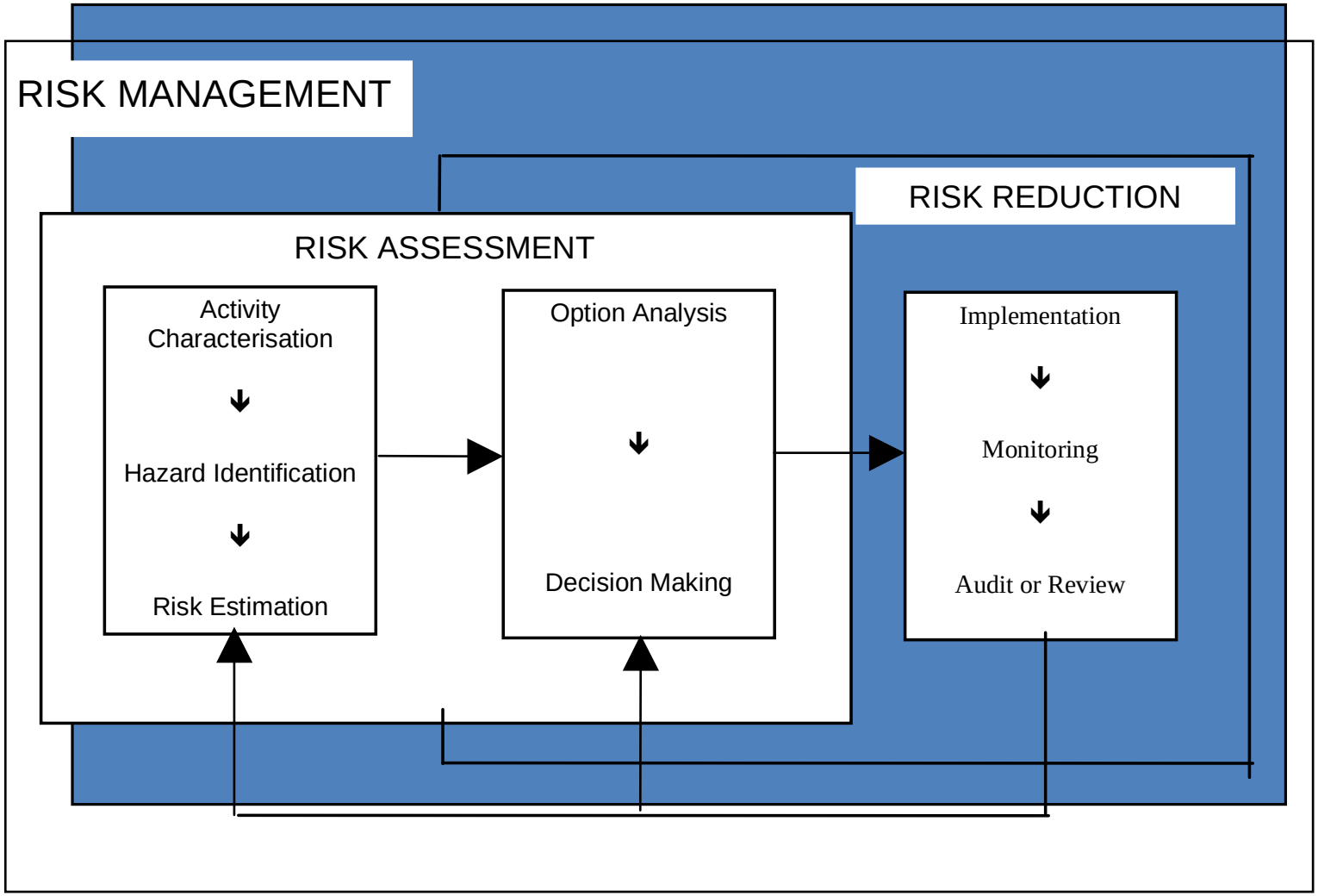
UNIT V

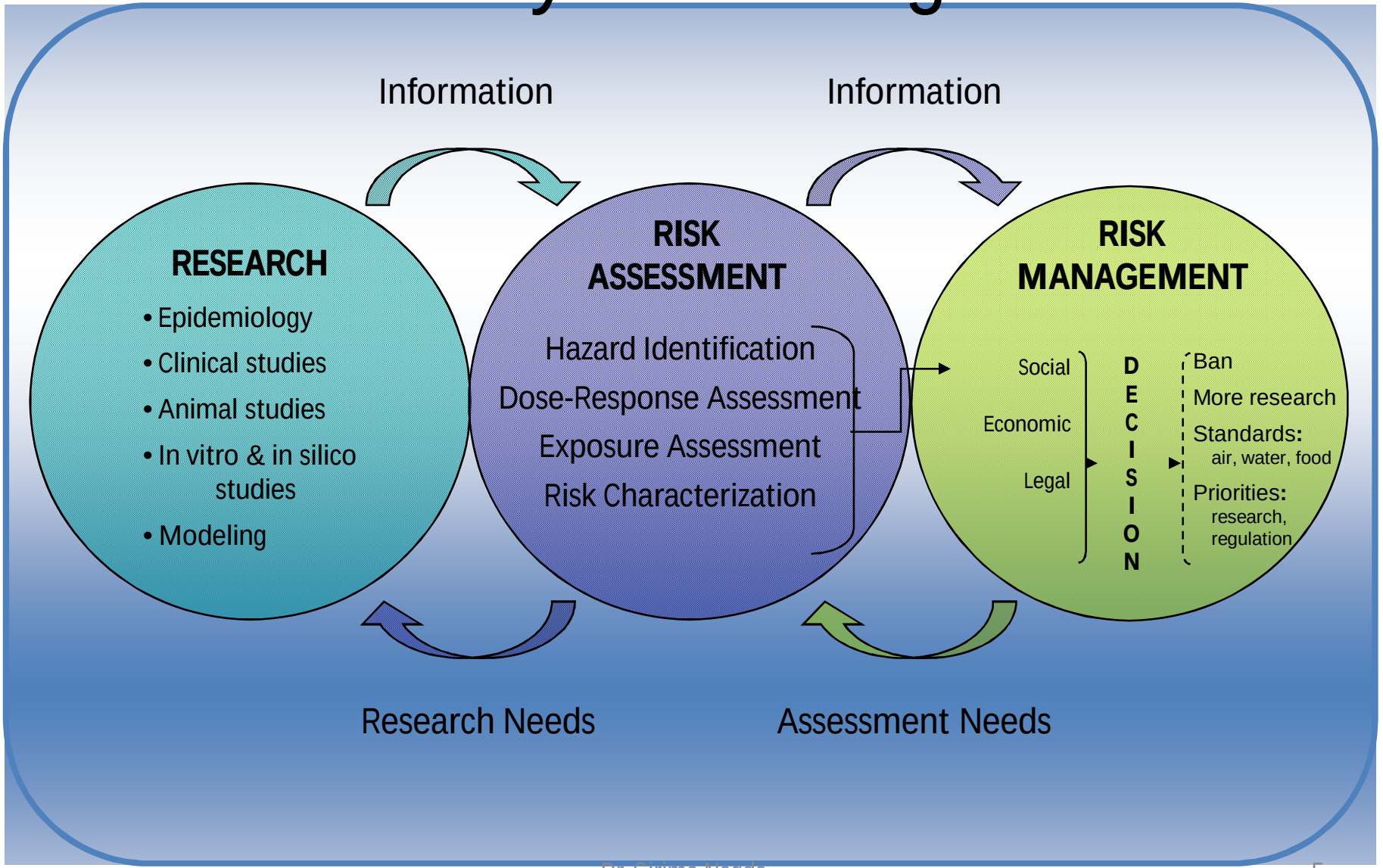
- ENVIRONMENTAL HAZARDS AND RISK ASSESSMENT,
- RISK MANAGEMENT AND MONITORING

- HAZARD: Capability of a substance to cause an adverse effect.
  - It is the biological property of the chemical in interacting with the species concerned.
  - Can be determined by experiments
- RISK: Probability that the hazard will occur under specific exposure conditions.
  - It is statistical term which expresses the probabilities of hazard
  - Cannot be determined by experiments

