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HUMAN HEALTH RESEARCH PROGRAM

BUILDING A SCIENTIFIC FOUNDATION FOR SOUND ENVIRONMENTAL DECISIONS

Human Health Research Program (2006-2013)

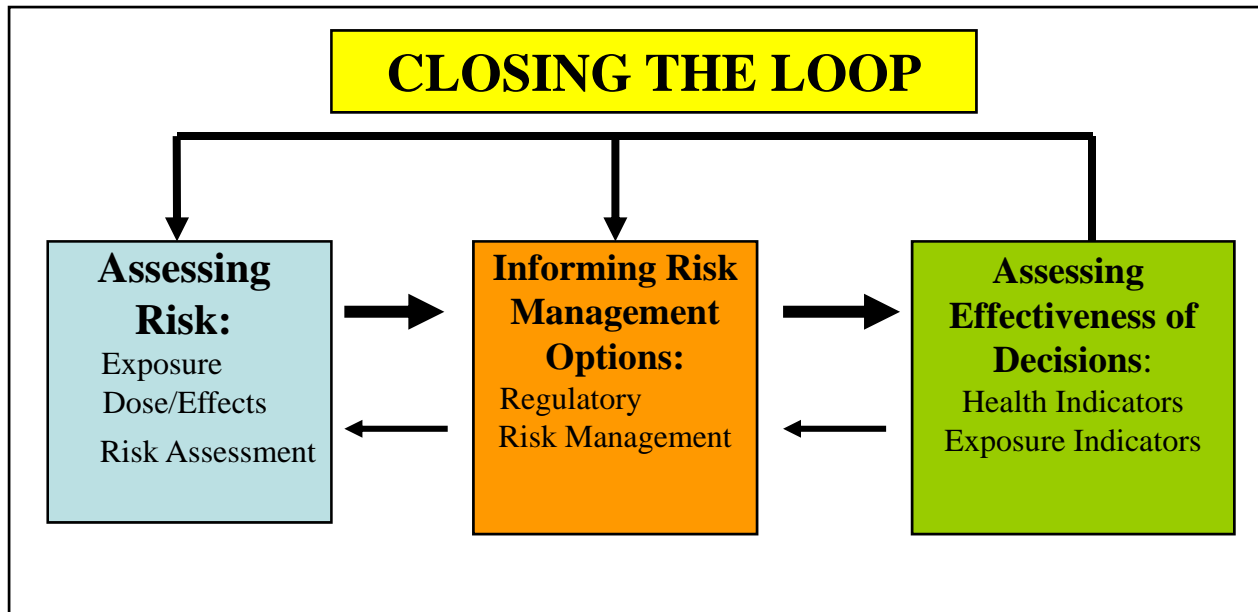
**Overview of LTG-4:
Developing tools to evaluate risk management decisions**

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LTG 4: Risk assessors and risk managers use ORD's methods and models to evaluate risk management decisions

- **What are trends in health status in the US?**
- **What tools are available to determine the impact of regulatory decisions on exposures to environmental stressors that lead to adverse health outcomes?**

What does it mean to “Evaluate Risk Management Decisions”?



What are the drivers for this research?

1997 NRC	“...confirm that environmental policies are having the desired effect”
2001 ORD Strategic Plan	How can we conduct research to evaluate the consequences of risk management decisions on public health?
2001 US EPA	Environmental Indicators Initiative
2003 EPA Strategic Plan	Evaluate the scientific validity of environmental indicators; evaluations of public health outcomes resulting from risk management decisions
2003 ORD Human Health Research Strategy	Research to enable evaluation of public health outcomes from risk management decisions
2004 GAO	EPA should “...identify specific milestones, resources, and other requirements for developing and using environmental indicators ...”

Develop, evaluate, and link indicators that can be used to demonstrate the effectiveness of risk reduction and risk management decisions.

Links to other LTGs / MYPs

LTG 1: Generation of bio-indicators of effects, early markers of disease

LTG 2: Biomarkers of exposure, linkage models for ambient monitoring to exposure to internal dose

LTG 3: Considering susceptible or vulnerable populations

Links to Air, Water MYP






HUMAN HEALTH RESEARCH PROGRAM

Combining MOA, Susceptibility, and Cumulative Risk Science for Risk Assessment: Asthma



Development of immune response, allergic airway disease

Mode of Action



Relative potency of molds, dust mite allergens, PM

Cumulative Risk

Susceptibility



Lifestage-specific processes, gene-environment interactions

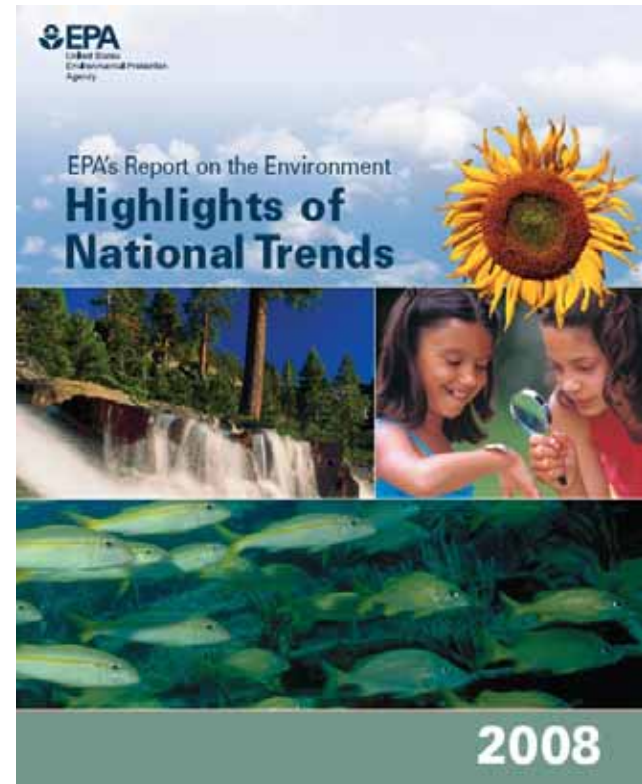
Scientific basis for rule-making on pollutants that affect this large, susceptible population

