The very Fundamentals of Risk Assessment

Ohio EPA Division of Response and Revitalization

Today's organization

- Introduction ~~ Mike Allen (10:30 to 10:45)
- Site Characterization ~~ Brian Tucker (10:45 to 11:30)
- Exposure ~~ Audrey Rush (11:30 to 12:05)
- Lunch (12:05 to 1:15)
- Toxicity ~~ Audrey Rush (1:15 to 1:30)
- Risk Characterization ~~ Carrie Rasik (1:30 to 2:05)
- Conclusion ~~ Mike Allen (2:05 to 2:15)

Introduction: What is Risk?

How do we talk about it, where is it from, and how do we use it.

What is Risk?

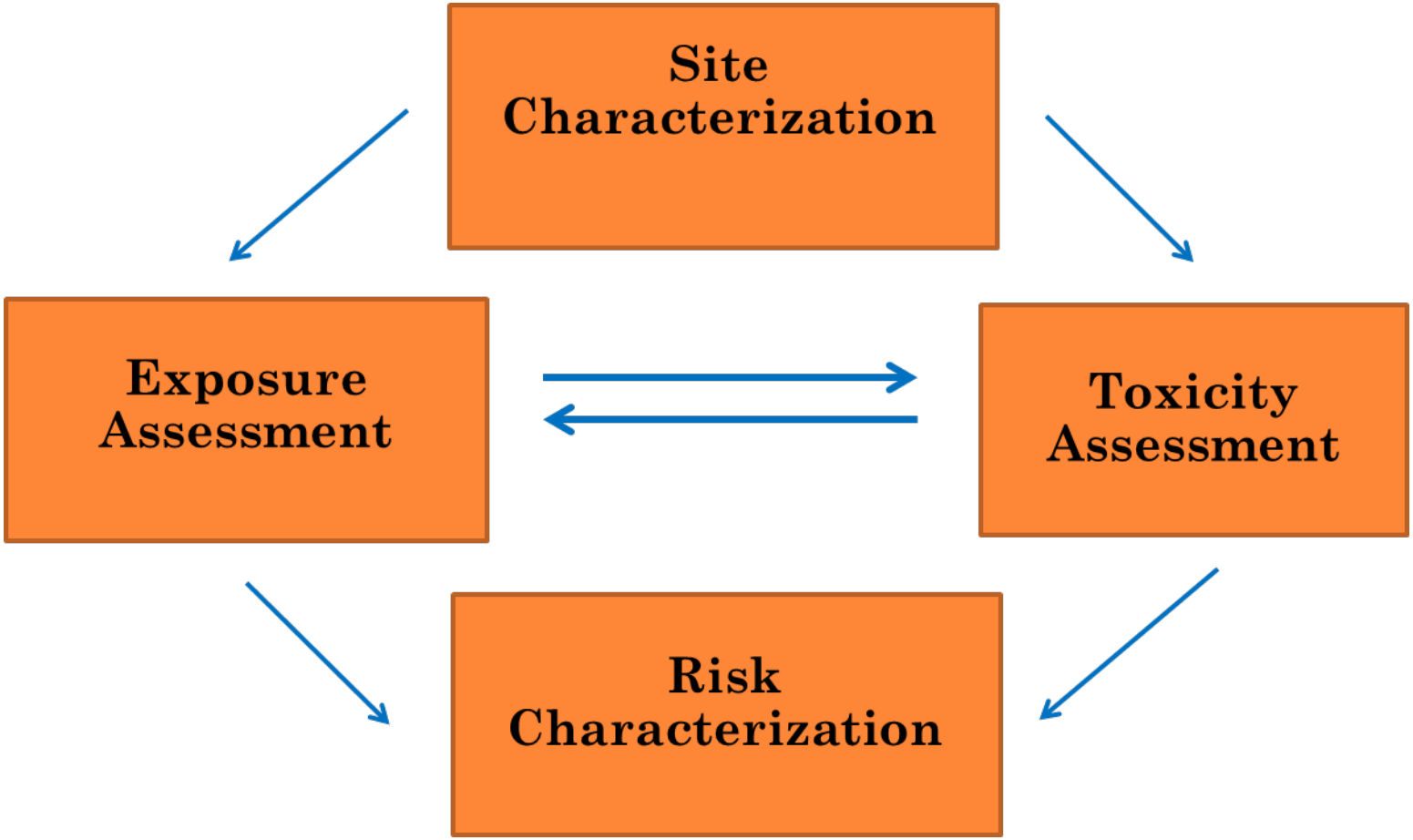
- Risk of dying?
- Risk of lighting a cigarette for the first time?
- Risk of smoking cigarettes your entire life?
- Risk of driving a car?
- Risk of investing in the stock market?
- Risk of living in one neighborhood vs. another?
- Risk of flying?
- Risk of giving birth?
- Risk of being born?