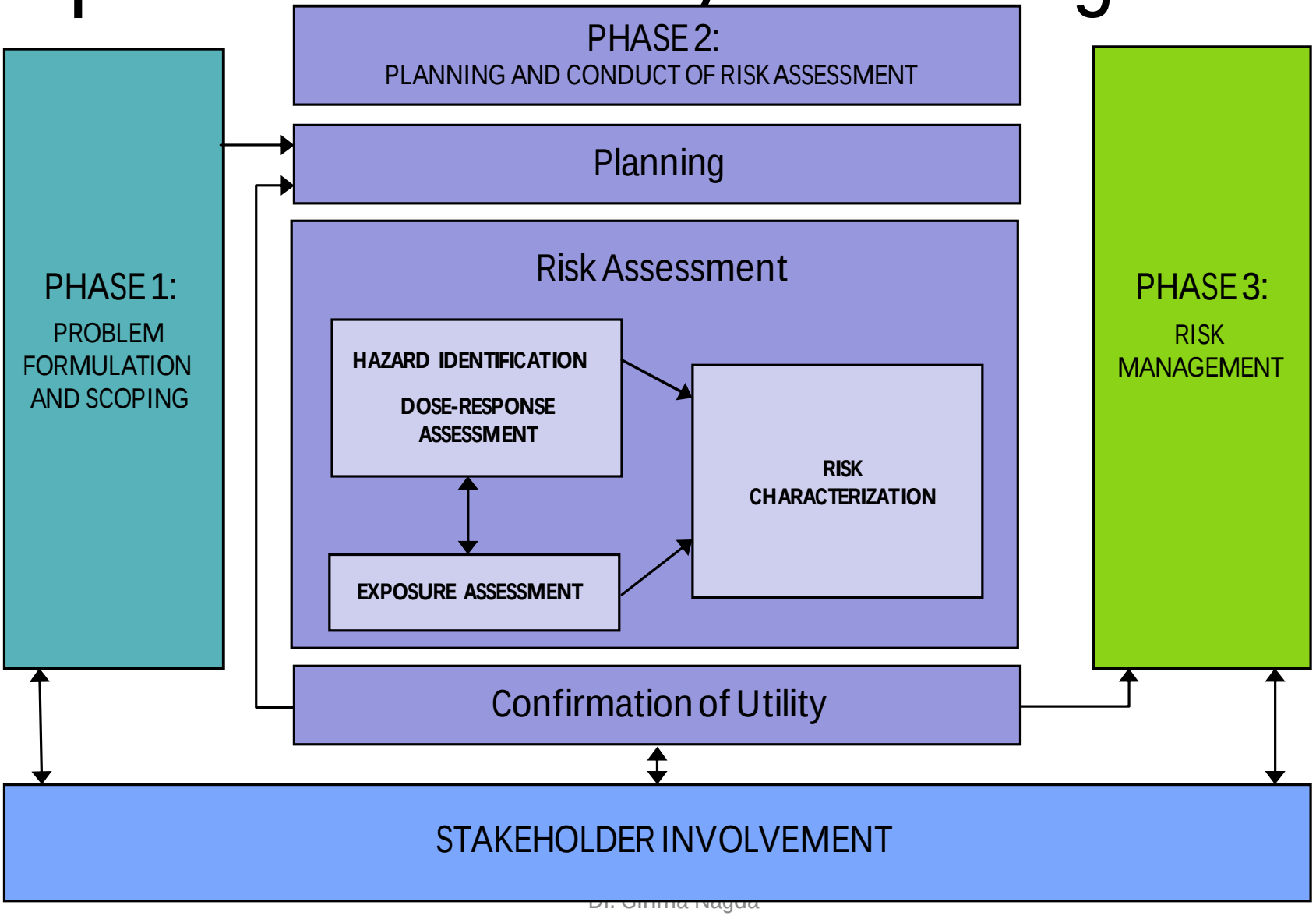
- RISK ASSESSMENT: The process by which hazard, exposure and risk are characterized.
- RISK MANAGEMENT: The process of weighing policy alternatives and selecting the most appropriate regulatory action based on the results of risk assessment and social, economic and political concerns.


RISK MANAGEMENT
RISK REDUCTION
RISK ASSESSMENT
Activity Characterisation
Hazard Identification
Risk Estimation
Option Analysis
Decision Making
Implementation
Monitoring
Audit or Review

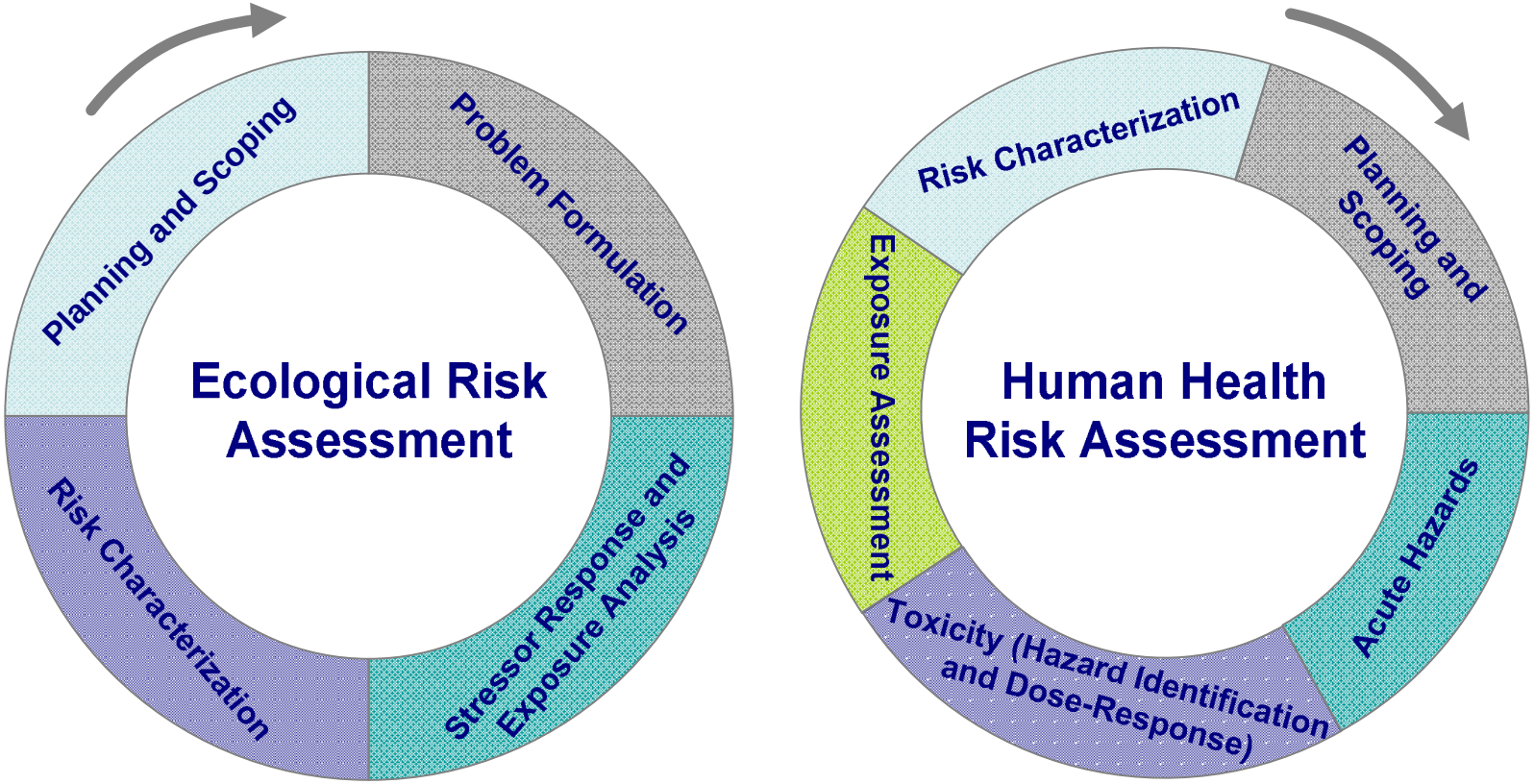
Risk Analysis Paradigm



Updated Risk Analysis Paradigm



Superfund: An Application of Risk Assessment

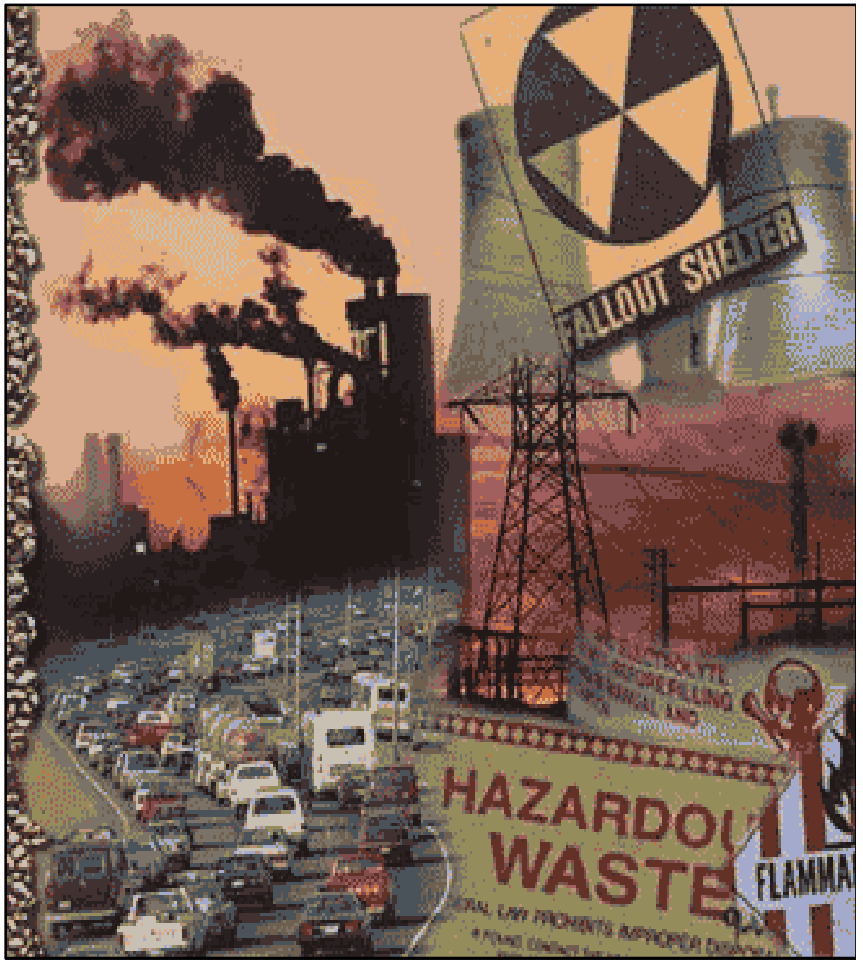


http://www.epa.gov/oswer/riskassessment/risk_superfund.htm

Regulatory Toxicology
Risk Assessment

Is the mathematical modeling process that yields estimates for safe or allowable chemical concentrations

