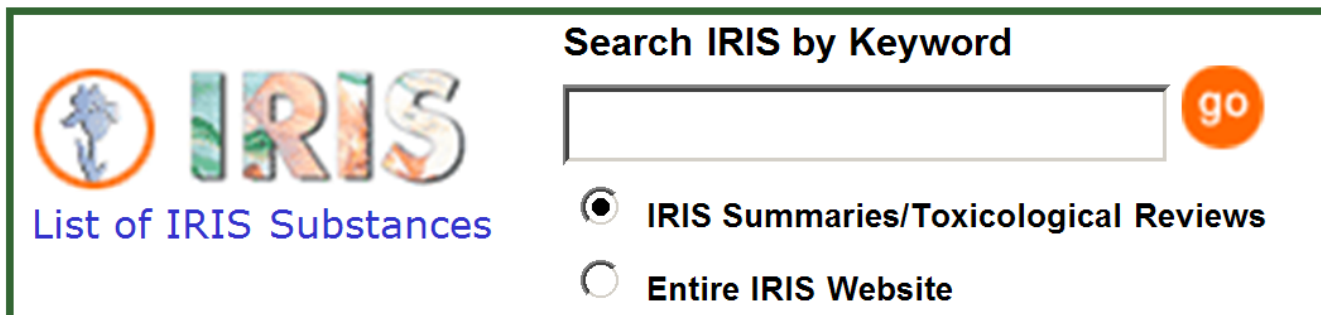


- **Most recently released February 2013**
  - **4,000+ studies considered; 2,270 studies cited**
  - **1,038 new since 2006 Ozone Air Quality Criteria Document (AQCD)**
- **Implemented new weight of evidence framework for at-risk factors**
  - **Which individual- and pollutant-level factors result in increased (decreased) risk of an air pollutant induced health effect?**
  - **Four level classification of evidence for potential at-risk factors**
- **Multiple associated peer-reviewed journals**





# IRIS: US EPA's Preferred Reference Values

A screenshot of the IRIS search interface. On the left, there is a logo for IRIS (Integrated Risk Information System) with the text "List of IRIS Substances" below it. On the right, there is a search bar with the text "Search IRIS by Keyword" above it. Below the search bar is a radio button selection for "IRIS Summaries/Toxicological Reviews" (which is selected) and "Entire IRIS Website". An orange "go" button is located to the right of the search bar.

Search IRIS by Keyword

List of IRIS Substances

IRIS Summaries/Toxicological Reviews


Entire IRIS Website

## EPA's Integrated Risk Information System (IRIS)

- Supports EPA's programmatic actions and other entities.
- Intended to be the highest-quality, science-based toxicity reference values.
- Contains peer-reviewed, Agency-derived values.
- Derived for specific chemical substances.
- Based on review of all relevant toxicity, toxicokinetic, and mode of action (MOA) information.



# General Public Reference Values: IRIS

Guideline	Organization and Context
<b>RfD</b> Reference dose for noncancer endpoints (ingestion)	 <p>Integrated Risk information System (IRIS) values are:</p> <p>Developed to support hazard identification and dose-response assessment.</p> <p>Used to characterize public health risks of a given substance in a given situation.</p> <p>Used to form the basis for risk-based decision-making, regulatory activities, and other risk management decisions.</p>
<b>RfC</b> Reference concentration for noncancer endpoints (inhalation)	
<b>OSF</b> Oral slope factor of cancer risk	
<b>IUR</b> Inhalation unit risk for cancer	



**Review of the Integrated Risk Information System (IRIS) Process (NRC, May 2014):**  
**“EPA has made substantial improvements to the IRIS Program in a short amount of time”**

