CE 213A
Introduction to Environmental Science

L18
Unit 3: Impact of Pollution
Health Risk Assessment

Dr. Anubha Goel

FB 319, anubha@iitk.ac.in, x 7027

Schedule : LEC Mon Wed Fri 5:10 – 6 pm

Content

- Risk vs. Hazard
- Risk Assessment
  - Definition and types
- Conducting Risk Assessment
- Steps for conducting H.R.A.

Risk vs. Hazard

- H**azard** is something that can cause harm, e.g. electricity, chemicals, working up a ladder, noise, a keyboard, a bully at work, stress, etc.
- **Risk** is the chance, high or low, that any **hazard** will actually cause somebody harm.

What is Risk Assessment?

Risk Assessment is where the severity of the Hazard and its potential outcomes are considered in conjunction with other factors including the level of exposure and the numbers of persons exposed and the risk of that hazard being realised.

Types of Risk Assessment

1. Human Health Risk Assessment (H.R.A)
2. Ecological Risk Assessment (E.R.A)

Human Health Risk Assessment (H.R.A)-

- The characterization of the probability of potentially adverse health effects from human exposures to environmental hazards.

Ecological Risk Assessment –

- A process that estimates the likelihood of undesirable ecological effects occurring as a result of human activities.
- An E.R.A. would use different species in different tropic levels; the test species selected are generally representative of naturally occurring species with practical considerations such as ease of culture, sensitivity, availability, and existing databases also involved.

Steps for risk assessment

- Step 1: Identify hazards, i.e. anything that may cause harm.
- Step 2: Decide who may be harmed, and how?
- Step 3: Assess the risks and take action.
- Step 4: Record significant findings
- Step 5: Review the data obtained and update if necessary

Some useful links

- https://worksmart.org.uk/health-advice/health-and-safety/hazards-and-risks/what-are-five-steps-risk-assessment

- https://www.westernsydney.edu.au/__data/assets/pdf_file/0020/12917/12917_Hazard_Identification,_Risk_Assessment_and_control_Procedure.pdf