- Hazard identification
- Dose-response assessment
- Exposure characterization
- Identify unique effects of chemical mixtures
- Risk assessment
- Risk characterization
- Right to know and understand
- Uncertainty characterization

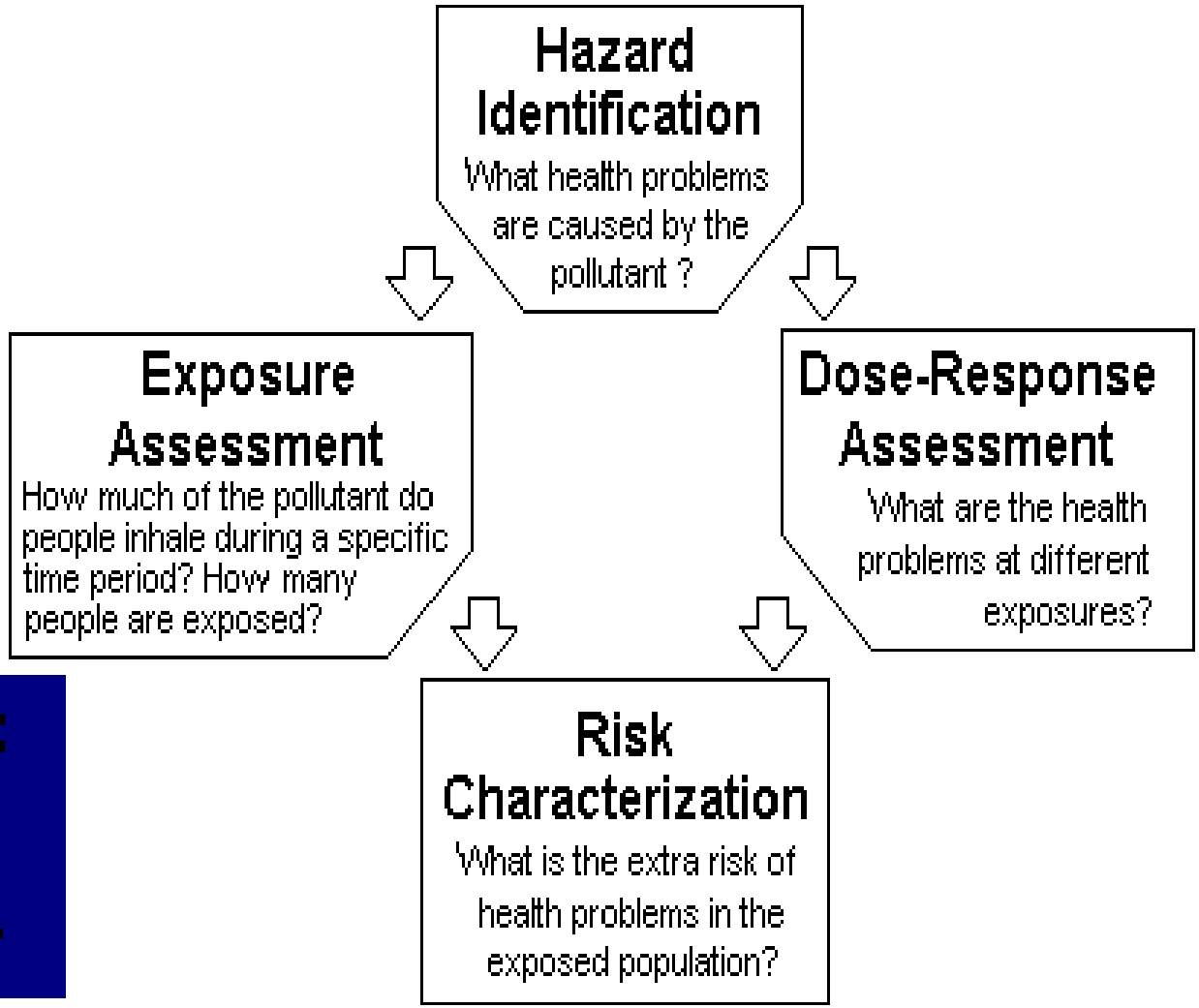


Risk Assessment: Two Roads

- **Qualitative**
- - virtually the same thing as "hazard evaluation" step of "Quantitative" Risk Assessment
- - is the material harmful to humans under *any* circumstances
- - Codified by agencies, especially for cancer

- **Quantitative**
- A formal process with four steps
- Ends with a mathematical estimation of *actual risk*, usually quantified as deaths per 1,000,000 per year or less.

The 4-Step Risk Assessment Process



Risk Management:

Putting the elements together

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

Hazard Identification

Dose-response Assessment

Exposure Assessment

Risk Characterization

Risk assessment is the evaluation of scientific information on:

- the hazardous properties of environmental agents,
- the dose-response relationship, and
- 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.

From EPA's IRIS Glossary

https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary

Risk Assessment

- Risk- probability that a particular adverse effect will result from some exposure or condition
- We assess risk daily with four steps
  1. Hazard identification
  2. Dose response assessment
  3. Exposure assessment
  4. Risk characterization

Risk assessment involves four steps

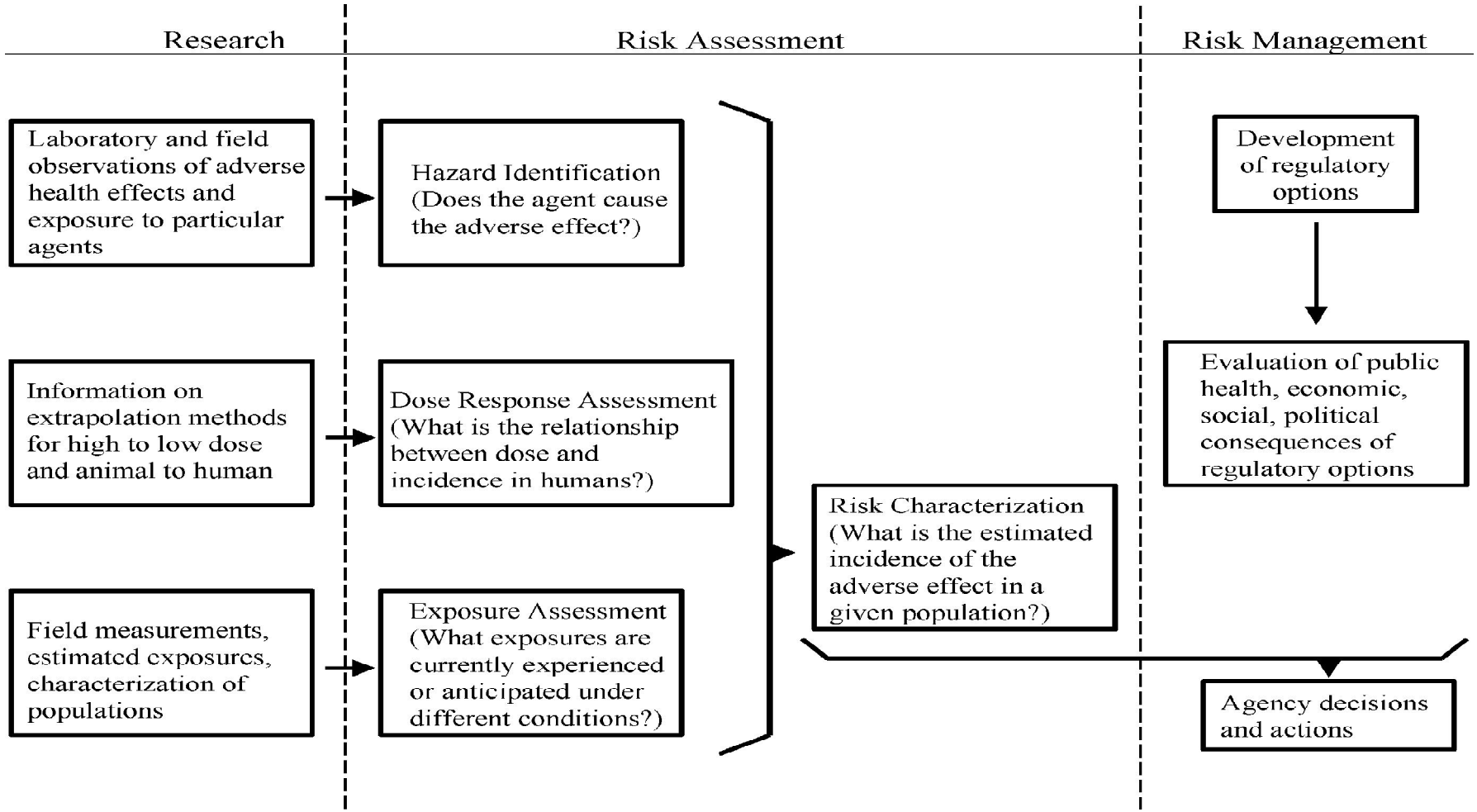
1. ***Hazard identification :*** is the process of determining whether exposure to an agent can increase the incidence of a health condition
2. ***Dose-response assessment:*** is the process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations; it expresses incidence as a function of exposure to the agent.