- **Development process** <http://epa.gov/iris/>
  - **Planning and scoping**
  - **Public meetings on released literature search and strategy, evidence tables, and exposure-response figures**
- **Improving the science**
  - **Systematic review**
  - **Concise, compact and clear document structure**
  - **SAB Chemical Assessment Advisory Committee (CAAC)**
- **Improving productivity and transparency**
  - **Workforce planning**
  - **Agency needs assessment**
  - **Stopping rules** [http://www.epa.gov/iris/pdfs/IRIS\\_stoppingrules.pdf](http://www.epa.gov/iris/pdfs/IRIS_stoppingrules.pdf)



<http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/Chemical%20Assessment%20Advisory%20Committee>





## Example Application: IRIS Reference Value Used to Establish Fish Advisory



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



# Example Application: IRIS Reference Value Used at Superfund Sites

## 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





# Emergency Response Values: Characteristics

- **Exposure Type:** Workplace or general public
- **Duration:** Generally acute
- **Medium:** Generally concentrations in air or water
- **Enforceability:** Not legally enforceable
- **Applicability:** Inform emergency response and public health planning (e.g., determine egress and re-entry)
- **Adaptability:** Often specify levels of harm (e.g., mild or severe)





# Provisional Peer-reviewed Toxicity Values (PPRTV)

- **Limited data sets**
- **Peer-reviewed with legal standing**
  - **Determine cleanup levels**
  - **Establish monitoring**
- **Superfund Technical Support Center**
  - **Human health**
  - **Ecological**