So what Risk are we looking to describe? Environmental

- The risk of what?
  - Carcinogenic Risk
  - Non-carcinogenic Hazard

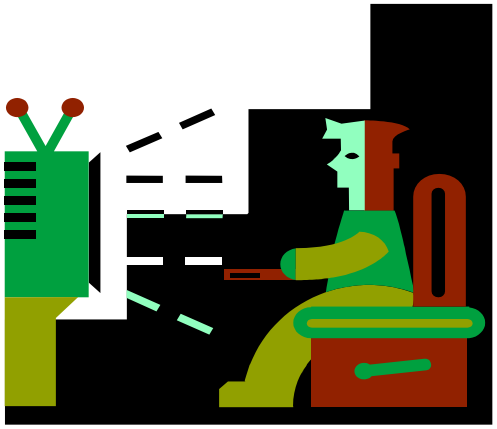
- The risk from what?
  - Chemicals, all of them?
  - Hazardous Substances
  - Naturally occurring?
  - Ubiquitous anthropogenic?

Environmental Risk



So what Risk are we looking to describe?

- The risk to who?
  - Residents on the site
  - Workers on the site
  - Residents off the site
  - Ecological too but we're not talking about that today



Where are we assessing this risk?

- We characterize the risk from an area
- We call this area a site, a property, a facility, a closure unit, an area of contamination, a decision unit etc.
- These terms are typically programmatic but they usually describe where and when the release has occurred and tie that release to a responsible party

Introduction to numerical terms

- Risk Goal ~~ Slope Factor
  - Excess Lifetime Cancer Risk (ELCR)
  - 1 E^{-5} or 0.00001 or 1 in 100,000 ~~ Ohio's chosen risk goal
  - A probability, an increased likelihood of a tumor occurring

- Hazard Index ~~ Reference Dose (RfD)
  - Non-carcinogenic effects
  - A representation of a threshold
  - Below 1 these effects are probably not going to be present

Environmental Risk

- The likelihood of an adverse health effect from the exposure to contamination
- Fundamentally three or four steps depending on who you talk to..
  - Characterize the Site
  - Characterize the Exposure
  - Characterize the Toxicity
  - Characterize the Risk
- Of course inside of each of these there is a lot of work to be done

- Questions?

Site Characterization

A first step in Risk Assessment

Why is Risk Assessment Important to You?

$

Liability.. You too can own a superfund site!

Public health.. Which could mean yours

Note!

RISK ASSESSMENT IS PART OF A LARGER DECISIONS MAKING PROCESS!

