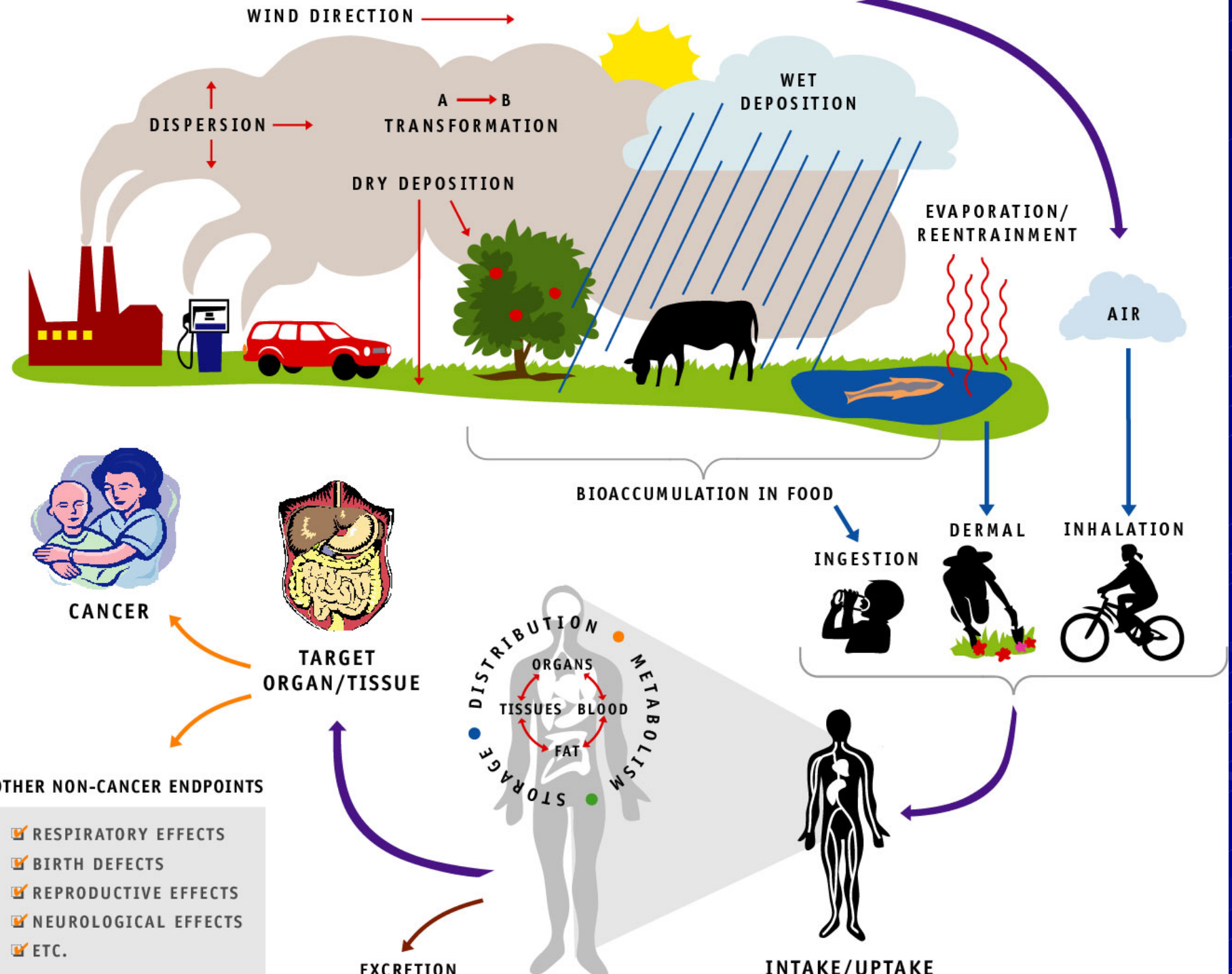
Risk Assessment Basics

Perry R. Pandya
Air Protection Division
U.S. EPA Region III

Risk Assessment Steps

- Hazard Identification
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization


WIND DIRECTION
DISPERSION
A → B
TRANSFORMATION
DRY DEPOSITION
WET
DEPOSITION
EVAPORATION/
REENTRAINMENT
AIR
BIOACCUMULATION IN FOOD
INGESTION
DERMAL
INHALATION
CANCER
TARGET
ORGAN/TISSUE
DISTRIBUTION
METABOLISM
STORAGE
ORGANS
TISSUES
BLOOD
FAT
OTHER NON-CANCER ENDPOINTS
RESPIRATORY EFFECTS
BIRTH DEFECTS
REPRODUCTIVE EFFECTS
NEUROLOGICAL EFFECTS
ETC.
EXCRETION
INTAKE/UPTAKE

Key Risk Assessment Questions

Exposure Assessment

Who is exposed?

What chemicals are they exposed to?

How does the exposure occur?

Toxicity Assessment

Is a chemical toxic?

What is the relationship between the dose of a chemical and the response that results?