Risk assessment - videos

- https://www.youtube.com/watch?v=fY6KGN72d7Q

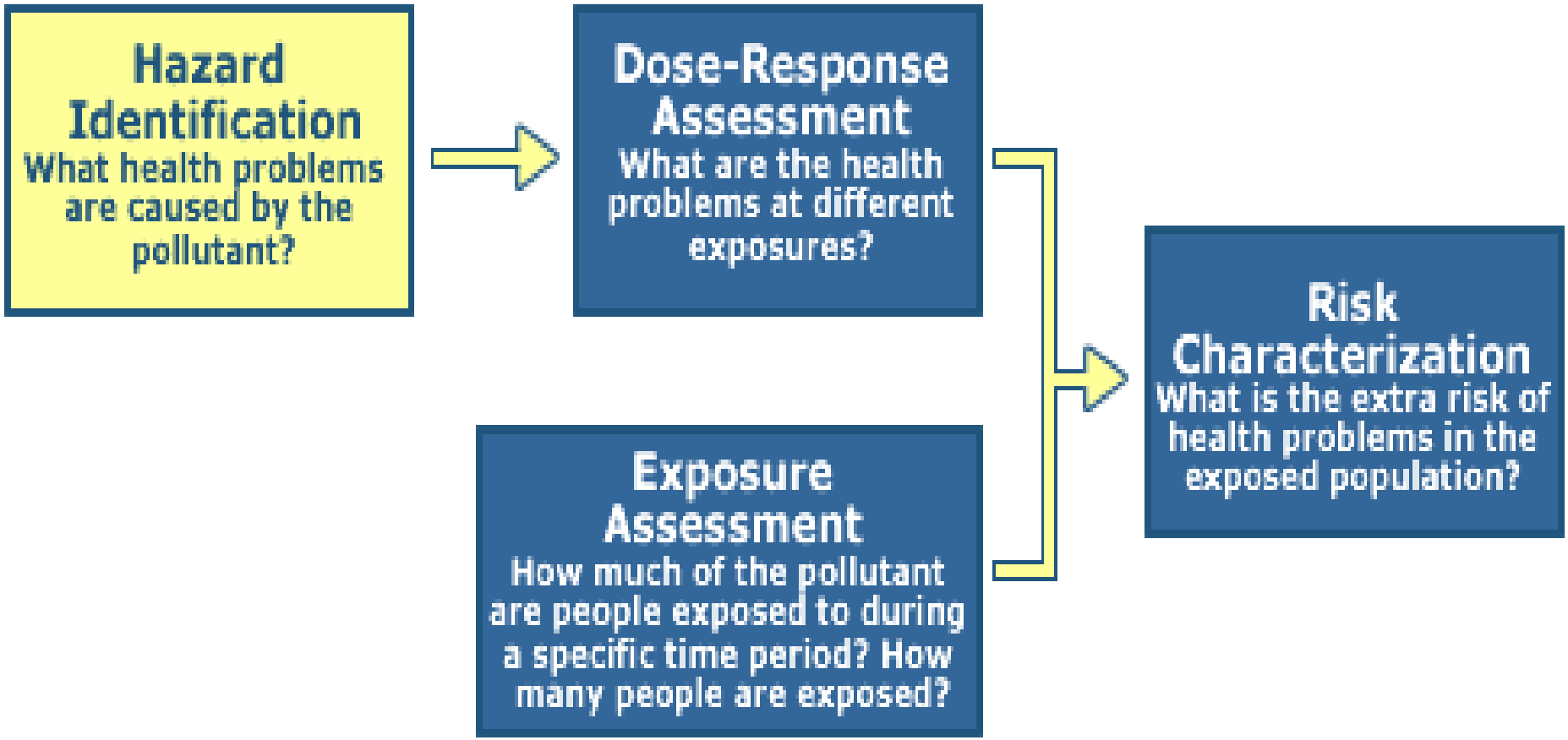
Conducting a Human Health Risk Assessment

Four Steps towards :

1. Hazard Identification
2. Dose-Response Assessment
3. Exposure Assessment
4. Risk Characterization

Conducting a Human Health Risk Assessment
https://www.epa.gov/risk/conducting-human-health-risk-assessment

The 4 Step Risk Assessment Process



Step 1. Hazard Identification

- Hazard identification involves gathering and evaluating toxicity data on the types of health injury or disease that may be produced by a chemical and the conditions of exposure under which injury or disease is produced.
- The subset of chemicals selected for the study is termed "***chemicals of potential concern***".

The objective of Step 1 is to identify the types of adverse health effects that can be caused by exposure to some agent in question, and to characterize the quality and weight of evidence supporting this identification.

- It involves quantification of risk through understanding hazard, vulnerabilities and exposure patterns. This knowledge is essential for development of strategies and measures for reducing the risks.
- Data from dose-response studies of different duration of exposure (acute, subchronic, and chronic) are used.
- H.R.A. would have a priority ranking of studies that would involve humans and other mammals.

Acute: present or experienced to a severe or intense degree.
Chronic - persisting for a long time or constantly recurring.
Sub chronic -intermediate between acute and chronic; more chronic than acute

Step 2. Dose-Response Assessment

- The dose-response assessment involves describing the quantitative relationship between the amount of exposure to a chemical and the extent of toxic injury or disease.
- The description is different for non-carcinogenic versus carcinogenic effects.

The objective of Step 2 is to document the relationship between dose and toxic effect.

a. Non-Carcinogenic Effects

- Allowable Daily Intake - The US Food and Drug Administration, the World Health Organization, and the Consumer Product Safety Commission use the **Allowable Daily Intake (ADI)** to calculate permissible chronic exposure levels.
- The ADI is determined by applying safety factors to the highest dose in chronic human or animal studies that has been demonstrated not to cause toxicity.

- Reference Dose - The US Environmental Protection Agency has slightly modified the ADI. For the EPA, the acceptable safety level is known as the **Reference Dose (RfD)** .
- An estimate of a daily exposure level for human populations, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious health effects during a lifetime .