Risk assessment involves four steps

3. ***Exposure assessment :*** is the process of measuring or estimating the intensity, frequency, and duration of human exposures to an existing agent or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment .
4. ***Risk characterization:*** is the process of estimating the incidence of a health effect under the various conditions of human exposure described in the exposure assessment

An Integrated Framework for Risk Management and Population Health

(1983)



U.S. National Research Council framework for risk assessment(1983).

Hazard Identification

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

Identify Hazards

Broad categories of hazard

To help with the process of identifying hazards it is useful to categorise hazards in different ways, for example by topic, e.g.:

- Mechanical.
- Electrical.
- Radiation.
- Substances.
- Fire and explosion.

- **Toxicology: Assessing Chemical Hazards**
- **Toxicity measures how harmful a substance is in causing injury, illness, or death to a living organism.**
- **Harm depends on factors:**
  - **Dose: amount of a substance.**
  - **Frequency of exposure**
  - **Age and size of the individual exposed,**
  - **Body's detoxification system, and**
  - **Genetic makeup of the individual,**

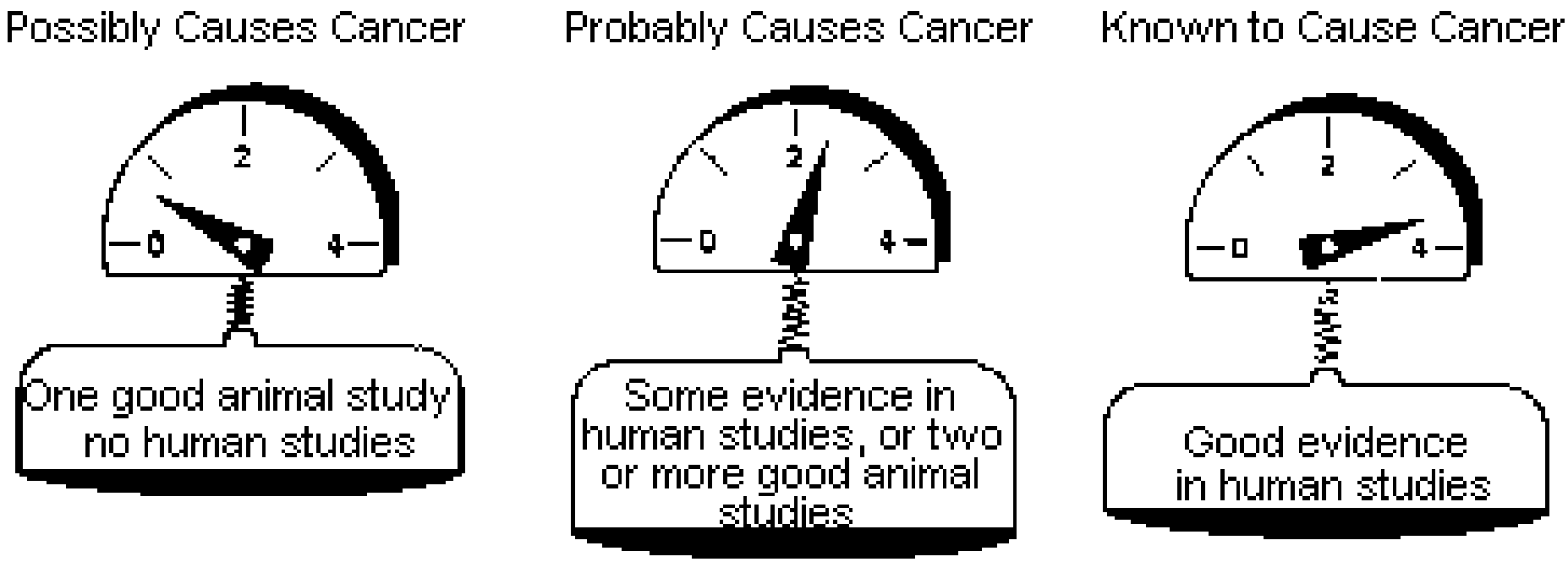
Five major factors can affect the harm caused by a substance.

- **Solubility: Water-soluble toxins can move throughout the environment. Oil- or fat soluble toxins can in the body.**
- **Persistence: resist breakdown and have long-lasting harmful effects.**
- **Bioaccumulation: absorbed and stored in the body at higher than normal levels.**
- **Biomagnification: moved up from one trophic level to the next higher one.**
- **Chemical interactions: can decrease or multiply the harmful effects. Antagonistic interaction reduces. Synergistic interaction multiplies the harmful effects.**

“Hazard Evaluation” is the equivalent of Qualitative Risk Assessment.

(in many instances the three further steps are not taken)

Examples: EPA, IARC Cancer Monographs



- Information is gathered and analysed in a weight-of-evidence apporach.
- Types of data usually consist of:
  - Human epidemiology data
  - Animal bioassay data
  - Supporting data

- Based on these results, one or more toxic hazards may be identified *(such as cancer, birth defects, chronic toxicity, neurotoxicity)*. The **primary hazard of concern** is one in which there is a serious health consequence *(such as cancer)* that can occur at lower dosages than other serious toxic effects. The primary hazard of concern will be chosen for the dose-response assessment.

Human epidemiology data

- Most desirable
- Given highest priority since they avoid the concern for species differences in the toxic response.
- Unfortunately, reliable epidemiology studies are rarely available.
- Have incomplete and unreliable exposure histories. For this reason, it is rare that risk assessors can construct a reliable dose-response relationship for toxic effects based on epidemiology studies.

Animal Bioassay Data

- Generally the primary data used in risk assessments.
- Animal studies are well-controlled experiments with known exposures and employ detailed, careful clinical, and pathological examinations.
- The use of laboratory animals to determine potential toxic effects in humans is a necessary and accepted procedure.
- Effects in laboratory animals are usually similar to those observed in humans at comparable dose levels.

Supporting data

- Derived from cell and biochemical studies may help the risk assessor make meaningful predictions as to likely human response. For example, often a chemical is tested with both human and animal cells to study its ability to produce cytotoxicity, mutations, and DNA damage.
- The cell studies can help identify the mechanism by which a substance has produced an effect in the animal bioassay.
- In addition, species differences may be revealed and taken into account.

A chemical's toxicity may be predicted based on its similarity in structure to that of chemical for which the toxicity is known. This is known as a **structure-activity relationship (SAR)**. The SAR has only limited value in risk assessment due to exceptions to the predicted toxicity.

Consequence - definition

Harm to people

No.	Description
0	**No Injury or damage to Health**
1	**Slight Injury or health effects** (including first aid case and medical traement case) -Not affecting work performance or causing disability
2	**Minor injury or health effects(**Lost Time Injury) - Affecting work performance, such as restriction to work activities (Restricted Workday Case) or a need to take a few days to fully recover(Lost Workday Case). Limited health effects are reversible e.g. skin irritation, food poisoning.
3.	**Major injury or health effects** (including Permanent Partial Disability) - Affecting work performance in the longer term,such as prolonged absence from work. Irreversible health damage without loss of life, e.g. noise induced hearing loss, chronic back injuries
4.	**Single fatalit**y- From accident or occupational illness (poisoning, cancer)
5.	**Multiple fatalities** - From accident or occupational illness(poisoning, cancer)

Damage to Asset

No.	Description
0	**Zero Damage**
1	**Slight damage -** No disruption to operation
2	**Minor damage** - Brief disruption
3.	**Local damage -** Partial shutdown
4.	**Major damage -** Partial operation loss
5.	**Extensive damage -** Substantial or total loss of operations

Effect on the Environment

No.	Description
0	**Zero effect** - No environmental damage. No cahange in environment. No financial consequences
1	**Slight effect** - Local environment damage. Within the fence and within systems. Negligible financial consequences
2	**Minor effect -** Contamination. Damage sufficiently large to attack the environment. Single exceedance of statutory or prescribed criterion. Single complaint. No permanent effect on the environment.
3.	**Localised effect -** Limited loss of discharges of known toxicity. Repeated exceedance of statutory or prescribed limit. Affecting neighbourhood.
4.	**Major effect -** Severe environmental damage. The company is required to take extensive measures to restore the contaminated environment to its original state. Extended exceedance of statutory or prescribed limits
5.	**Massive effect -** Persistent severe environmental damage or severe nuisance extending over a large area. In terms of commercial or recreational use of nature conservancy, a major economic loss for the company. Constant, high exceedance of statutory or prescribed limits.