Assess effectiveness of risk mitigation strategies on incidence of asthma, frequency and severity of attacks

Research Track: Trends in Health Status Report on the Environment

The ROE Human Exposure and Health chapter presents biomonitoring and health outcome indicators to address three fundamental questions:

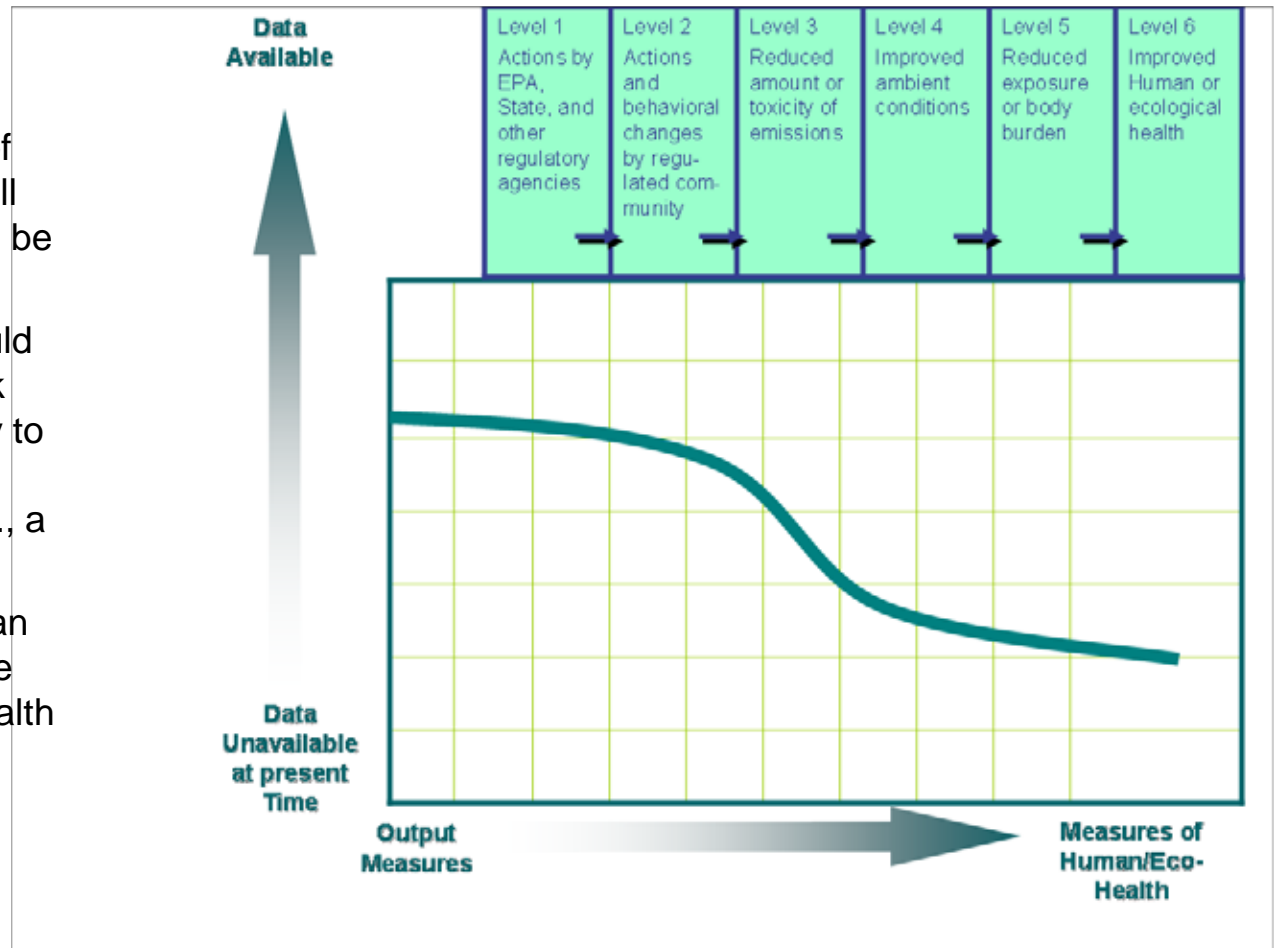
- What are the trends in human exposure to environmental contaminants, including across population subgroups and geographic regions?
- What are the trends in health status in the United States?
- What are the trends in human disease and conditions for which environmental contaminants may be a risk factor, including across population subgroups and geographic regions?