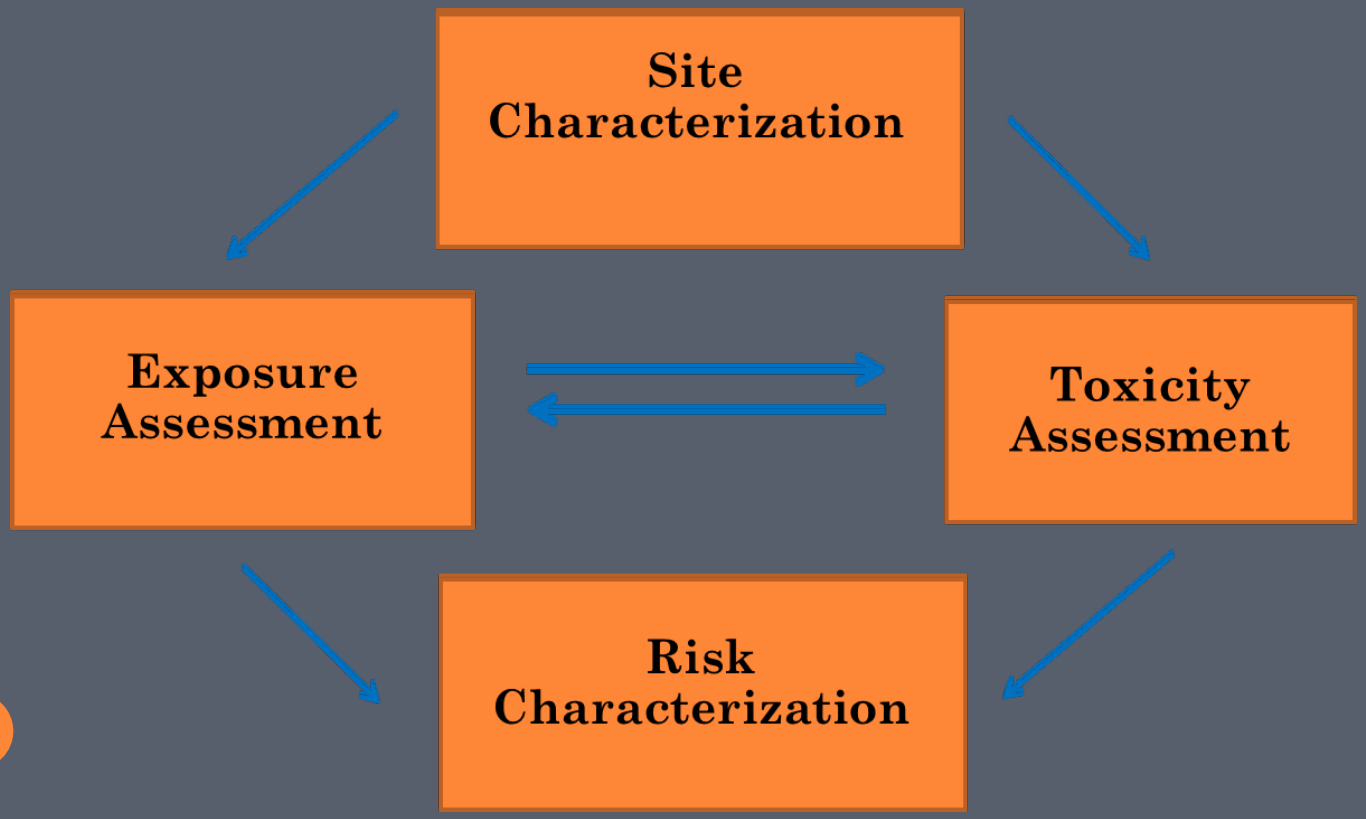
Why are risk assessments completed?

- Characterize current and potential threats to human health
- Identify which media need to be treated
- Develop cleanup criteria
- Provide risk managers (decision makers) with understanding of actual and potential health risk associated with the releases
- Select remedial actions (which may include no action)

Why are risk assessments completed?

- How much will my cleanup cost?
- Should I purchase this property?
- Who may be harmed by contamination?
- Does this project seem reasonable?
- What environmental decisions can I make about this property?

Risk Assessment Basic Paradigm



Site Characterization Goals

- Sometimes referred to Data Collection and Evaluation/analysis

- Gather available information
- Collect data based on some sort of sampling and analysis plan
- Determine nature and extent of contamination
- Different programs have variations on the nature and extent of contamination and "site" or property
- Superfund/Remedial Response sites, full nature and extent
- VAP focuses more on releases/history and identified areas

- List of Chemicals and actual or potential receptors

Planning/Scoping the Assessment

- Work plan (RI work plan for CERCLA sites)
- Other planning document

Conceptual Site Model (CSM)

Visual representation of the risk assessment

Iterative

Critical tool for planning and implementing the assessment

Plan where data are needed, what data will be collected, what detection limits are needed and how those data will be used…

Which media, where, what receptors, how exposed?