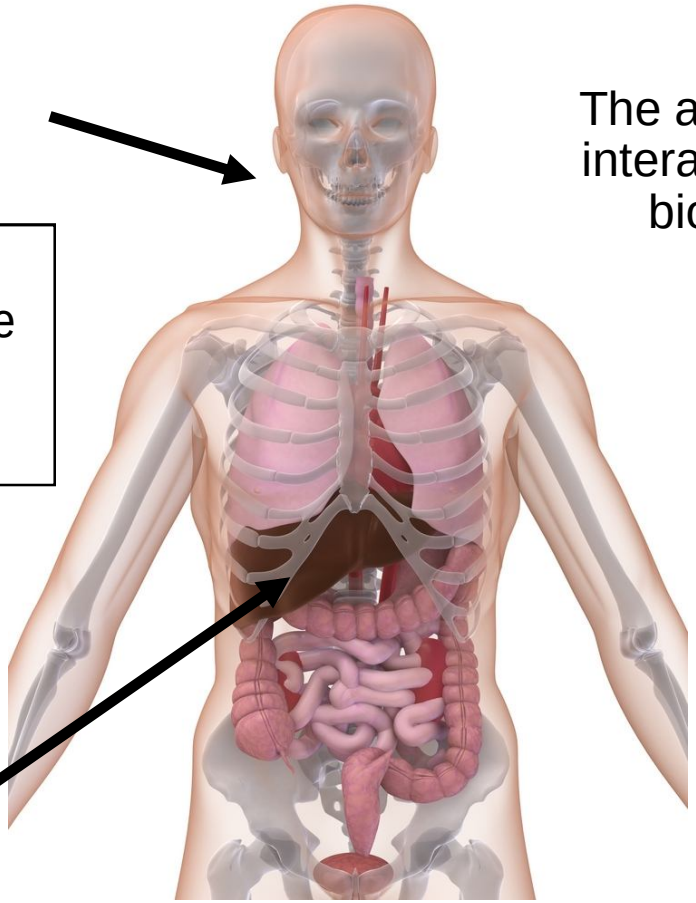
Impact on Reputation

No.	Description
0	**No impact -** No public awareness.
1	**Slight impact** - Public awareness may exist, but there is no public concern.
2	**Limited impact -** Some local public concern. Some local media and / or local political attention with potentially adverse aspects for company operations.
3.	**Considerable impact -** Regional public concern. Extensive adverse attention in local media. Slight national media and/ or local / regional political attention. Adverse stance of local government and / or action groups.
4.	**National impact -** National public concern. Extensive adverse attention in the national media. Regional / national policies with potentially restrictive measures and / or impact on grant of licences. Mobilisation of action groups.
5.	**International impact -** International public attention. Extensive adverse attention in international media. National / International policies with potentially severe impact on access to new areas, grants of licences and / or tax legislation

Dose

Potential dose:
Ingested, inhaled, applied to skin

Applied dose:
Present in exposure medium
(**µg / m^3**)



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

The amount of a substance available for interactions with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism.

From EPA's IRIS Glossary

Dose-Response Assessment

- Evaluating the quantitative **relationship** between **dose** and toxicological **responses**.

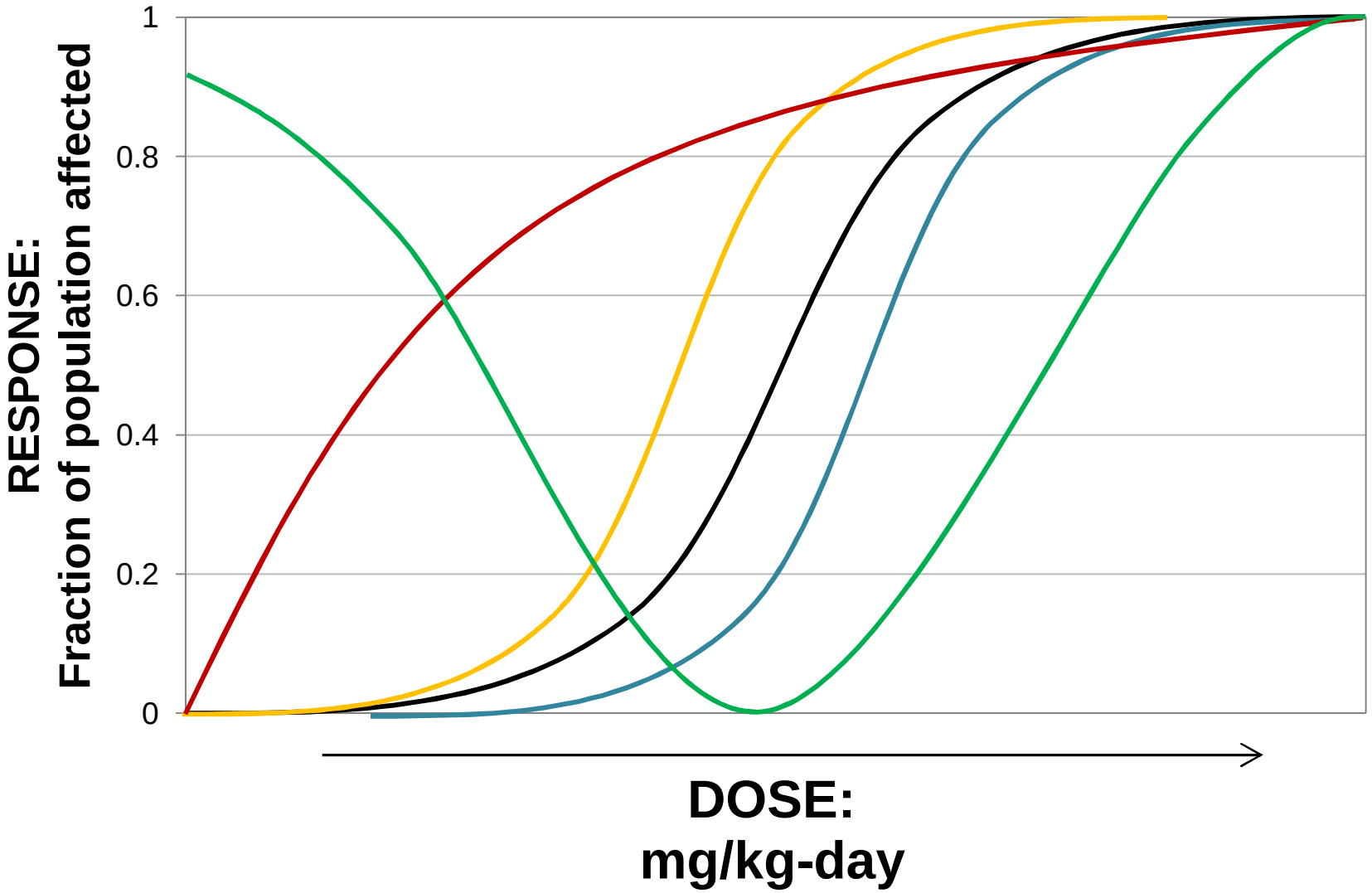
From EPA's "Terms of Environment" Glossary

- 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.

Example Dose-Response Curves



Dose-Response Assessment

- Quantitates the hazards which were identified in the hazard evaluation phase.
- It determines the relationship between dose and incidence of effects in humans.
- There are normally two major extrapolations required. The first is from high experimental doses to low environmental doses and the second from animal to human doses.
- The procedures used to extrapolate from high to low doses are different for assessment of carcinogenic effects and non-carcinogenic effects. **Carcinogenic effects** are not considered to have a threshold and mathematical models are generally used to provide estimates of carcinogenic risk at very low dose levels.

  Noncarcinogenic effects *(e.g. neurotoxicity)* are considered to have dose thresholds below which the effect does not occur. The lowest dose with an effect in animal or human studies is divided by Safety Factors to provide a margin of safety.

Cancer risk assessment

- Involves two steps.
- The first step is a qualitative evaluation of all epidemiology studies, animal bioassay data, and biological activity *(e.g., mutagenicity)*. The substance is classified as to carcinogenic risk to humans based on the weight of evidence. If the evidence is sufficient, the substance may be classified as a definite, probable or possible human carcinogen.

- The second step is to quantitate the risk for those substances classified as definite or probable human carcinogens. Mathematical models are used to extrapolate from the high experimental doses to the lower environmental doses.