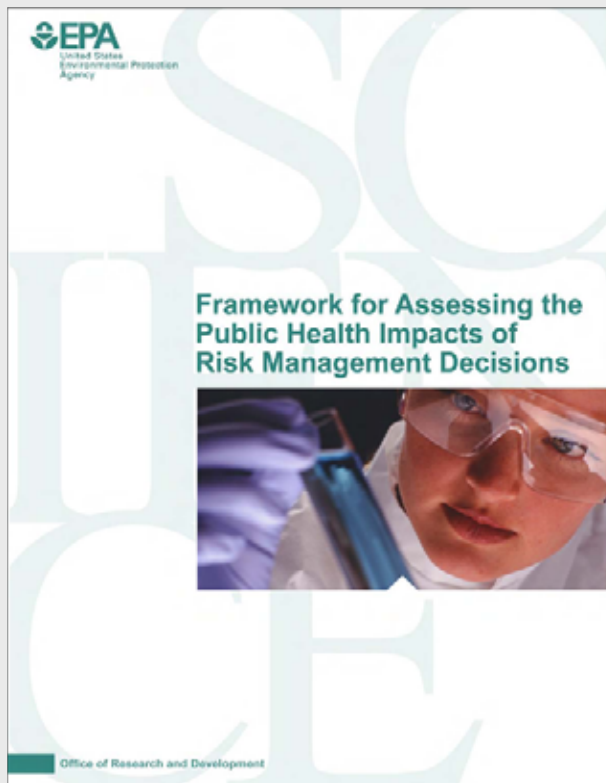
Research Track: Trends in Health Status Report on the Environment

Challenges

- Develop an integrated set of health indicators for use at all spatial scales and that could be assessed over time;
- Develop indicators that would allow risk assessors and risk managers with the capability to distinguish acceptable from unacceptable conditions (i.e., a threshold);
- Establish the link between an indicator of exposure and the change in risk of a public health measure.



Research Track: Tools for Evaluating Outcomes of Risk Management Decisions



