RISK ASSESSMENT AND MANAGEMENT

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Risk Assessment

Risk assessment — the process of correlating the amount of exposure with the amount of harm.

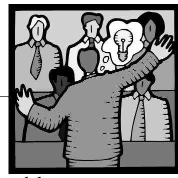
The question:

How much of a chemical is OK?

Steps in Risk Assessment

1. Hazard identification
2. Exposure assessment (*DOSE*)
3. Quantitative toxicological assessment (*DOSE-RESPONSE*)
4. Risk characterization

Risk *Management*



- Decisions on whether to act and how
- Uses the numbers from risk assessment
- Considers cost of alternatives
- Is influenced by risk perception

1. Hazard Identification

Toxicological concepts:

- Any substance is toxic if dose is high enough, but only some chemicals can cause cancer
- Non-cancer toxicity: Protecting against the most sensitive effect protects against all effects: “threshold”
- Cancer: Any dose of a carcinogen carries some risk, but the smaller the dose, the smaller the risk

Key question for hazard identification:
Is it a carcinogen or not?

Current methods:

- Epidemiology
- Animal testing
- *In vitro* (bacterial and mammalian cell) testing
- Structure-activity relationships

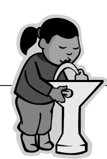
Scope of the identification problem

- Synthetic chemicals cause only 1-5% of all human cancers
- >1 million chemical substances are known
- ~3 thousand produced in high volumes
  - Full information available for 7%
  - No information available for 43%
- Tests (mutagenicity but not carcinogenicity) cost $200,000 per chemical

Questions in Hazard Identification

- Is human cancer predicted well enough by
  - animal cancer tests?
  - mutagenicity?
- Are we controlling the right chemicals?

2. Exposure Assessment



"How does the dose of a chemical depend on its concentration in air, water, soil, etc.?"

Routes of exposure

- Oral – food, water, soil & dust
- Inhalation – particulates and gases
- Dermal – water, soil & dust

Who's Exposure?

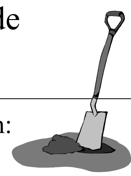
Numerical estimate of exposure

- Must know frequency and duration of contact
- Depends on physiology and activities

Uncertainty

- Report both central tendency and upper bound values

Example – methylene chloride (MC) in soil



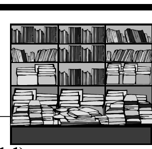
Adult central tendency soil ingestion:

Dose =

[redacted]

= 2.3×10^{-3} mg MC/kg/day

3. Quantitative Toxicological Assessment



<u>Non-Cancer Toxicity</u> (has a threshold)

Determine which species, durations, and endpoints have been studied

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Identify the most sensitive effect

No Observed Adverse Effect Level: NOAEL (or Lowest Observed Adverse Effect Level: LOAEL)

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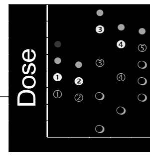
Non-Cancer Toxicity
(continued)



NOAEL (or LOAEL)

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Use *uncertainty factors* to account for within-human variability (÷10), animal-to-human variability (÷10), threshold (÷10), durations (÷10), and completeness of data (÷10)

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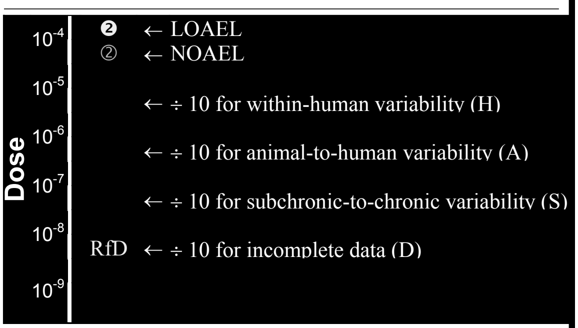
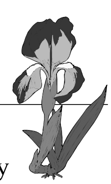
"Safe" dose = RfD

Derivation of Reference Dose (RfD)



Example – methylene chloride RfD

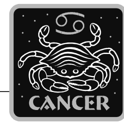


NOAEL: 5.85 (male mice) and 6.47 (female mice) mg/kg/day, liver toxicity

Uncertainty factors: 10 for within-human variability and 10 for animal-to-human variability

RfD = 6×10^{-2} mg/kg/day

Only if the chemical is a "carcinogen"



Cancer toxicity (no threshold)

Identify the most sensitive tumor

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Extrapolate risk to low doses