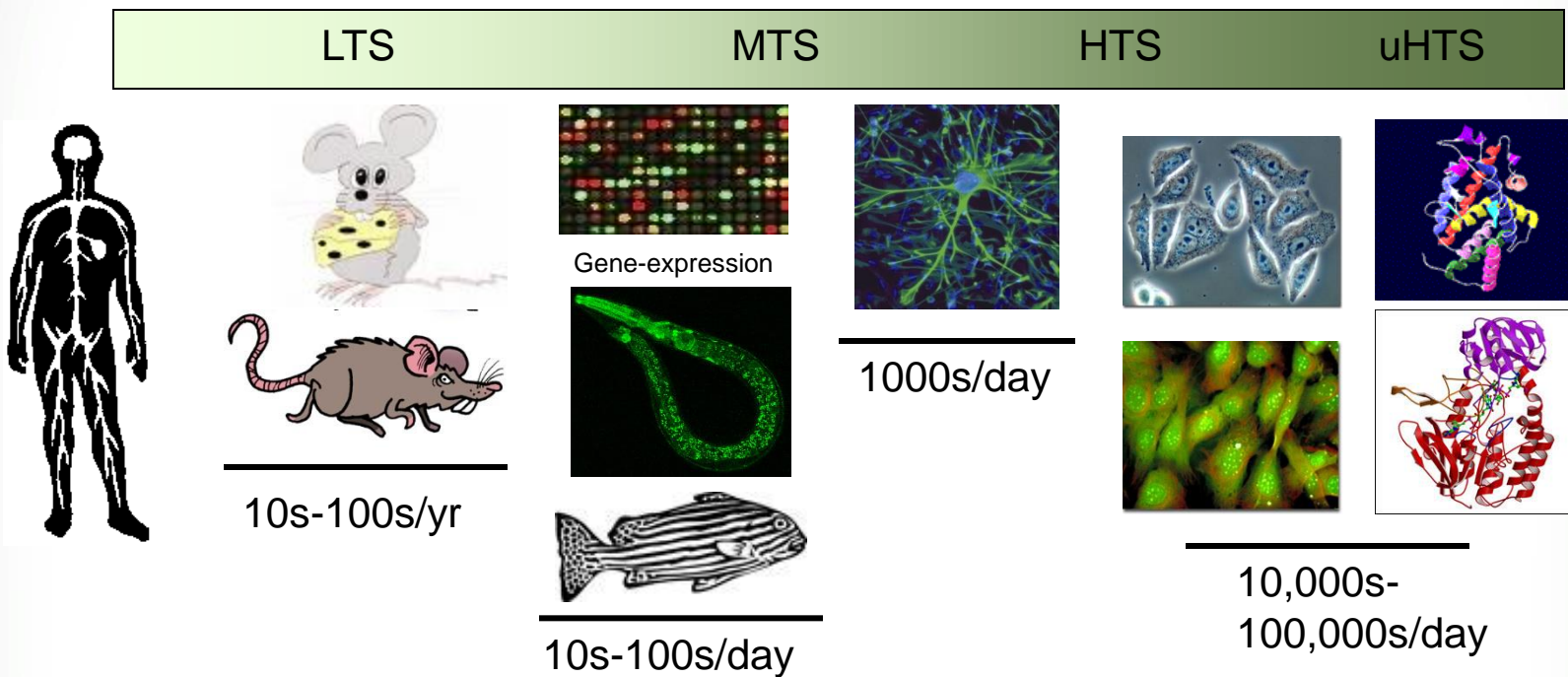


Provisional Peer-Reviewed  
Toxicity Values for  
Styrene-Acrylonitrile (SAN)  
Trimer  
(Various CASRNs)

Superfund Health Risk Technical Support  
Center  
National Center for Environmental  
Assessment  
Office of Research and Development  
U.S. Environmental Protection Agency  
Cincinnati, OH 45268