Assessing the impact of a risk management decision is seen as an integral part of the risk assessment and risk management paradigm.

Understanding linkages in the source-to-exposure-to effects paradigm is essential to developing valid indicators of health outcomes.

Research Track: Tools for Evaluating Outcomes of Risk Management Decisions

Framework for Indicator Research

Indicators should be ranked by levels based on the relationship of the indicator to a health outcome, with the highest level given to health effects data linked to environmental exposures and sources.

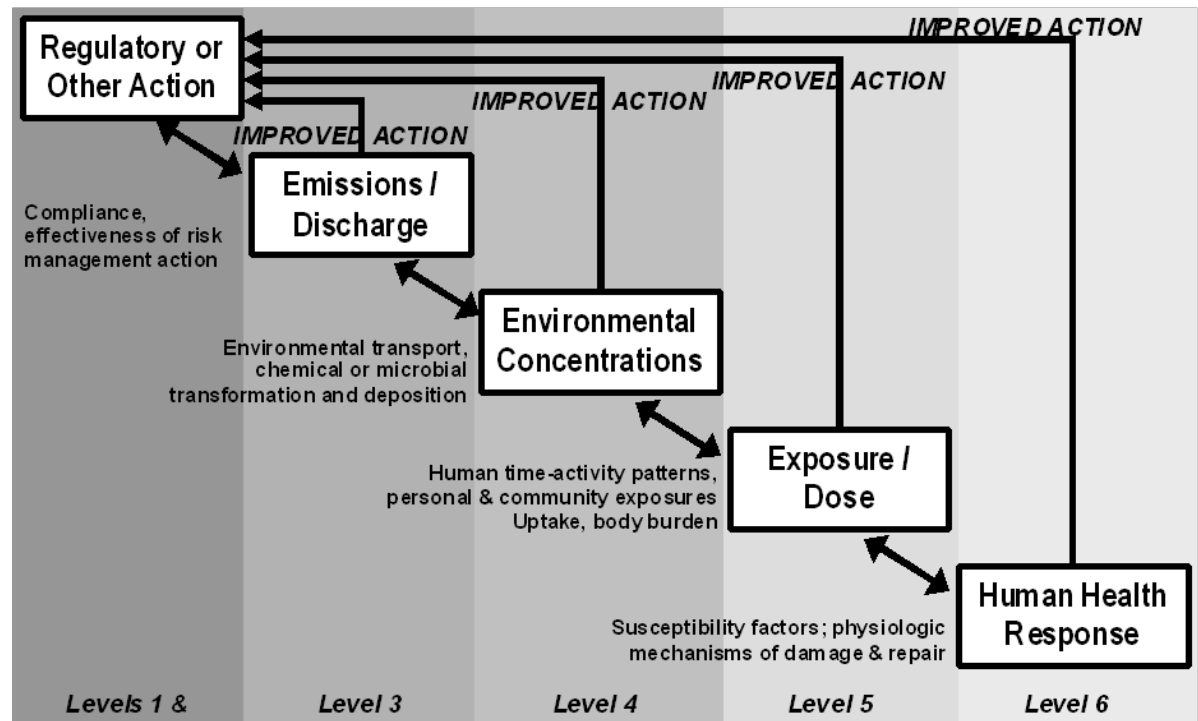
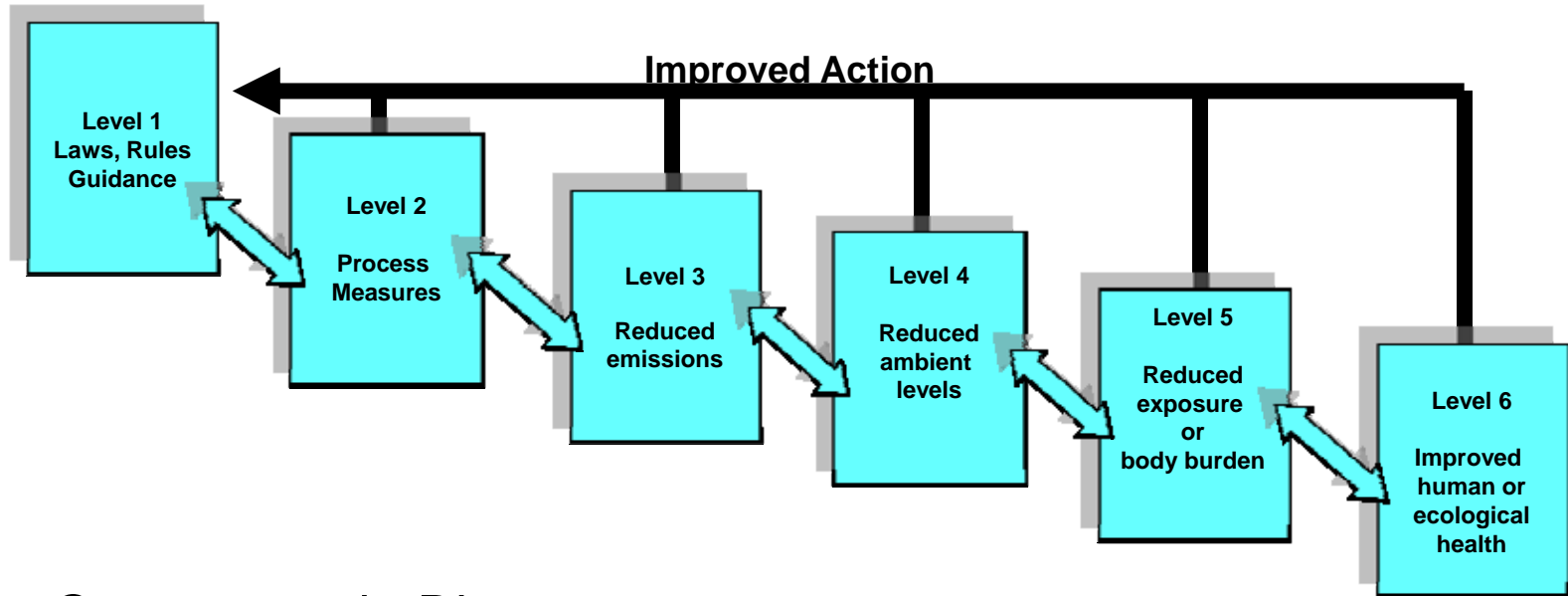