NOAEL and LOAEL

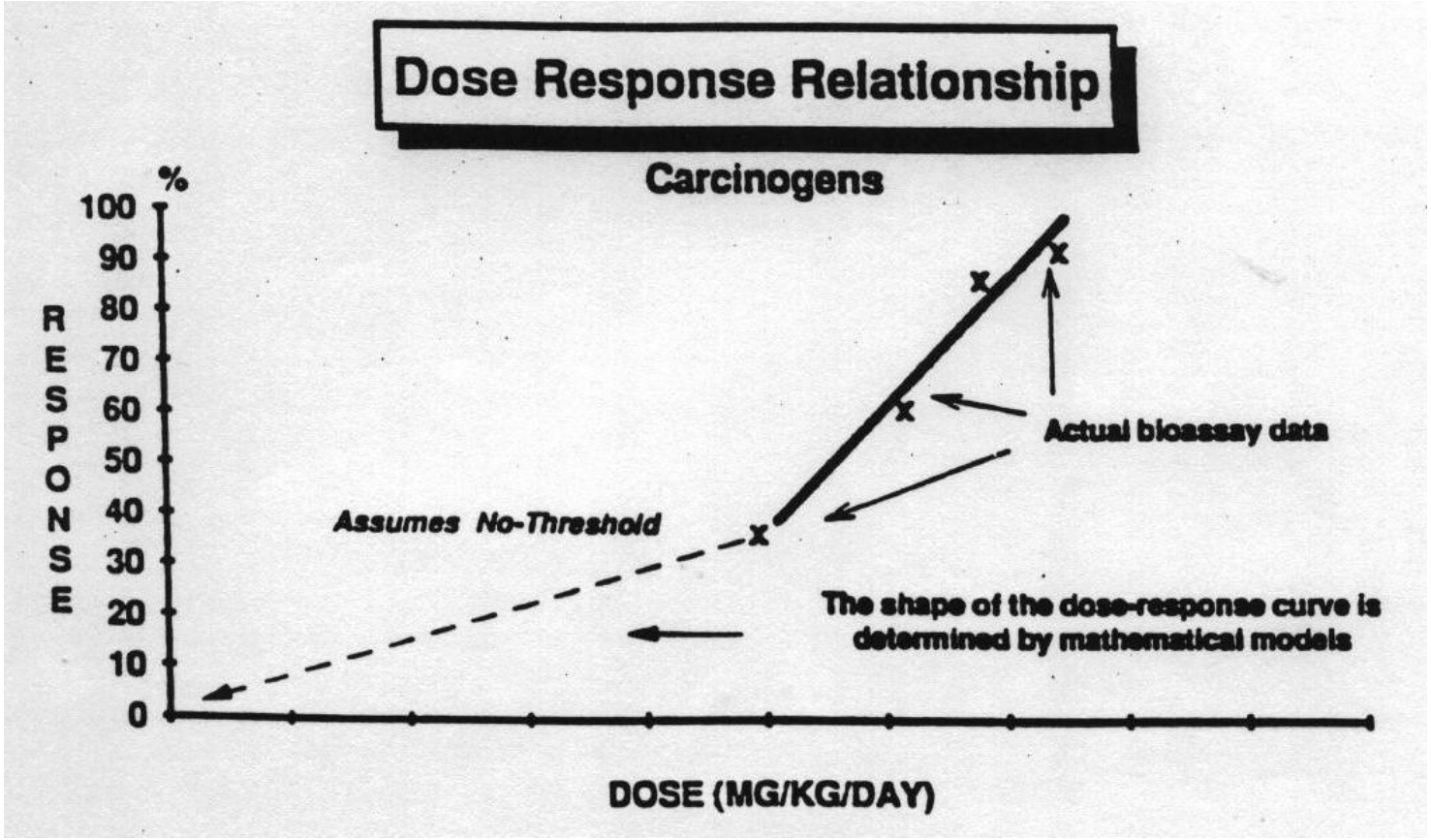
- A **No-Observed-Adverse-Effect Level (NOAEL)** is the highest exposure level at which no statistically or biologically significant increases are seen in the frequency or severity of adverse effect between the exposed population and its appropriate control population.
- In an experiment with several NOAELs, the regulatory focus is normally on the highest one, leading to the common usage of the term NOAEL as the highest experimentally determined dose without a statistically or biologically significant adverse effect.
- In cases in which a NOAEL has not been demonstrated experimentally, the term **"lowest-observed-adverse-effect level (LOAEL)"** is used, which this is the lowest dose tested.