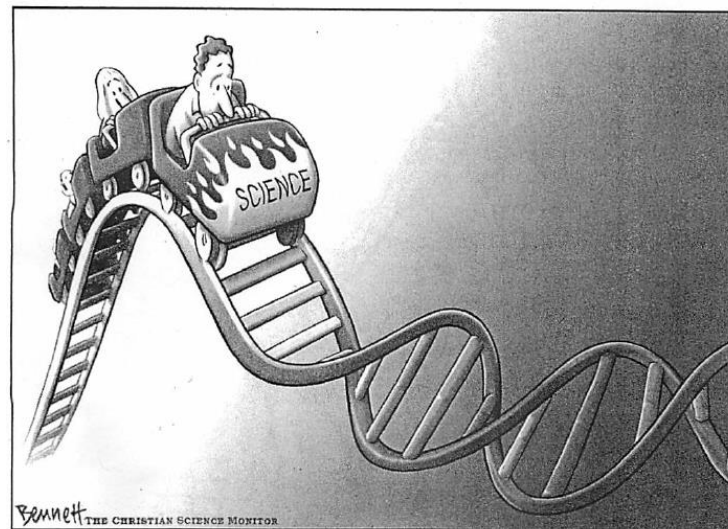
# New Data: New Opportunities



Human Relevance/  
Cost/Complexity

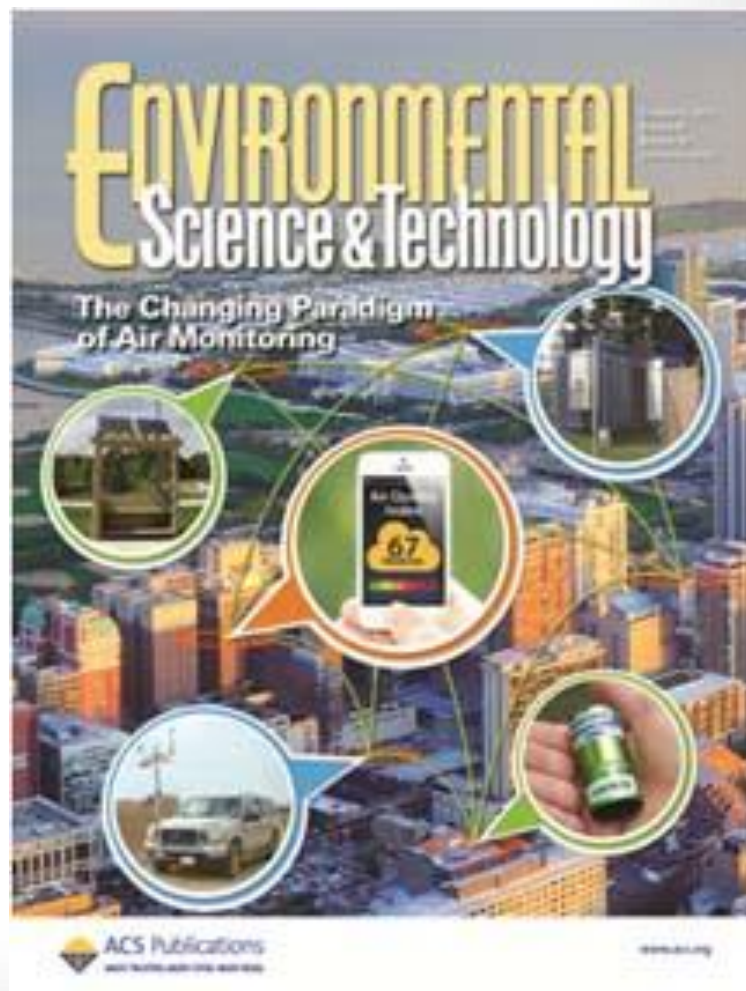
Throughput/  
Simplicity

- Current characterization context: Comprehensive scope of disease pathogenesis
- Increased sophistication of measurements
- Growing understanding of mechanisms at molecular level (e.g., QSAR, HT and HTC assays)
- Animal models of susceptibility
- Enhanced computational capacity (*in silico* models) to describe processes quantitatively



# Emerging Challenges: Sensor Data and Citizen Science

- Factors influencing measurement
  - Detection limits
  - Location
  - Collection conditions
- Representativeness, relevance, utility
- Curation and data management
- Interpretation





## Application of Emerging Data in Risk Assessment

- **Advance biotechnology and systems understanding → Pathway-based assessment to predict adversity**
  - **Protecting the public health and environment requires analysis, translation, and integration of data along source to effect pathways**
  - **Optimization of economic, environmental and societal concerns to support sustainability**
- **Requires transparent and tractable integration of diverse data types across scales**
  - **Spatial**
  - **Temporal**
  - **Biological**





## Creating Context to Transition Risk Assessment

- Characterize **dose-response** using new endpoints with linkage to traditional outcome measures such as morbidity, mortality, histopathology and tumors
- Requires **integration** of diverse data sets across different domains (e.g., genomic versus population), methods (e.g., measurements / mining / models) and observational contexts
  - *in vivo / ex vivo*
  - **Laboratory animal or other test species**
  - **Human and ecological**
- **Repurposing** of data is typical problem area: Provide explicit evaluation of data quality, utility, and relevance to facilitate formal inferences
- Highlight how individual **judgments** concerning data on parameters for **causality** of specific steps influence the confidence in ultimate decision; emphasize accuracy and predictive power to establish **confidence**

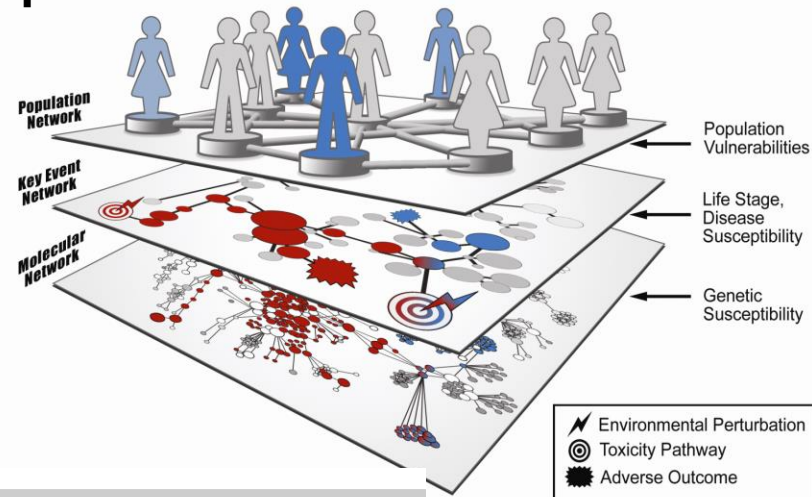
- **Disease-based context for other critical endpoints of interest**

- Respiratory, liver, cardiovascular, ...