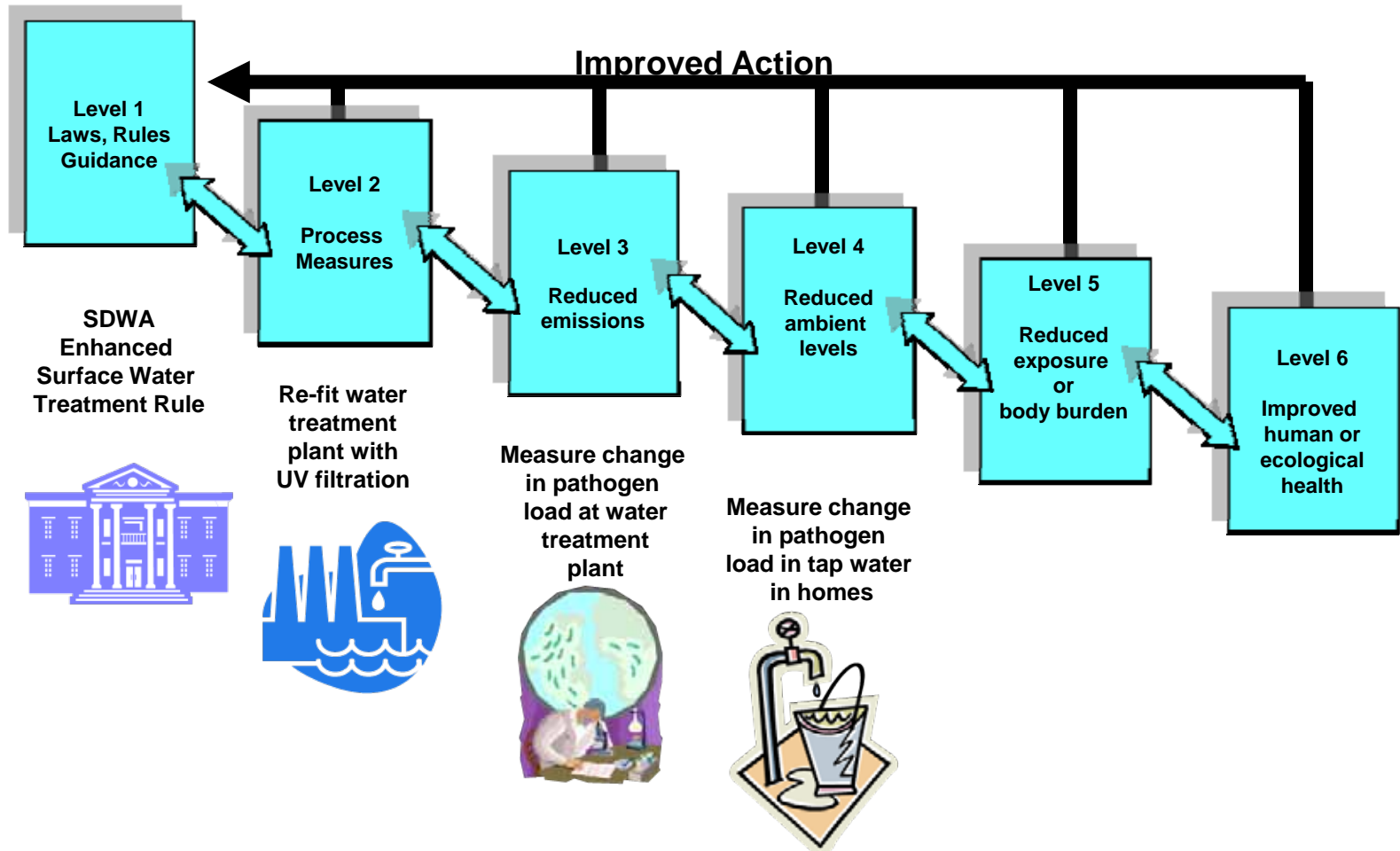
Figure 4. Essential Framework Guiding Research on Indicator Development