- RfD is an estimate with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's non cancer health assessments.
- The reference dose is an oral or dermal dose derived from the NOAEL, LOAEL or BMDL by application of generally order-of-magnitude uncertainty factors (UFs).
- The position of the EPA is that humans are as sensitive as the most sensitive test species unless other data are available.

$$\text{RfD} = \frac{\text{NOAEL or LOAEL}}{\text{UF1 x UF2 … x Ufx}}$$

b. Carcinogenic Effects

- Mathematical models are used to extrapolate from the high doses used in animal experiments to the low doses to which humans are normally exposed in a chronic setting.



Carcinogenic Effects - Continued

TABLE 21.5. Primary Models Used for Assessment of Nonthreshold Effects

Linearized multistage model	Assumes that there are multiple stages for cancer Fits curve to the experimental data Linear from upper confidence level to zero
One hit model	Assumes there is a single stage for cancer and that one molecular or radiation interaction induces malignant change Very conservative
Multihit model	Assumes several interactions needed before cell becomes transformed Least conservative model
Probit model	Assumes probit (log-normal) distribution for tolerances of exposed population Appropriate for acute toxicity; questionable for cancer
Physiologically based pharmacokinetic models	Incorporates pharmacokinetic and mechanistic data into the extrapolation Data rich requirements and, while promising, are currently of limited availability

Slope factor

- The key risk assessment parameter derived from the carcinogen risk assessment process is the “slope factor”. The slope factor is a toxicity value that quantitatively defines the relationship between dose and response.
- A plausible upper bound estimate of the probability that an individual will develop cancer if exposure is to a chemical for a lifetime of 70 years.

Slope factor

- Slope Factor = a plausible upper-bound estimate of the probability of a response per unit intake of chemical over a lifetime.
  - Risk per unit dose
  - Units of Risk $(mg/kg\text{-}day)^{-1}$
  - Symbol for Slope Factor = q_1^*

ILCR – Incremental Lifetime Cancer Risk

- For carcinogens, the estimated exposure will be multiplied by the appropriate *Cancer Slope Factor* or *Unit Risk* to derive an estimate of the potential Incremental Lifetime Cancer Risk (ILCR) associated with that exposure (Health Canada 2004).
- The ILCR is derived as:

ILCR = Exposure (µg/kg/d) x Cancer Slope Factor (µg/kg/day)$^{-1}$

Where pathway-specific slope factors or unit risks exist, the risks via inhalation and the risks via oral and dermal exposure should be estimated separately. In other cases, the cancer risks posed by simultaneous inhalation/dermal/oral exposure can be estimated.

ILCR – Incremental Lifetime Cancer Risk

Case: Persistent Organic Pollutants like DDT

- Cancer risks will be considered "essentially negligible" where the estimated ILCR is 1-in-100,000 ($\leq 1 \times 10^{-5}$) (Health Canada 2004).
- If the ILCR is greater than 1×10^{-5}, the risk assessment should either be refined and/or risk management measures should be taken.

http://www.popstoolkit.com/riskassessment/module/risk+characterization/ilcr.aspx

Cancer Assessment Categories

TABLE 21.3. EPA Cancer Assessment Categories

Group A — human carcinogen	Sufficient human evidence for causal association between exposure and cancer
Group B1 — probably human carcinogen	Limited evidence in humans
Group B2 — probably human carcinogen	Inadequate evidence in humans, 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 epidemiology and animal studies which are negative

Risk Control Measures at workplace