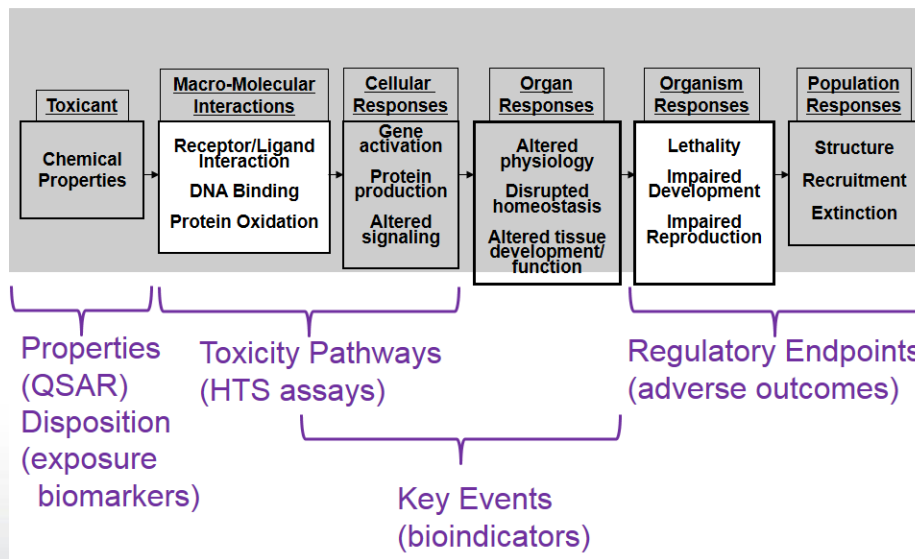
- **Data from diverse sources and approaches**

- High Throughput/Content Screening
- Adverse outcome Pathway/Mode of Action
- Biomonitoring
- Laboratory animal (*ex vivo*, *in vivo*)
- Human (clinical, epidemiological)
- Clinical chemistry
- Virtual tissues

*AOP and biomarkers serve to link elements and describe disease pathogenesis*



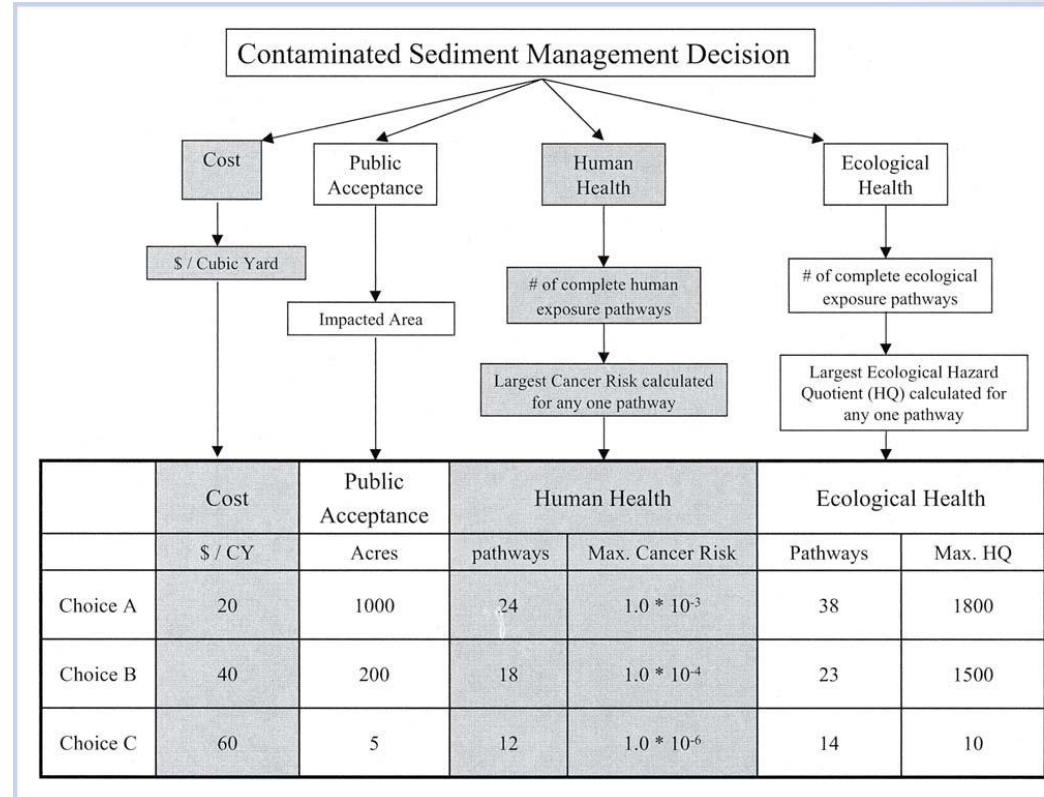
adapted from Edwards & Preston (2008), *Tox Sci*, 106(2):312-318