How does the CSM structure the Risk Assessments?

What exposure scenarios (*e.g.*, residential, recreational, commercial)

Current and future risks (reuse plan, professional judgment)

Where contamination is or may be

Who is exposed (which receptors)

Which exposure media (*e.g.*, soil, ground water, sediment) (where located)

How exposed (exposure route) (*e.g.*, inhalation, ingestion, direct contact)

Example CSM

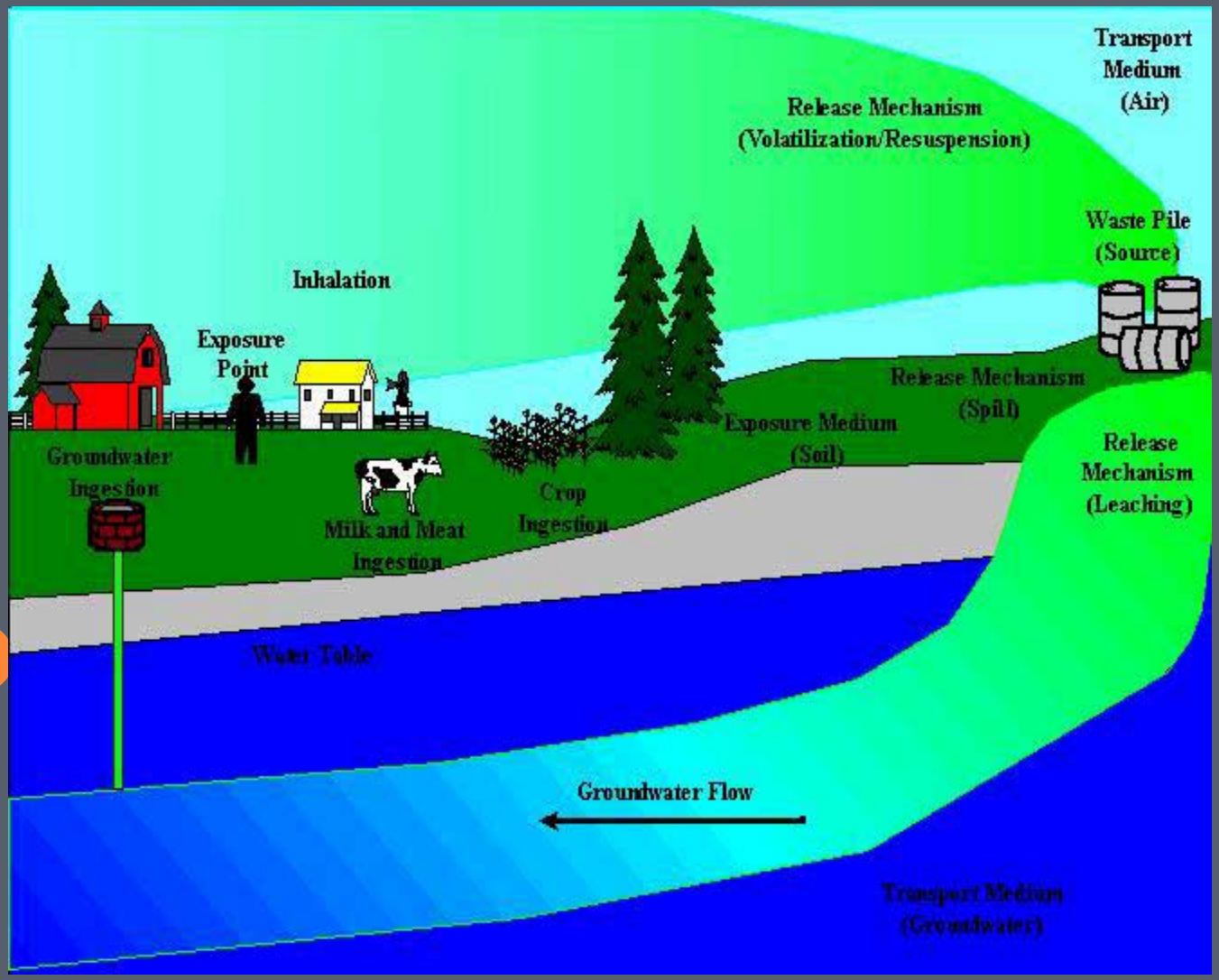
This figure can be modified for use on specific sites.