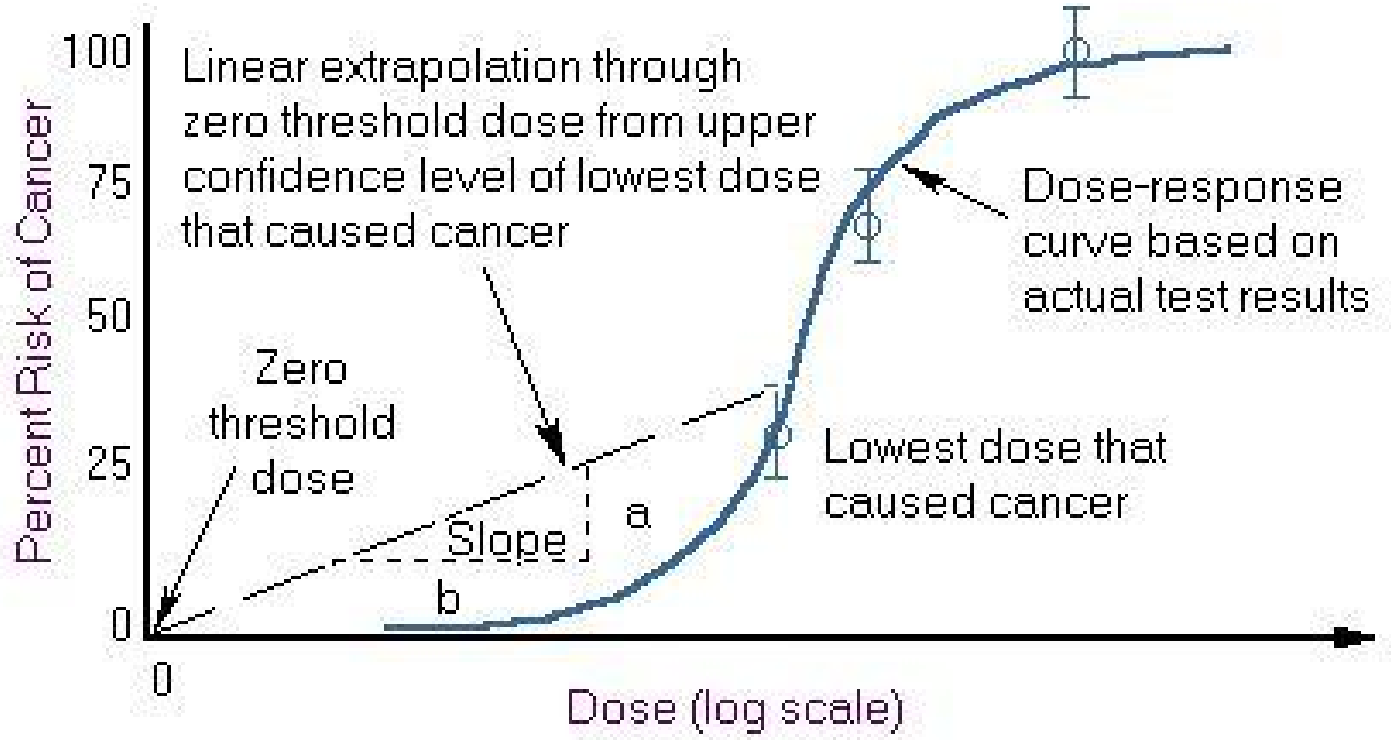
The two primary cancer classification schemes are those of the Environmental Protection Agency (EPA) and the International Agency for Research on Cancer (IARC). The EPA and IARC classification systems are quite similar.

The EPA's cancer assessment procedures have been used by several Federal and State agencies. The Agency for Toxic Substances and Disease Registry (ATSDR) relies on EPA's carcinogen assessments. A substance is assigned to one of six categories as shown below:

Group A	*Human Carcinogen*	sufficient human evidence for causal association between exposure and cancer
Group B1	*Probable Human*	limited evidence in humans
Group B2	*Probable Human*	inadequate evidence in humans and sufficient evidence in animals
Group C	*Possible Human Carcinogen*	limited evidence in animals
Group D	*Not Classifiable as to Human Carcinogenicity*	inadequate evidence in animals
Group E	*No Evidence of Carcinogenicity in Humans*	at least two adequate animal tests or both negative epidemiology and animal studies

CANCER SLOPE FACTOR

- The key risk assessment parameter derived from the EPA carcinogen risk assessment is the **cancer slope factor**. This is a toxicity value that quantitatively defines the relationship between dose and response. The cancer slope factor is a plausible upper-bound estimate of the probability that an individual will develop cancer if exposed to a chemical for a lifetime of 70 years. The cancer slope factor is expressed as mg/kg/day.


100
75
50
25
0
0
Percent Risk of Cancer
Dose (log scale)
Linear extrapolation through zero threshold dose from upper confidence level of lowest dose that caused cancer
Dose-response curve based on actual test results
Zero threshold dose
Lowest dose that caused cancer
Slope
a
b

- EPA uses the **Linearized Multistage Model (LMS)** illustrated above to conduct its cancer risk assessments. It yields a cancer slope factor, known as the q1* *(pronounced Q1-star)* which can be used to predict cancer risk at a specific dose. It assumes linear extrapolation with a zero dose threshold from the upper confidence level of the lowest dose that produced cancer in an animal test or in a human epidemiology study.

Other models

One hit model	This is a very conservative model. It assumes that there is a single stage for cancer and that one molecular event induces a cell transformation.
Multi hit model	This model is one of the least conservative models. It assumes several interactions are needed before a cell can be transformed.
Probit model	This model assumes log normal distribution *(Probit)* for tolerances of exposed population. While sometimes used, it is generally considered inappropriate for the assessment of cancer risk.
Physiologically Based Pharmacokinetic Models (PB-PK models)	This model incorporates pharmacokinetic and mechanistic data into the extrapolation process. It requires extensive data and is becoming commonly used.

Non-carcinogenic Risk Assessment

- **Acceptable Daily Intake (ADI)** procedure has been used to calculate permissible chronic exposure levels for humans based on non-carcinogenic effects.
- The ADI is the amount of a chemical to which a person can be exposed each day for a long time *(usually lifetime)* without suffering harmful effects.
- It is determined by applying safety factors *(to account for the uncertainty in the data)* to the highest dose in human or animal studies which has been demonstrated not to cause toxicity *(NOAEL)*.

$$\text{ADI } \textit{(human dose)} = \frac{\text{NOAEL } \textit{(experimental dose)}}{\text{Safety Factor(s)}}$$

Reference Dose

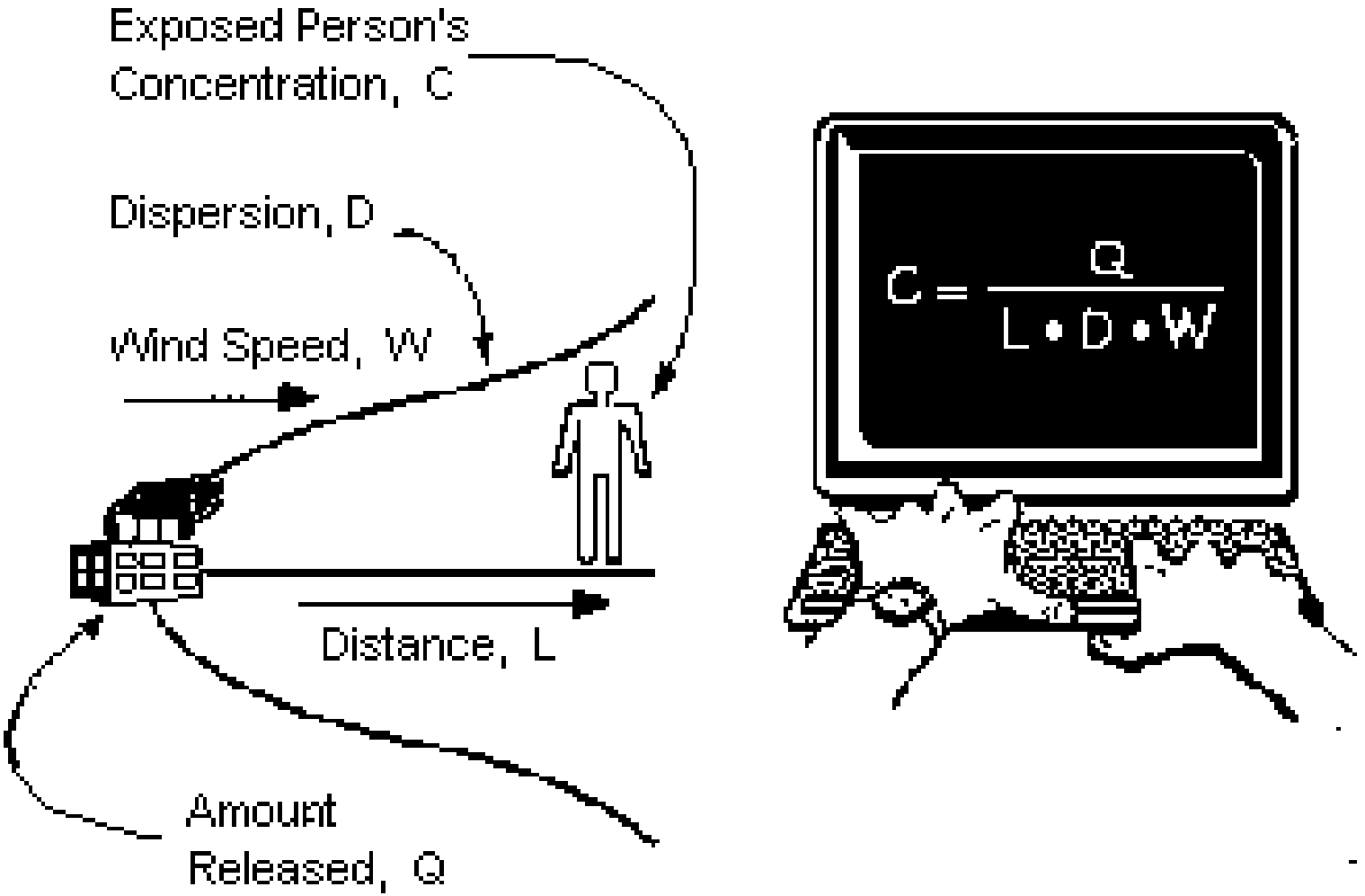
- The EPA has slightly modified the ADI approach and calculates a **Reference Dose (RfD)** as the acceptable safety level for chronic non-carcinogenic and developmental effects. Similarly the ATSDR calculates **Minimal Risk Levels (MRLs)** for noncancer end points.