# Multi-criteria Decision Analysis (MCDA)

- **System construct to evaluate impacts of modifying factors, including data gaps, on resultant decision**
- **Flexible – clearly defines parameters included (or not) in process and aids transferability**
- **Transparent valuation of choices**
- **Stakeholder engagement**



Kiker et al (2005) *Integrated Environ Assess Management* 1(2), 95.



## Cultural and Operational Needs

- **Access to discover, collect, and integrate data in a coordinated fashion**
  - Encourage data repositories with maintenance and management
  - Enhance open access and change publication practice
- **Mitigating uninformed use of models**
  - Making application limitations known
  - Documentation of parameter values
- **Facilitating collaboration *and* accommodating confidentiality**
- **Repurposing of data for new analysis requires context for data (meta data) including annotation and curation history; also requires dedicated data management**
- **Peer review: Transparency of assumptions and uncertainty propagation**
- **Visualization**
- **Simplicity of interfaces**



### *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





# ORD Research Programs

**Air, Climate & Energy**



**Sustainable & Healthy Communities**



**Homeland Security**



**Chemical Safety for Sustainability**



**Human Health Risk Assessment**



**Safe & Sustainable Water Resources**





# ORD Research Aligned with EPA Strategic Goals

## Cross-Agency Strategies

- Sustainable Future
- Visible Difference in Communities
- New Era of Partnerships
- High-Performing Organization

## EPA Goals 2014-2018

Addressing Climate Change and Improving Air Quality

Protecting America's Waters

Cleaning Up Communities and Advancing Sustainable Development

Ensuring the Safety of Chemicals and Preventing Pollution

Enforcing Laws, Ensuring Compliance

## Research Programs

Air, Climate & Energy

Safe and Sustainable Water Resources

Sustainable and Healthy Communities

Chemical Safety for Sustainability

Human Health Risk Assessment

Homeland Security



# Resources: Databases

**Health & Environmental Research Online (HERO)**

**HERONet Home**

**What is HERO?**

The Health and Environmental Research Online is a database of scientific studies and other references used to develop EPA's risk assessments aimed at understanding the health and environmental effects of pollutants and chemicals. It is developed and managed in EPA's Office of Research and Development (ORD) by the National Center for Environmental Assessment (NCEA).