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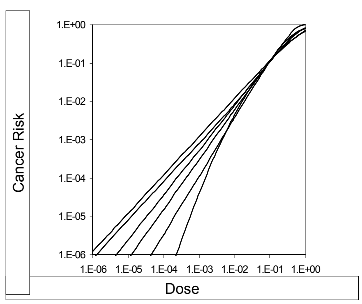
An estimate of carcinogenic potency

Uncertainties in low-dose extrapolation methods



Linerized Multistage Model

$P(d) = 1 - \exp[-(q_0 + q_1 d + q_2 d^2 + \ldots + q_k d^k)]$

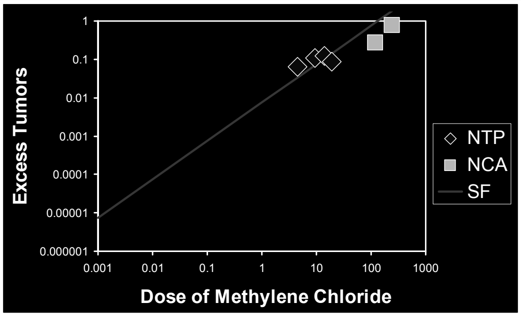
q_1 – coefficient of linear term

q_1* – upper 95% confidence limit of q_1

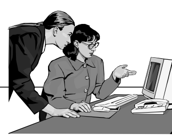
– also called Slope Factor (SF)

– used by EPA for carcinogenic potency

Methylene Chloride Slope Factor



4. Risk Characterization



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Example – methylene chloride

Dose = 2.3×10^{-3} mg MC/kg/day

RfD = 6×10^{-2} mg/kg/day

→ Dose is *less than* RfD so no noncancer risk

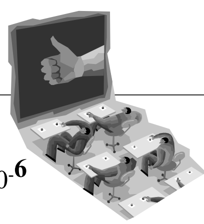
SF = 7.5×10^{-3} per (mg/kg/day)

Risk = 1.7×10^{-5}

Risk assessment is done!

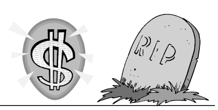
Now What?

Rules of thumb



- If risk is less than 10^{-6} rarely take action
- If risk is greater than 10^{-4} usually take action

Cost-Benefit Analysis

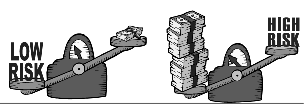


- Risk analysis:
  How many premature deaths would action *X* prevent?
- Cost analysis:
  How much would action *X* cost?
- Benefit analysis:
  How much is preventing each premature death worth?

Approaches to benefit analysis

- ❖Human capital
- ❖Willingness-to-pay
  - ➢Survey
  - ➢Occupational behavior
  - ➢Consumer behavior
- ❖Credible range from above:
  - ➢$2.1 million to $11 million (1995 dollars)
  - ➢$2.5 million to $13 million (2003 dollars)

Risk Perception



Dread Factor

Perceived as More Risky	Perceived as Less Risky
Uncontrollable	Controllable
Involuntary	Voluntary
Inequitable	Equitable
Dread result	Commonplace result
Global consequences	Localized consequences
Risk to future generations	Risk to existing people

Risk Perception (continued)

Familiarity Factor

Perceived as More Risky	Perceived as Less Risky
New risk	Old risk
Not observable	Observable
Delayed effect	Immediate effect
No scientific consensus	Scientific consensus

EPA's Seven Cardinal Rules of Risk Communication

CR 1 — Accept and involve the public as a legitimate partner.

CR 2 — Plan carefully and evaluate your performance.

CR 3 — Listen to the public's concerns and feelings.

CR 4 — Be honest, open and frank.

CR 5 — Coordinate and collaborate with other credible sources.

CR 6 — Meet the needs of the media.

CR 7 — Speak clearly and with compassion, kindness and respect.

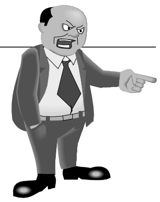
Guide to Ineffective Risk Communication

1. Avoid eye contact, keep your arms and legs crossed, and act nervous and/or bored
2. Use jargon and mountains of technical details
3. Emphasize the benefits of industry and the cost of cleanup

Guide to Ineffective Risk Communication (continued)

4. Blame others for mistakes and confusion
5. Make unrealistic promises
6. Be sarcastic when people express concerns or don't understand you
7. Give long, prepared, technical speeches when someone asks a question

Guide to Ineffective Risk Communication
(continued)



8. Get angry; attack opponents
9. Refuse to answer personal questions
10. Minimize risks and make inappropriate comparisons

Bottom Line

Risk assessment can't give the "right" answer

More modest goal:

Assessments are

- ❖ Consistent
- ❖ Transparent