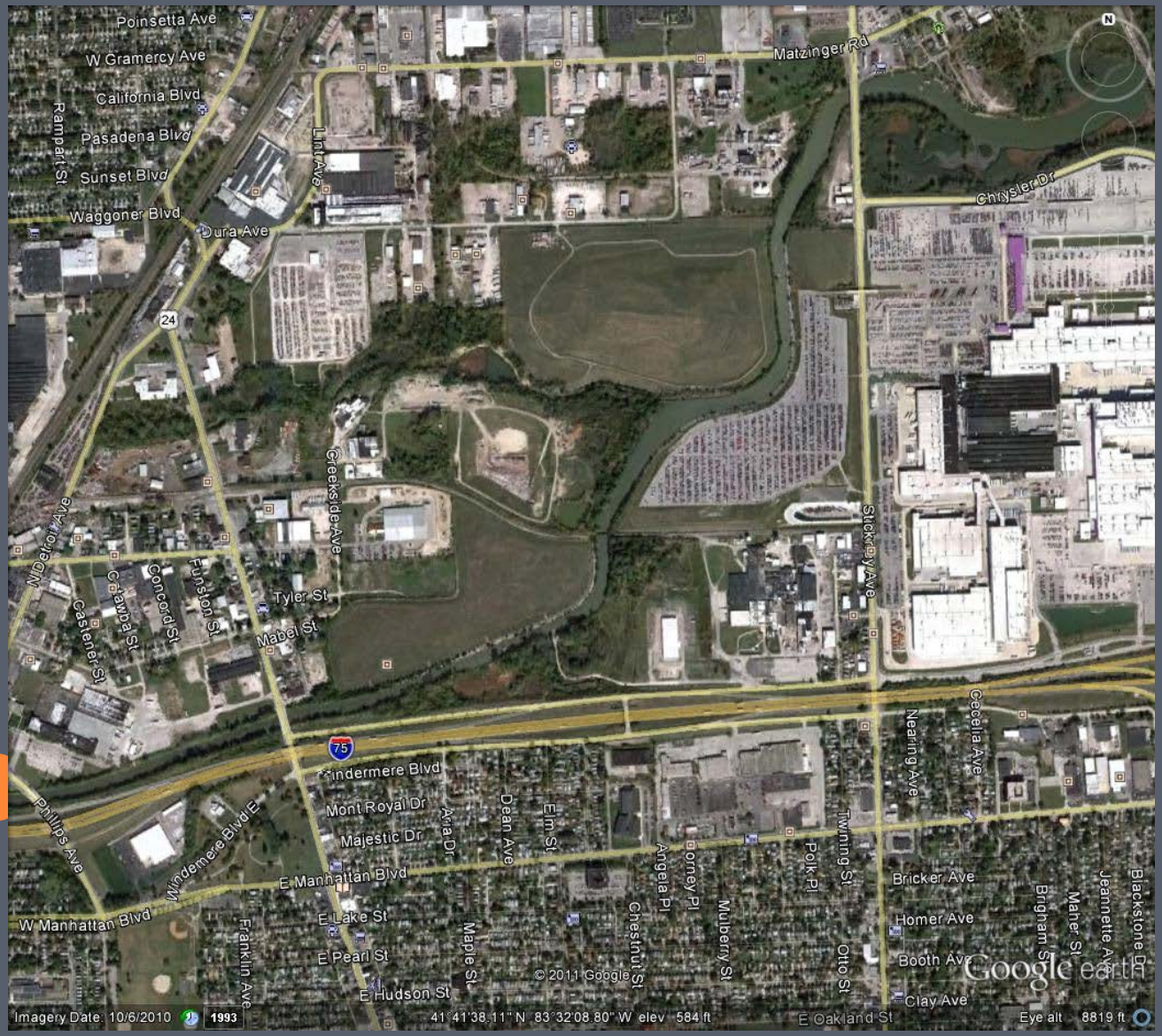
PRIMARY SOURCES	PRIMARY RELEASE MECHANISMS	SECONDARY SOURCES	TRANSPORT MECHANISMS	TERTIARY SOURCES	EXPOSURE ROUTES	POTENTIAL RECEPTORS: Residential (1) Current	Residential (1) Future	Occupational Current	Occupational Future	Construction & Excavation (2) Current	Construction & Excavation (2) Future
UST	Leaking	Surface Soils (< 3 feet)	Particles/Volatiles	Air (Outdoor)	Inhalation	+	+	+	+	+	+
					Ingestion	+	+	+	+	+	+
					Dermal Contact	+	+	+	+	+	+
		Subsurface Soils (> 3 feet)	Particles/Volatiles	Air (Outdoor)	Inhalation	-	-	-	-	+	+
					Ingestion	-	-	-	-	+	+
					Dermal Contact	-	-	-	-	+	+
			Volatilization	Air (Outdoor)	Inhalation	-	+	+	+	-	-
				Air (Indoor)	Inhalation	-	+	+	+	-	-
			Leaching	Groundwater	Ingestion	-	+	+	+	-	-
					Vol. Inhalation	-	+	+	+	-	-
		Groundwater	Vol. at the Tap	Air (Indoor)	Inhalation	-	+	+	+	-	-
					Ingestion	-	+	+	+	-	-
			Volatilization	Air (Outdoor)	Inhalation	-	+	+	+	-	-
				Air (Indoor)	Inhalation	-	+	+	+	-	-
					Dermal Contact	-	-	-	-	+	+
			Volatilization	Air (Excavation)	Inhalation	-	-	-	-	+	+
			Discharge	Surface Water (3)							