Risk Characterization

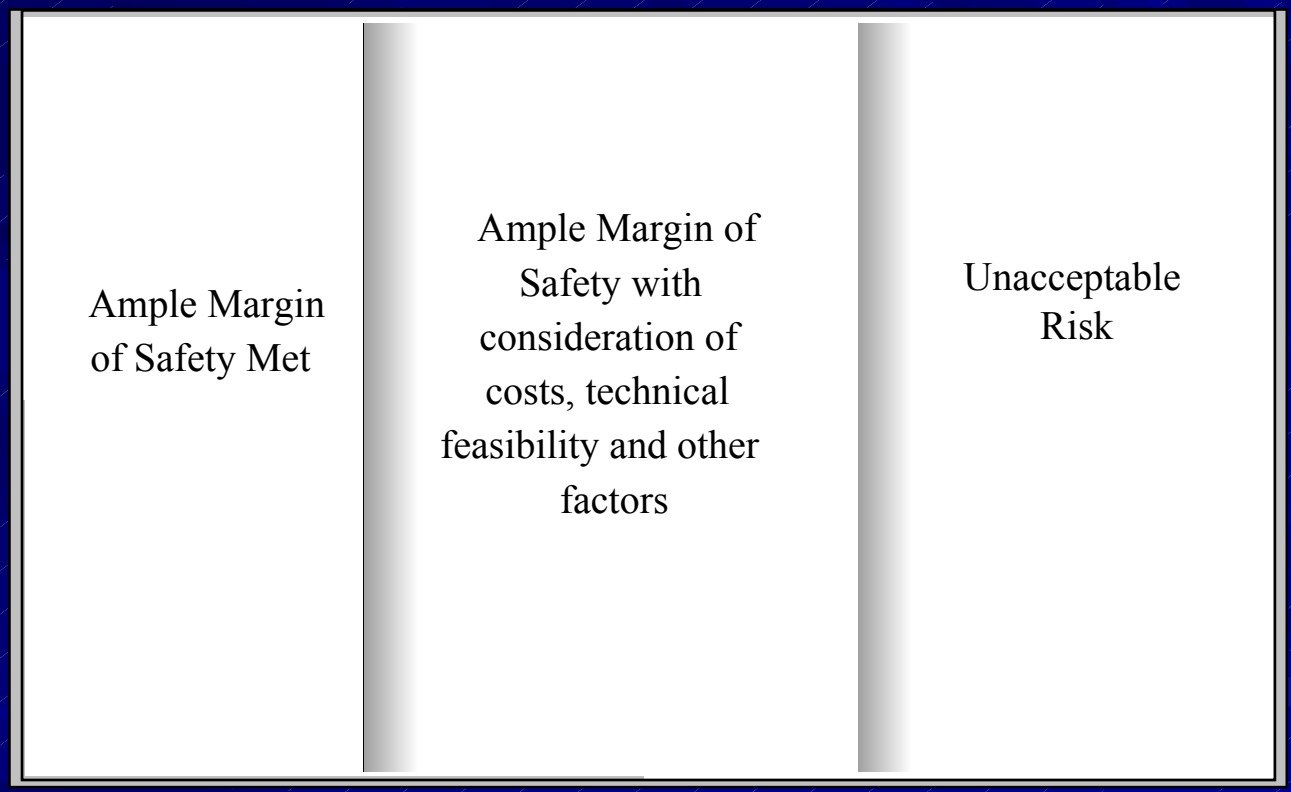
What is the likelihood that the exposure will result in an adverse health effect?

How sure are we our answers are correct?

Cancer Risk

- Incremental Cancer Risk (ICR)
- Expressed as a probability
- Calculated:
  - ICR = dose x cancer slope factor
- Interpretation
  - Example, ICR = 3 e-5: 3 excess cancers are expected out of 100,000 exposed individuals. (30 in 1 million)