**What data does HERO provide?**

For each reference, HERO contains:

- Reference type
- Citation elements: authors, title, year of publication, reference, the citation will also include volume and page numbers
- Abstract or brief description
- Topic areas that describe the reference (e.g., air quality, water quality, etc.)
- Assessment(s) in which the reference was used

**LitSearch**  
Journal Finder Citation Linker

Basic Search Advanced Search Search tips

Select databases by category | Select databases individually

Year: (Format: yyyy)

Select All  
AGRICOLA - Indexes literature from agriculture, ecology, and related disciplines  
American Association for Cancer Research - content from the AACR



## Risk Assessment Training and Education (RATE)

- Approximately 30 modules
  - General to detailed instruction on concepts and approaches
- *Can be tailored to user needs*
- Multiple international training events to date
  - Chile
  - Egypt
  - Europe
  - Saudi Arabia
  - New Zealand
- Exploring possibilities for web-based training in future



# Resources: Research and Tools to Advance Applications

- **Exposure science and support**
  - **EPA ExpoBox enhancements: New tools**
  - **Updating of specific exposure factors**
- **Scientific workshops**
  - **IRIS process: NRC review**
  - **Specific assessment issues: Inorganic arsenic**
  - **Critical challenges: MOA for mouse lung tumors**
- **Reports**
  - **NexGen Report: Sets stage for new applications**  
<http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=286690>
- **Interoperability and access:**
  - **IRIS web access, IRIS calendar, analysis tools,...**
  - **HERO support**
- **Publications (*Available on Request*)**





# Resources: Bulletins, Blogs and Listservs

- Opportunities for public comment and peer review
  - IRIS Bi-monthly meetings
- Listservs
  - HHRA Bulletin (5,986 recipients)
  - BMDS-News (4,839 recipients)
  - IRIS Updates (1,608 recipients)
  - ExpoBox Bulletin (559 recipients)

HHRA Bulletin: May 2013



The latest news from EPA's Human Health Risk Assessment Research Program

#### Recent Accomplishments & Events

- EPA has released a revised [draft IRIS assessment of methanol \(noncancer\)](#) for public comment and external peer review.
- EPA recently released a [draft plan](#) for developing the Integrated Science Assessment (ISA) for nitrogen oxides (NOx).
- EPA recently published a [Federal Register Notice](#) requesting information on methods for cumulative risk assessment (CRA). Information gathered will be used to inform the Risk Assessment Forum (RAF) Technical Panel on Cumulative Risk in development of guidelines for CRA.
- EPA recently announced [several upcoming science workshops](#), the first of which will focus on systematic review of scientific studies. Public input is welcome; information on how to submit comments is available [here](#).
- Three articles authored by HHRA scientists were recently published: "Thoracic and Respirable Particle Definitions for Human Health Risk Assessment" in *Particle and Fiber Toxicology*; "Susceptibility of Older Adults to Health Effects Induced by Ambient Air Pollutants Regulated by the European Union and the United States Europe" in *Aging Clinical and Experimental Research*; and "Cardiovascular Outcomes and the Physical and Chemical Properties of Metal Ions Found in Particulate Matter Air Pollution: A QICAR Study" in *Environmental Health Perspectives*.



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# Resources: EPA Risk Assessment Portal



United States Environmental Protection Agency

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## Risk Assessment

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### How do I?

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- [Databases & Assessments](#)

Find out how to learn more about..

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- [Ecological Risk Assessment](#)

Find the risk related to..

- [Laws and Regulation](#)

### Resources

Expand Accordion

Basic Information

### Quick Finder

[Air Pollution](#)  
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[Climate Change](#)

[Data Finder](#)  
[Drinking Water](#)  
[FIFRA Sci. Advisory Pnl](#)  
[Fish Advisories](#)  
[Indoor Air](#)

[IRIS - Toxicity Data](#)  
[Lead](#)  
[Mercury](#)  
[Pesticides](#)  
[Science Advisory Board](#)

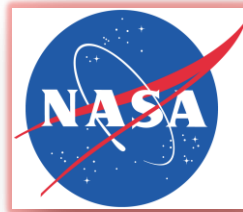
[TEACH - Children's Health Data](#)  
[TRI - Toxic Release Inv](#)  
[Water Science](#)  
[Waste & Cleanup](#)

This site provides basic information about environmental risk assessments for the public. Additionally, the site offers a comprehensive set of links to key EPA tools, guidance and guidelines.