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF1 \times UF2 \times \ldots}$$

The **Uncertainty Factors or Safety Factors** used to derive an ADI or RfD are:

10X	human variability
10X	extrapolation from animals to humans
10X	use of less than chronic data
10X	use of LOAEL instead of NOAEL
0.1 - 10X	modifying factor

Exposure Assessment



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

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**

- The determination or estimation (qualitative or quantitative) of the **magnitude, frequency, or duration, and route** of exposure

Exposure Assessment

- Exposure assessment is a key phase in the risk assessment process since without an exposure, even the most toxic chemical does not present a threat.

  Exposure assessment includes three steps:
  - characterization of the exposure setting *(e.g., point source)*
  - identification of exposure pathways *(e.g., groundwater)*
  - quantification of the exposure *(e.g., µg/L water)*

- The main variables in the exposure assessment are:
  - exposed populations *(general public or selected groups)*
  - types of substances *(pharmaceuticals, occupational chemicals, or environmental pollutants)*
  - single substance or mixture of substances
  - duration of exposure *(brief, intermittent, or protracted)*
  - pathways and media *(ingestion, inhalation, and dermal exposure)*

- Assessment of the chemical fate requires knowledge of many factors including:
  - organic carbon and water partitioning at equilibrium *(Koc)*
  - chemical partitioning between soil and water *(Kd)*
  - partitioning between air and water *(Henry's Law Constant)*
  - solubility constants
  - vapor pressures
  - partitioning between water and octanol *(Kow)*
  - bioconcentration factors

- A major aspect of the exposure assessment is to identify the exposure pathways. All potential exposure pathways are carefully considered as well as contaminant releases, movement and fate in the environment and the exposed populations.
- Exposure pathways may include:
  - groundwater
  - surface water
  - air
  - soil
  - food
  - breast-milk

Risk Characterization

- This final stage in the risk assessment process involves prediction of the frequency and severity of effects in exposed populations. Conclusions reached concerning hazard identification and exposure assessment are integrated to yield probabilities of effects likely to occur in humans exposed under similar conditions.

- Risk characterization is the process in which the dose-response assessment and exposure assessments are integrated to predict risk to specific populations. It is the final stage in the risk assessment process and involves the prediction of the frequency and severity of effects in exposed populations.

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.

- 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.

Effects of Safety and Health Hazards

Identify	Are people exposed to harm resulting from the company's operations?
Assess	What are the causes, consequences & effects? How likely is the loss of control? What is the risk & is it ALARP?
Control	Can the causes be eliminated? What controls are needed & can they be effective?
Recover	Can the potential consequences & effects be mitigated? What are the recovery measures required? Are the recovery capabilities suitable & sufficient?

HSE Risk - Definition

Risk = Consequence resulting from the release of a hazard

x

Probability of the occurrence of that event

Assessing the Risks

Risk

=

Severity of Harm

x

Likelihood of occurrence

- This simple computation gives a risk value of between 1 and 9 enabling a rough and ready comparison of risks.
- In this case the lower the number, the greater the risk, and so prioritises the hazards so that control action can be targeted at higher risks.

Controlling Risk

- **Risk Avoidance** — This strategy involves a conscious decision on the part of the organisation to avoid completely a particular risk by discontinuing the operation producing the risk e.g. the replacing a hazardous chemical by one with less or no risk potential.
- **Risk Retention** — The risk is retained in the organisation where any consequent loss is financed by the company. There are two aspects to consider here, risk retention with knowledge and risk retention without knowledge.

Controlling Risk

- **Risk Transfer** — This refers to the legal assignment of the costs of certain potential losses from one party to another. The most common way is by insurance.
- **Risk Reduction** — Here the risks are systematically reduced through control measures, according to the hierarchy of risk control described in earlier sections.

ALARP

- Legislation requires employers to reduce risks to a level that is as low as is reasonably practicable (sometimes abbreviated as ALARP).
- To carry out a duty *so far as is reasonably practicable* means that the degree of risk in a particular activity or environment can be balanced against the time, trouble, cost and physical difficulty of taking measures to avoid the risk.

Risk

Risk = the mathematical probability that some harmful outcome will result from a given action, event, or substance

Harmful outcome could be defined as injury, death, environmental damage, economic loss, etc.

Risk assessment

Analyzes risks quantitatively

Measures and compares risks involved in different activities or substances

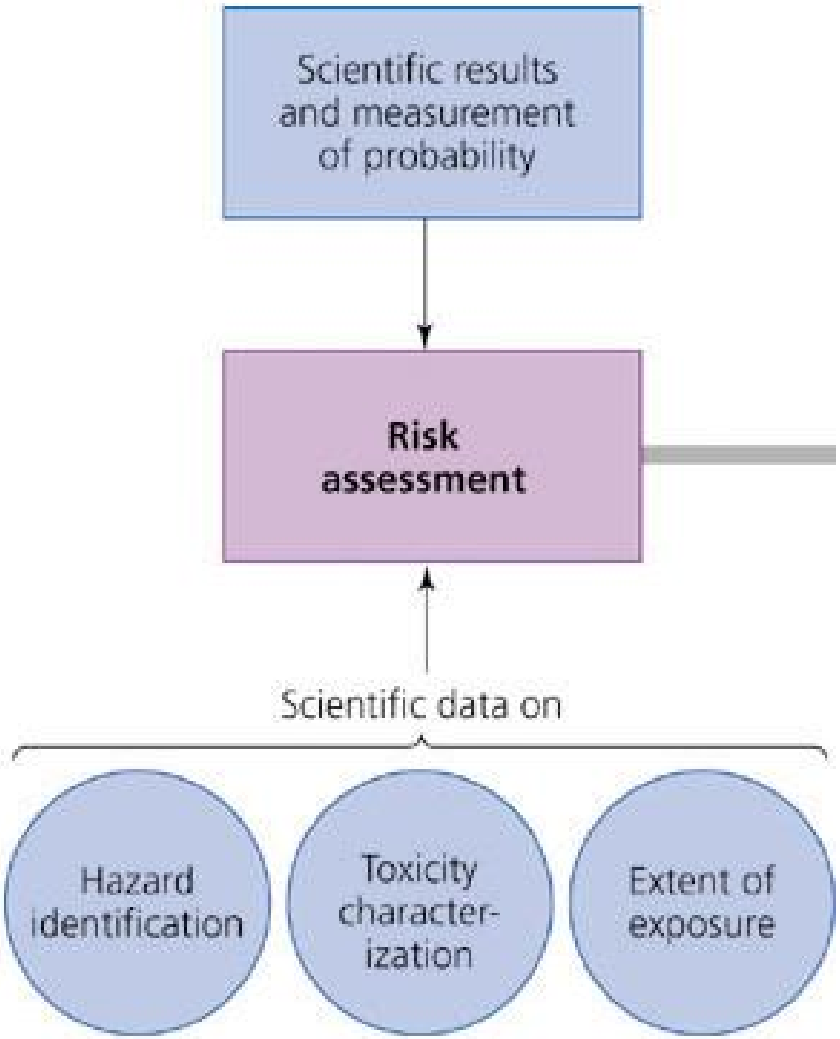
Helps identify and prioritize serious risks

Helps determine threats posed to humans, wildlife, ecosystems

Risk assessment

Involves:

- Dose-response analysis or other tests of toxicity
- Assessing likely exposure to the hazard *(concentration, time, frequency)*



Risk management

- ***Risk management :*** Refers to the process of evaluating alternative regulatory options and selecting among them. The results of risk characterization are used to identify potential options that are then evaluated in terms of expected public health, economic, social, and political consequences. The responsible agency then makes a decision and implements the selected option.

Risk Management consist of four steps

1. ***Decision:*** Is the process of choosing between the options .
2. ***Implementation :*** Is the process of creating the option that we had choose .
3. ***Monitoring and Evaluation :*** Is the process of controlling the option to be sure that we achieved our aim .
4. ***Review :*** Is the process of choosing other option in case we didn’t have the best results.

