



# Assessing and Managing Risk: First Things First

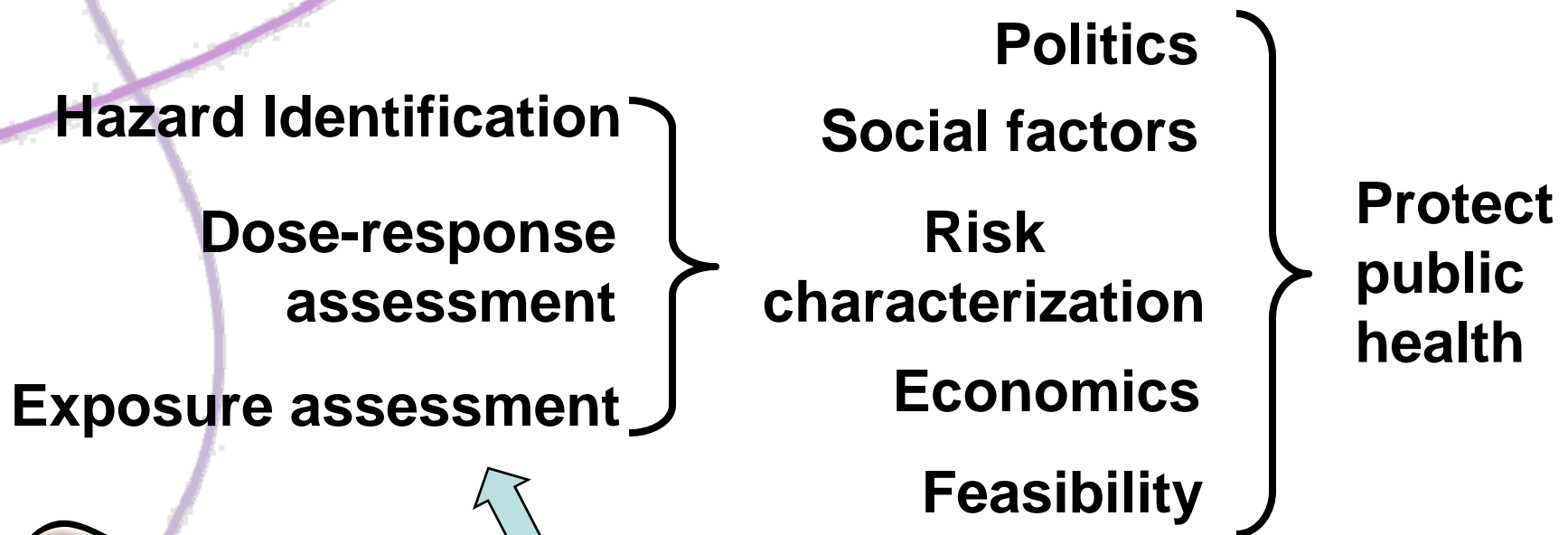
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[www.healthriskstrategies.com](http://www.healthriskstrategies.com)

# Regulatory Risk Analysis

- **Quantitative risk assessment:** developed in reaction to laws and judicial decisions calling for limits on chemical exposures that protect public health