Assessing Outcomes of Risk Management Decisions – a problem of linkages

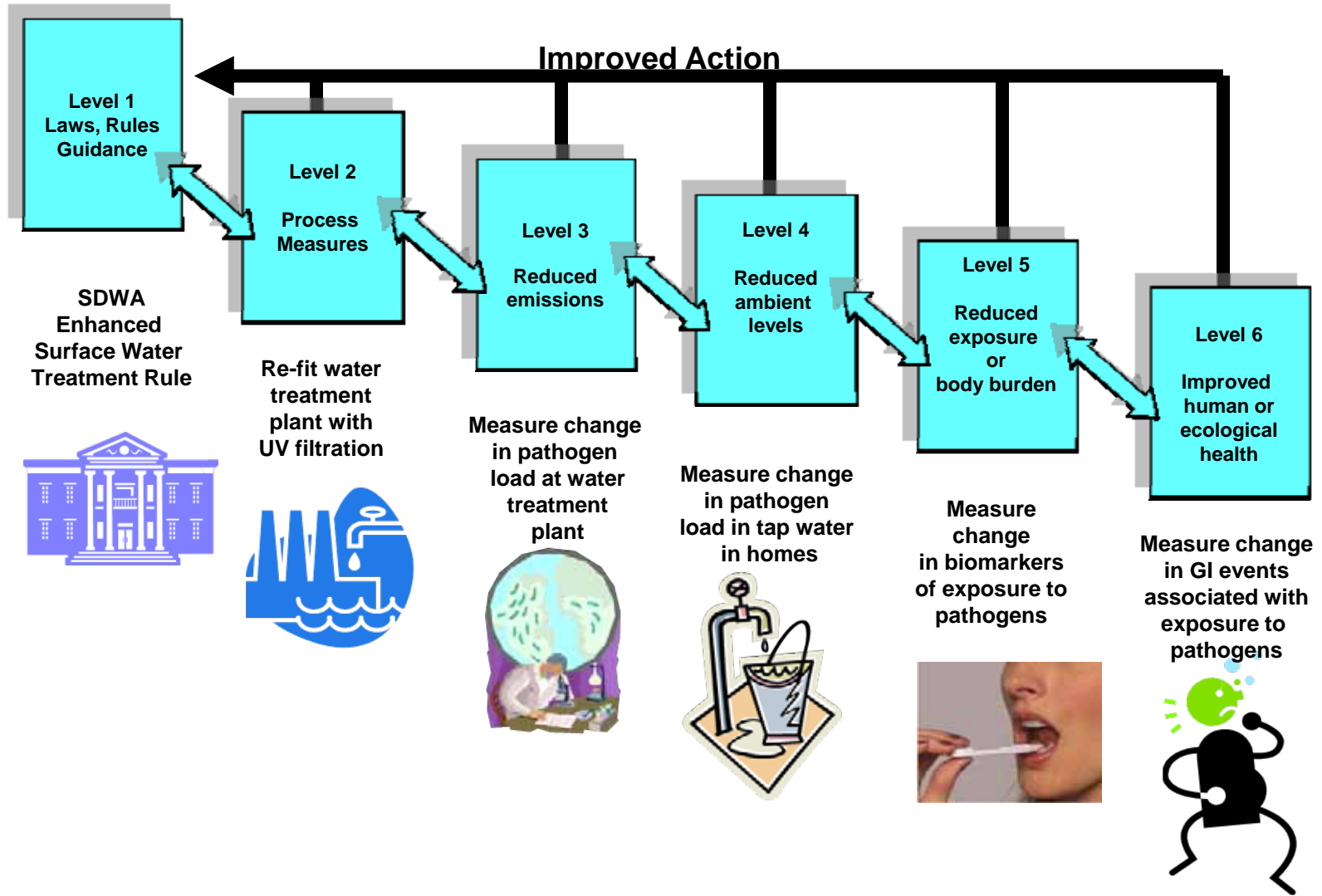


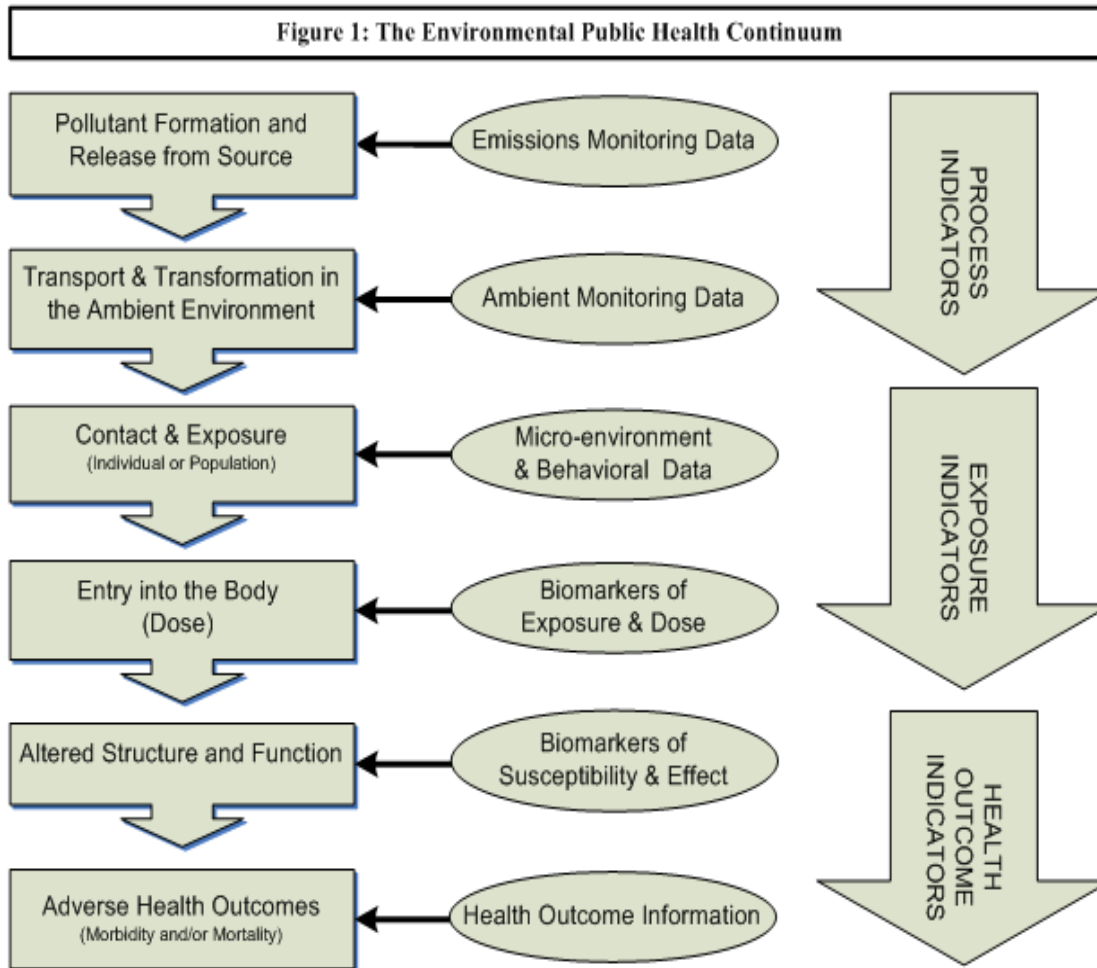
One approach: Direct development of biomarkers of exposure and effect