Relevant Cancer Risk Ranges



Non-Cancer Risk

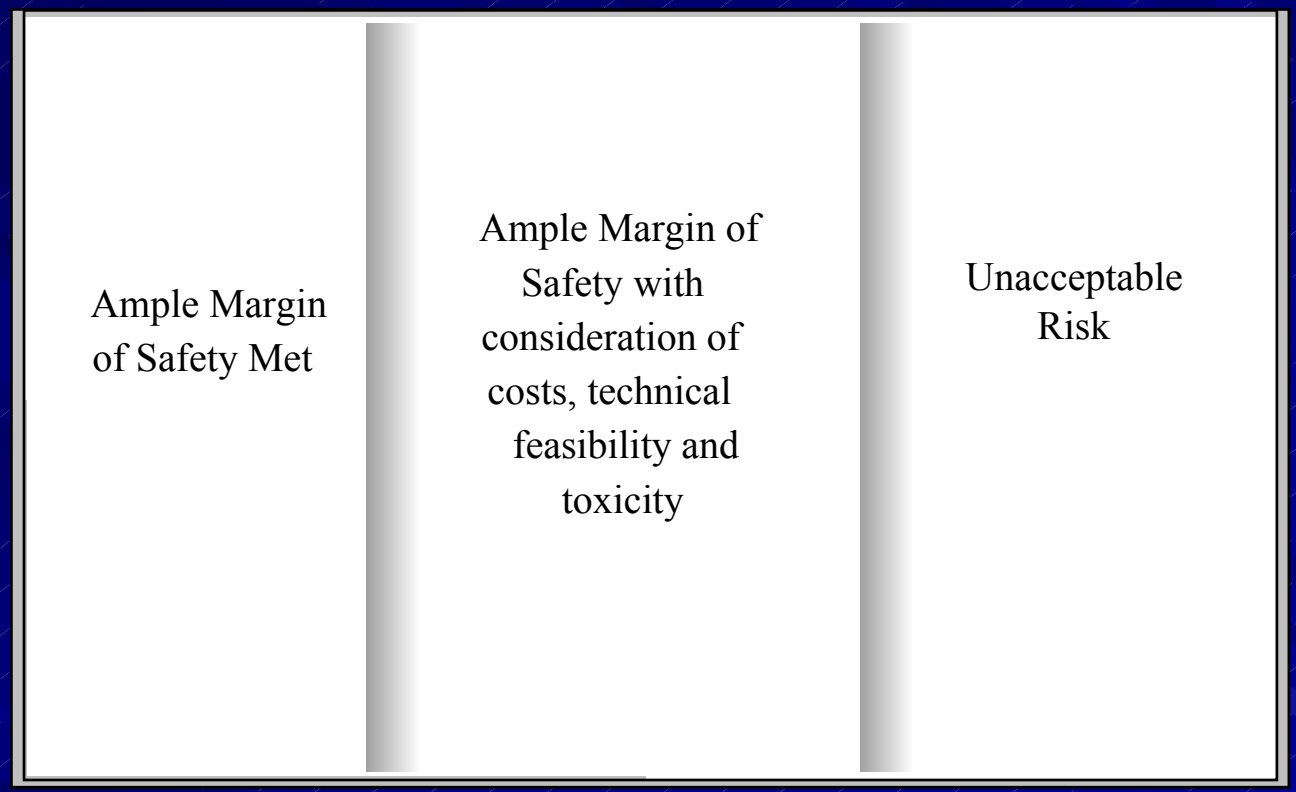
- Hazard Quotient (HQ)
- Not a probability
- Comparison of dose to safe dose
- RfC = Safe dose.
  - An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Non-Cancer

- Example
  - RfC = 30 µg/m^3 for Benzene
  - Dose = average long-term exposure
    - 15 µg/m3
    - HQ = 15/30 = 0.5
    - Exposure is less than safe dose. Risk Unlikely.

    - 60 ug/m3, HQ = 60/30 = 2.0
    - Exposure greater than Safe dose. Possible risk

Relevant Noncancer Hazard Ranges

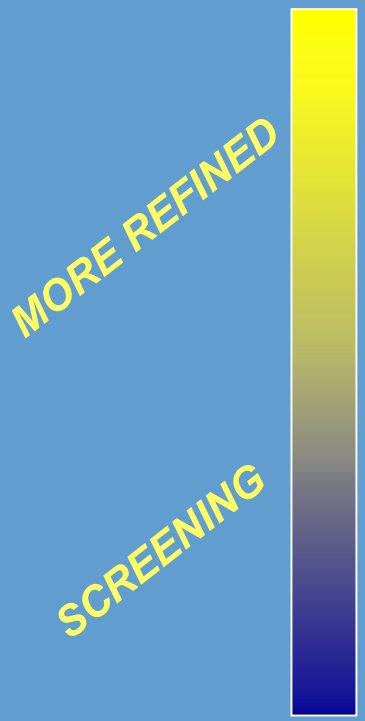


Tiered Approach to Risk Assessment

- Tier 1
  - Simple model
  - High uncertainty, biased towards risk.
- Tier 2
  - Moderate complexity
  - Better dispersion modeling
- Tier 3
  - More complex dispersion modeling.
  - Complex activity-based exposure estimates.

The Risk Assessment Continuum:
Tiered Approaches to the Process

Complete study-specific data, no assumptions; higher cost, lower uncertainty



Add quantitative uncertainty/variability analysis

More refined exposure assessment

More refined dispersion & exposure modeling

Simple dispersion model

Lookup Table

No data, all assumptions; lower cost, high uncertainty

Air Toxics Risk Assessment Reference Library

- Volume 1 – Technical Resource Manual
- Volume 2 – Facility Specific Assessment
- Volume 3 – Community Scale Assessment (currently under development)

Volumes 1 & 2 are now available on EPA's website:

http://www.epa.gov/ttn/fera/risk_atra_main.html

Upcoming Risk Assessment Training

- To be scheduled – Fall 2004
- Three day training in Philadelphia
- To be presented by:

Alvaro Alvarado, Ph.D
Toxicologist
Air Protection Division
U.S. EPA Region III