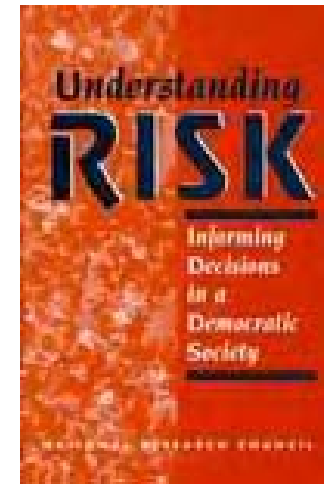


**Toxicity and exposure data**



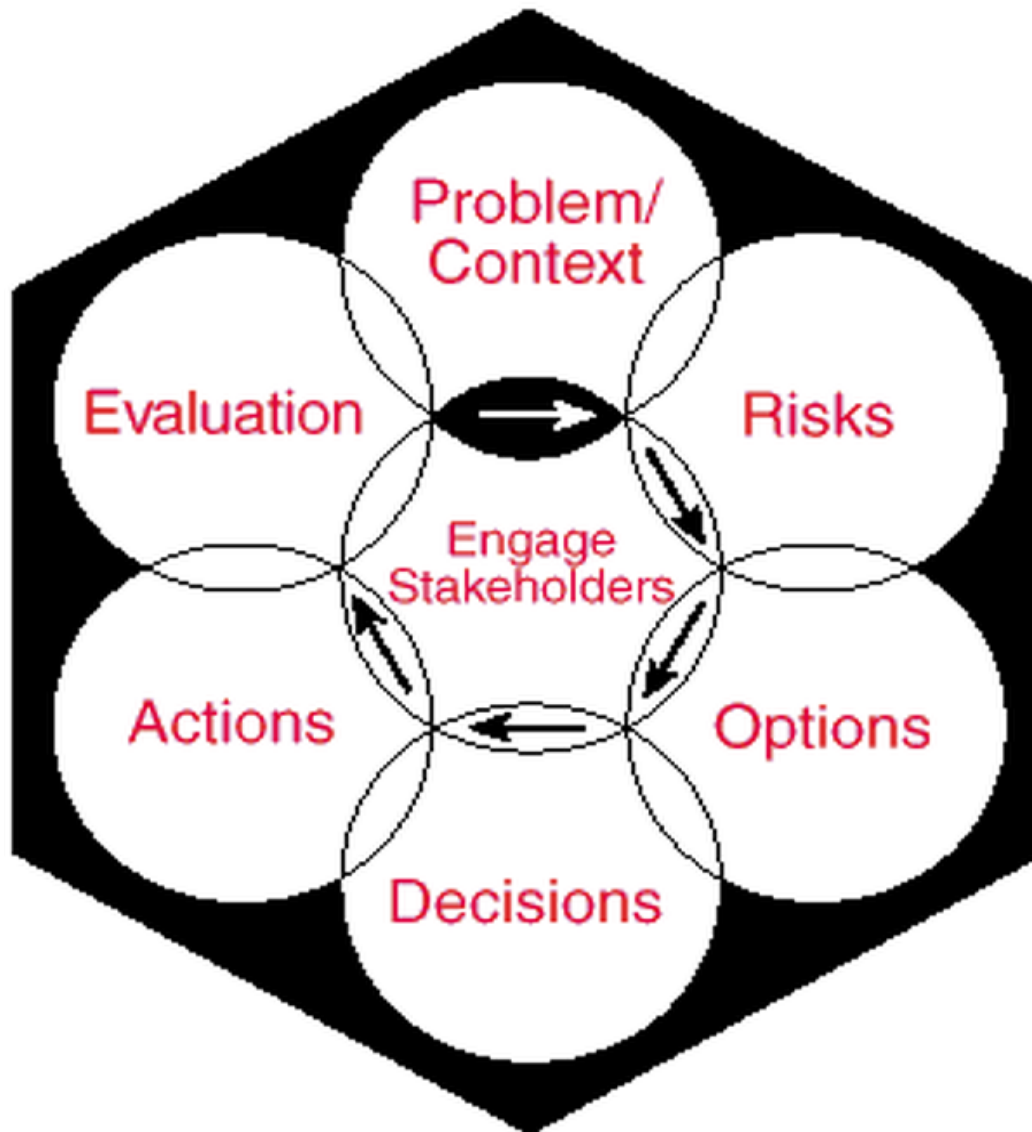
# Understanding Risk

National Academy of Sciences  
(1996)



“Risk characterization should be a *decision-driven activity*, directed toward informing choices and solving problems.”

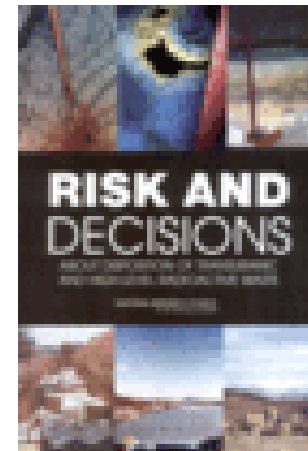
“The purpose of risk characterization is to enhance practical understanding and to illuminate practical choices.”



**Presidential/Congressional Commission on  
Risk Assessment & Risk Management (1997):  
Environmental Health Risk Management Decision-Making Framework**