The Framework for Environmental Health Risk Management

- The framework is intended primarily for risk decisions related to setting standards, controlling pollution, protecting health, and cleaning up the environment. The framework consists of **Six Steps**:
  1. **Define the problem and put it into context**;
  2. **Analyze the risks associated with the problem in context**;
  3. **Examine options for addressing the risks**;
  4. **Make decisions about which options to implement**;
  5. **Take actions to implement the decisions**; and
  6. **Conduct an evaluation of the results of the action**

The Framework for Environmental Health Risk Management

- The proposed *Decision-Making Framework* consists of a series of inter-connected steps that may be grouped into three phases:

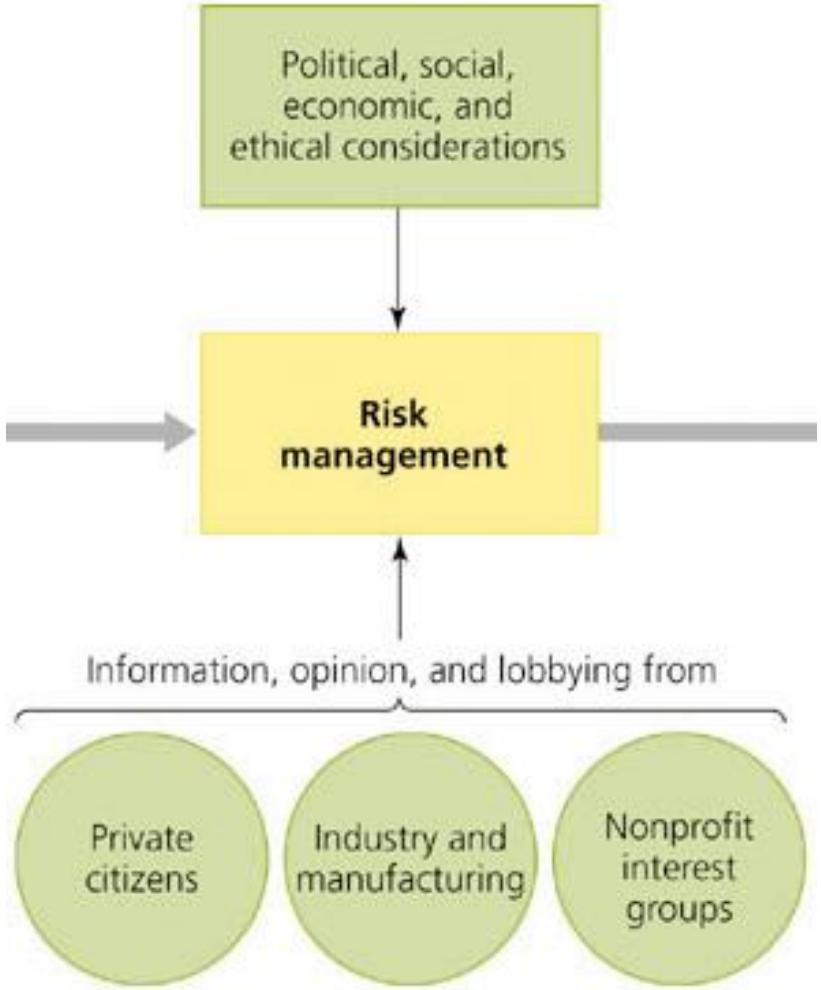
1. **Issue Identification** (identify the issue and put it into context);
2. **Risk Assessment** (assess potential risks and benefits—where appropriate); and
3. **Risk Management** (identify and analyze regulatory and non-regulatory options; select a strategy; implement the strategy; and monitor and evaluate the results).

Risk management

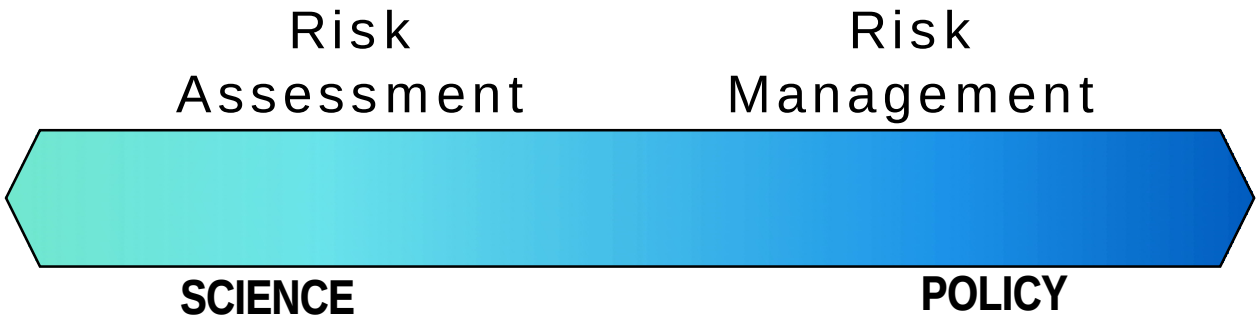
Consider risk assessments in light of social, economic, and political needs and values.

Weigh costs and benefits, given both scientific and nonscientific concerns.

Decide whether or not to reduce or eliminate risk.

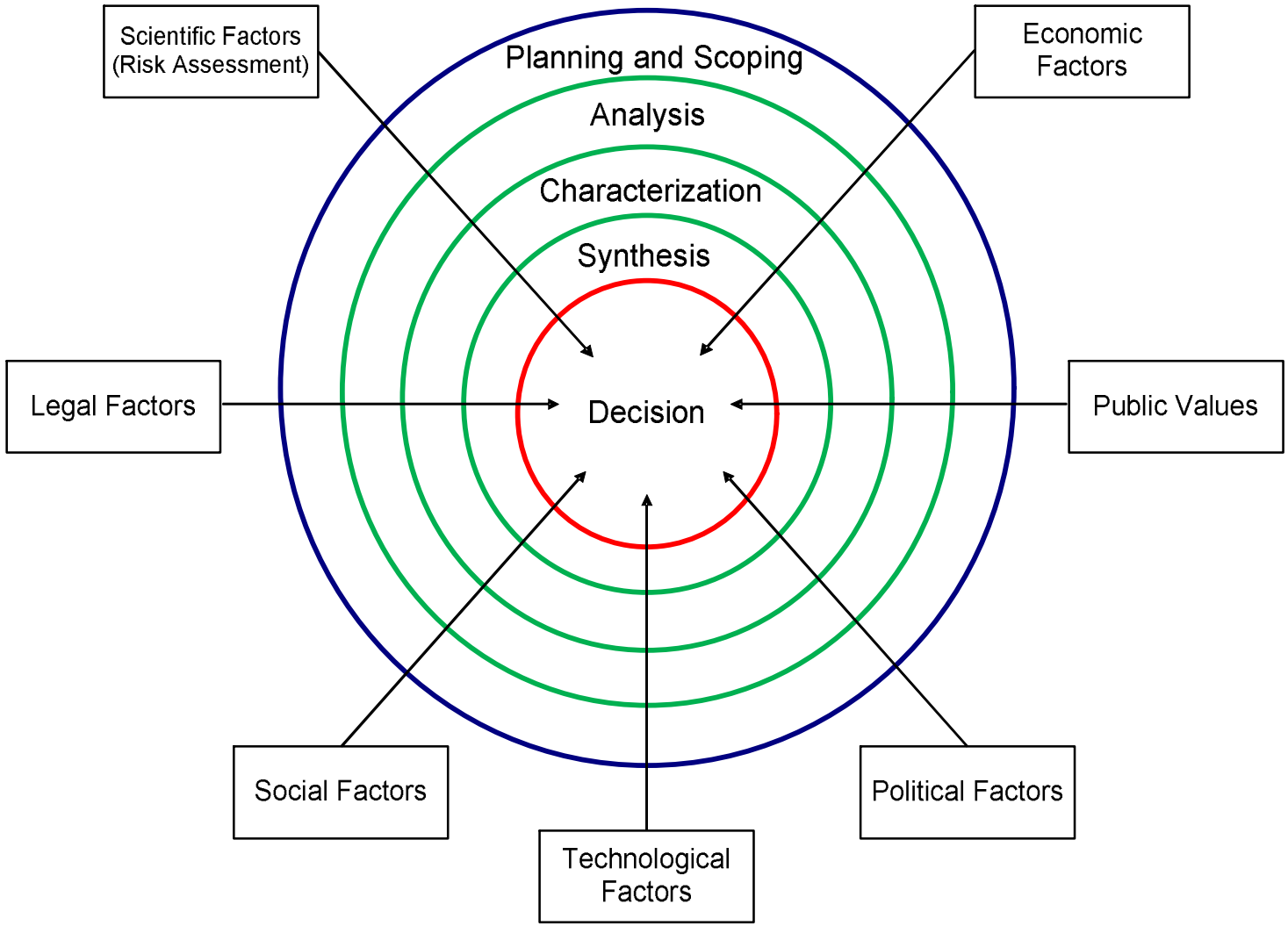


Risk Assessment and Risk Management Are Interrelated



- Some decisions are based on **scientific judgment**; others are **policy decisions** informed by science.
- How **separated** should risk assessment and risk management be?
- Most current frameworks recommend an **iterative process**.
- **Transparency** is key: "Conducting a risk assessment in such a manner that all of the scientific analyses, uncertainties, assumptions, and science policies which underlie the decisions made throughout the risk assessment are clearly stated"

Risk Management Decision Framework



EPA's Risk Characterization Handbook
https://www.epa.gov/risk/risk-characterization-handbook

Risk assessment and risk management inform policy

Following risk management, policy decisions are made.