# Collaborators and Reviewers

## Other Federal Agencies



## State Agencies



## Other Entities





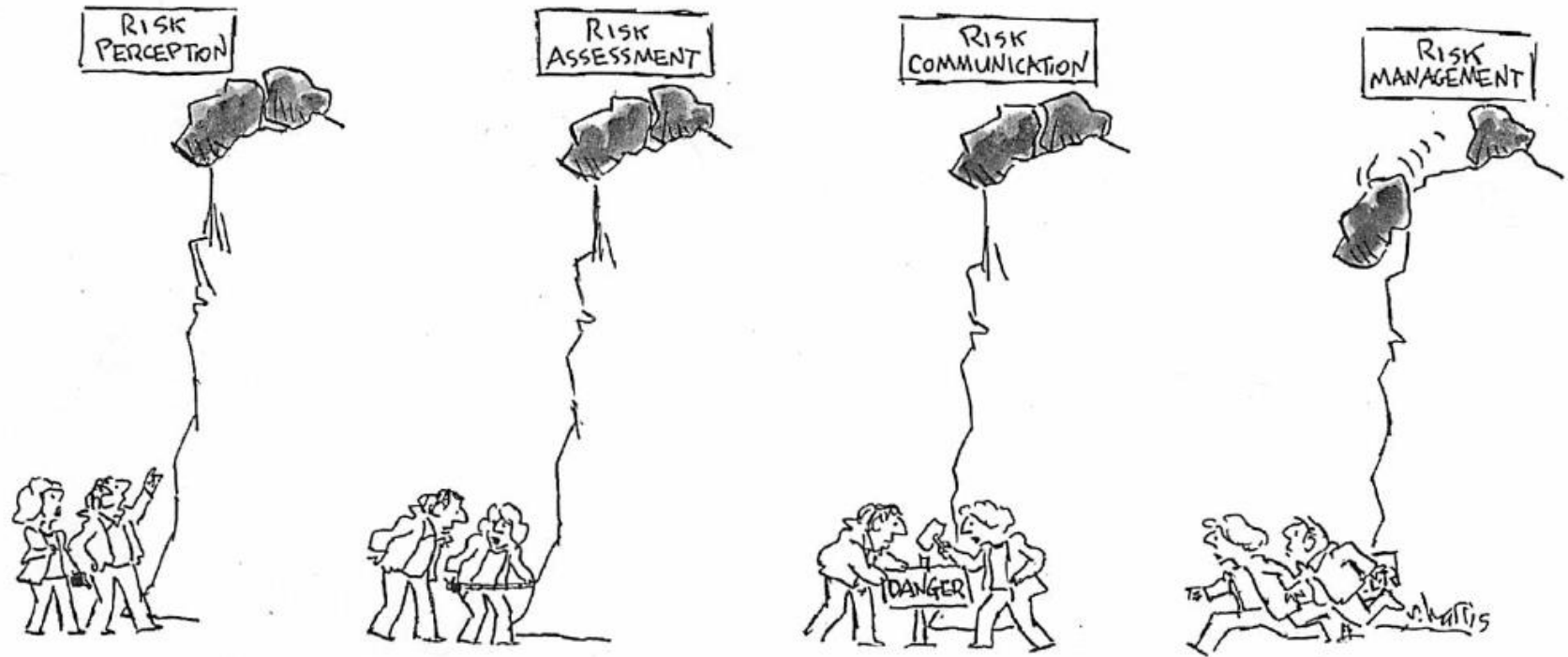
## Acknowledgments and Contact Information

John V. Vandenberg, National Program Director  
Human Health Risk Assessment

Abdel Kadry  
Senior Advisor for Scientific Organizational Development  
and International Activities

Annie M. Jarabek  
Mobile (best): 919-637-6016  
Office: 919-541-4847  
Email: [Jarabek.Annie@epa.gov](mailto:Jarabek.Annie@epa.gov)





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