Assessing Outcomes of Risk Management Decisions – a problem of linkages



Assessing Outcomes of Risk Management Decisions – a problem of linkages



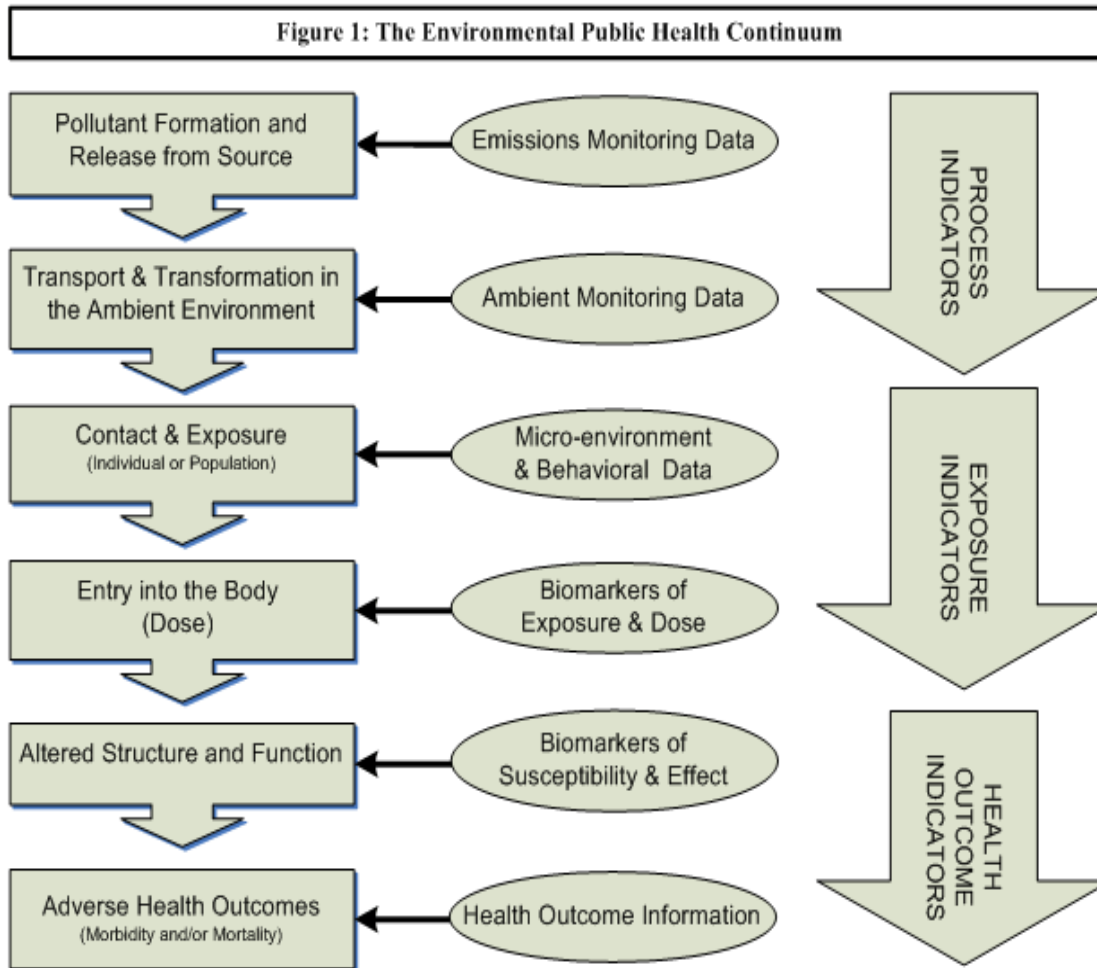


Approach 2: Using existing databases

- Clean Air Initiative
- Stationary and Mobile Source Emissions inventories

- Hybrid air quality models
 - Air concentrations
 - Population exposures

- Identifying sources and collaborations for health data

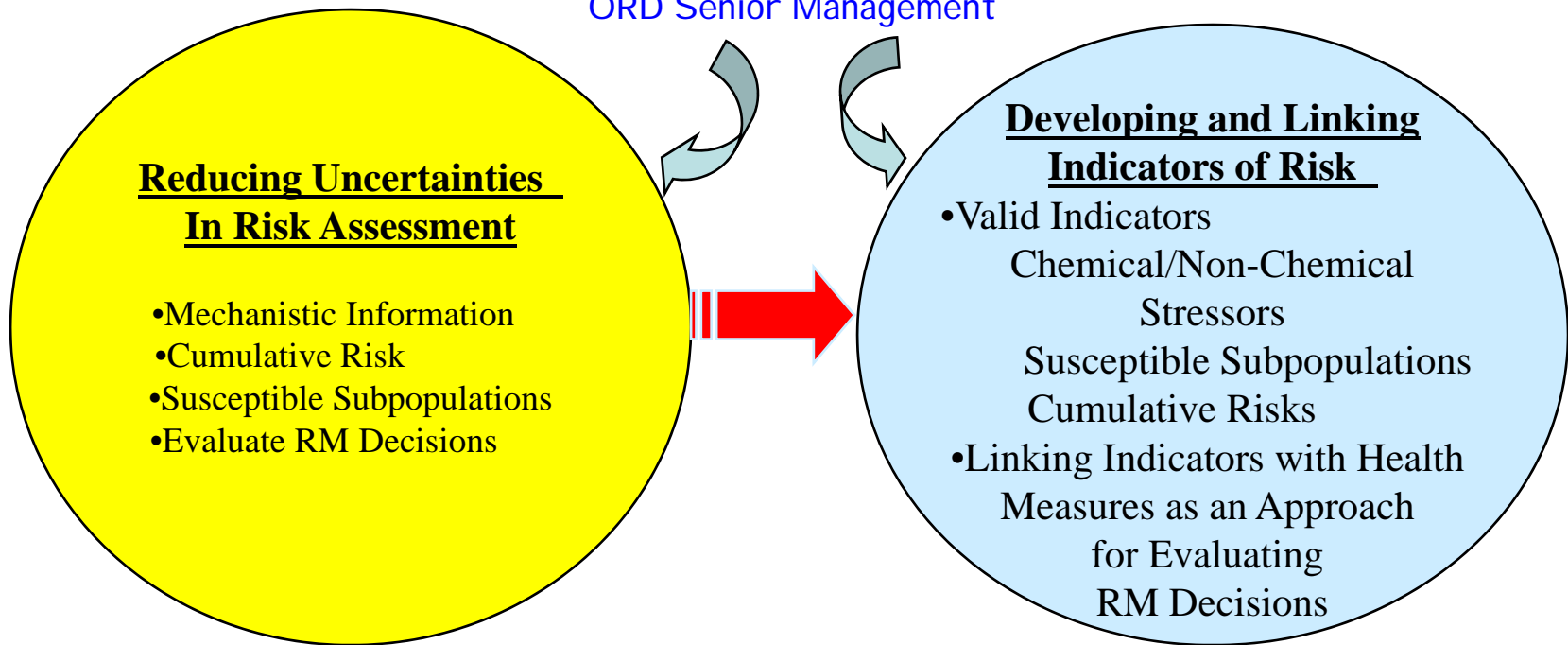


RfA: Using existing databases and developing biomarkers

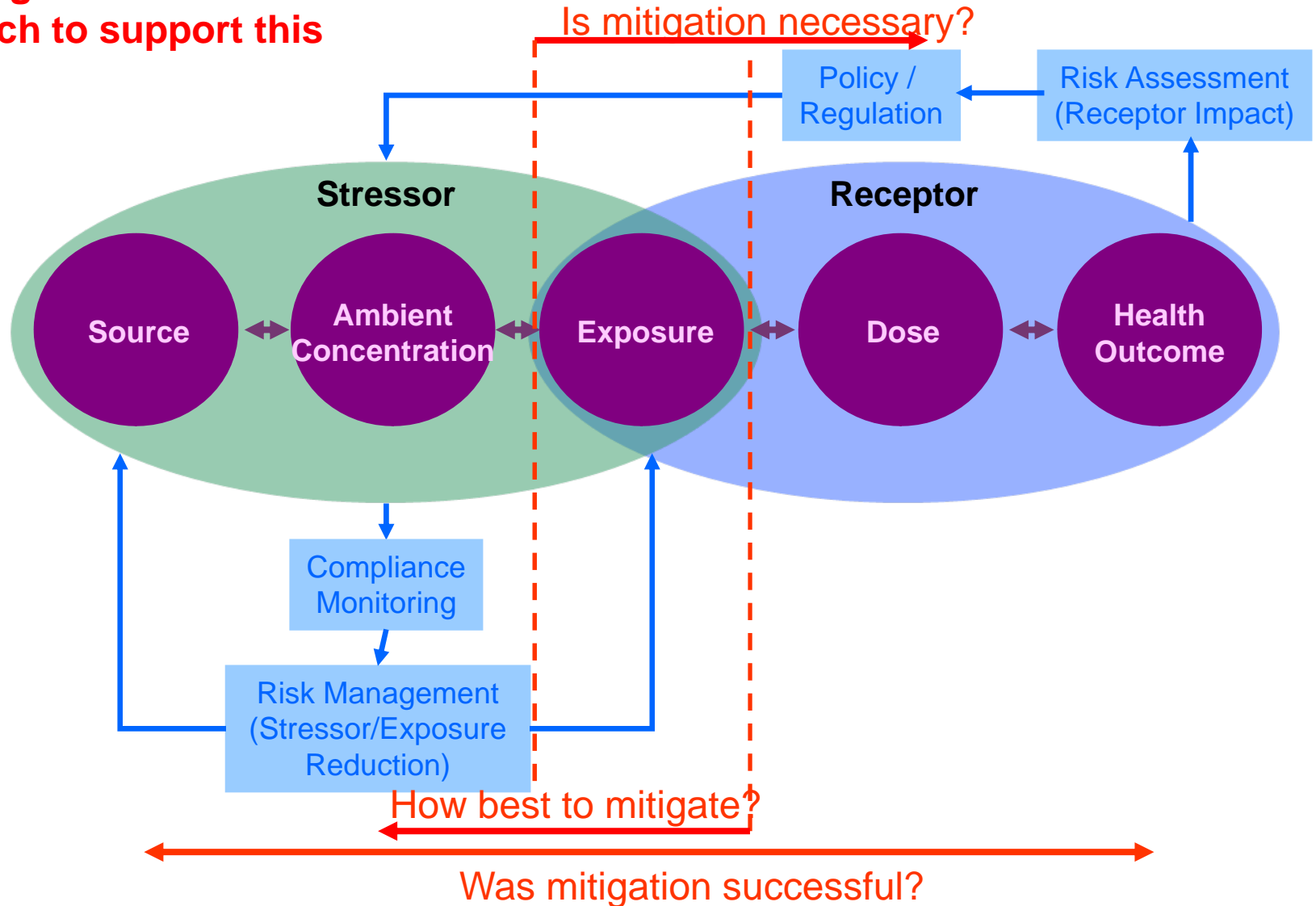
- Development of Environmental Health Outcome Indicators
- Issues in Tribal Environmental Research and Health Promotion
- Biomarkers and PBPK Modeling
- Application of Biomarkers to Environmental Health and Risk Assessment
- Early Indicators of Environmentally Induced Disease

Framing the current HHRP to support this effort

GPRM and Mission of the Agency
EPA Strategic Plan and ROE
GAO Report
HHRP BOSC Review
HHRP PART Review
Stakeholder Feedback
ORD Senior Management



Framing the current HHRP research to support this effort



Conclusion

- The HHRP has moved forward on LTG 4 since the 2005 and 2007 reviews of the HHRP
 - Drafting of the Framework document
 - Dedication of intramural and extramural resources to build the elements necessary to make the necessary linkages through source to outcome or population-based modeling
- There are great challenges to this charge, including the gaps between federal regulatory decisions and the implementation of these decisions at local levels, the multiple determinants of disease, and temporal lags between exposure and ultimate outcomes.
- Program retains the potential to serve as a unifying theme for the HHRP and to provide EPA with invaluable tools for assessing the impacts of its actions.