# Risk and Decisions

## National Academy of Sciences (2005)

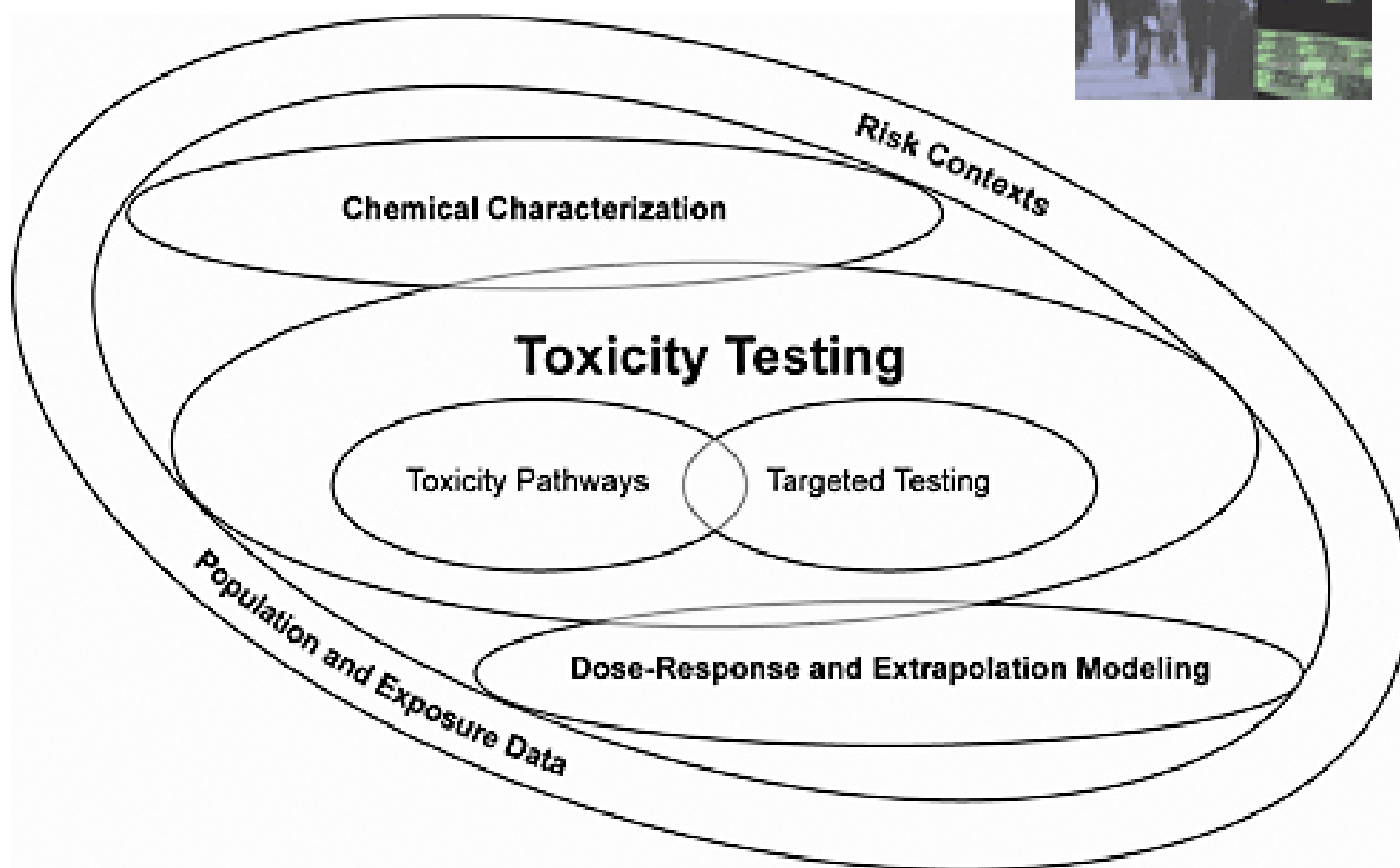


Recommended a six-step process for risk-informed decision-making:

- (1) Defining problem & identifying options and potential decisions with stakeholder input
- (2) Scoping analysis
- (3) Data collection
- (4) Risk assessment
- (5) Additional analysis & data collection
- (6) Decision

# Toxicity Testing in the 21<sup>st</sup> Century

National Academy of Sciences (2007)



# Science & Decisions

## National Academy of Sciences (2009)



“ . . . risk assessment should be viewed as a method for evaluating the relative merits of various options for managing risk rather than as an end in itself.”

3 phases: problem formulation, scoping, identify options; risk assessment; risk management; includes stakeholders



Characterize risk management problem  
& potential solutions



Perform analysis needed to  
decide among potential solutions



Choose & implement solution

# Public Health Approach

- Emphasizes prevention & effectiveness
- Characterizes adverse health effects, identifies possible causes & their relative contribution
- Targets risk management actions
- Moves past risk-by-risk, medium-by-medium, statute-by-statute, chemical-by-chemical, command-and-control

# Impediments/Solutions (1)

- Problem: Defining public health goals and accomplishments in terms of permitting, numbers of enforcement actions, numbers of chemical exposure limits set
- Solution: Redefine public health goals and accomplishments in terms of public health (with encouragement from OMB); generate public-health surveillance data to help connect outcomes with exposure & other factors

# Impediments/Solutions (2)

- Problem: Statutory constraints & requirements that focus on bottom-up, chemical-by-chemical approaches
- Solution: Creative statutory interpretation in terms of a top-down, public health context; regulatory effectiveness evaluation in public health terms (with encouragement from OIRA)