Notes:

- **+** This route is a primary source of exposure.
- **-** There is no exposure by this route.
- **(1)** Specify if urban residential or single-family residential. Include separate columns for these exposure scenarios if necessary.
- **(2)** Include separate columns for these two exposure scenarios if necessary.
- **(3)** Surface water contamination is not covered in the Table of RBCs and should be discussed with the Department.

PICTORIAL CSM




Poinsetta Ave
W Gramercy Ave
California Blvd
Pasadena Blvd
Sunset Blvd
Waggoner Blvd
Rampart St
Dura Ave
Lint Ave
Matzinger Rd
Chrysler Dr
24
Creekside Ave
N Detroit Ave
Catawba St
Concord St
Funston St
Castener St
Tyler St
Mabel St
Stickney Ave
75
Windermere Blvd
Mont Royal Dr
Majestic Dr
Aria Dr
Dean Ave
Elm St
Angela Pl
Torney Pl
Mulberry St
Polk Pl
Twining St
Nearing Ave
Cecelia Ave
Phillips Ave
Windermere Blvd E
E Manhattan Blvd
W Manhattan Blvd
E Lake St
E Pearl St
E Hudson St
Franklin Ave
Maple St
Chestnut St
Otto St
Bricker Ave
Homer Ave
Booth Ave
Clay Ave
Brigham St
Maher St
Jeannette Ave
Blackstone Dr
E Oakland St
© 2011 Google
Google earth
Imagery Date: 10/6/2010
1993
41°41'38.11" N 83°32'08.80" W elev 584 ft
Eye alt 8819 ft

Data Collection and Analysis

Chemical concentrations in the various media at your location

Source
Media

- **Soil (shallow and deep)**
- **Sediment**
- **Surface water**
- **Ground water**
- **Subsurface gas/Indoor air**

Screening step

- Has there been a release?
- Qualitative estimate on “how bad” is the contamination
- Focus investigation on “driver” compounds

Screening Values:

Risked based values (*e.g.*, Regional Screening Levels (RSLs, formerly PRGs)

Background (*e.g.*, Lead, As, PAHs)

Receptors… people

Present and future

Residential?
Commercial/industrial?
Recreational?

Future use analysis (*e.g.*, Superfund)

Results of Site Characterization

Understanding of the Contaminants

- **What are they and their concentrations?**
- **Where are the located?**
- **Which media are of concern?**

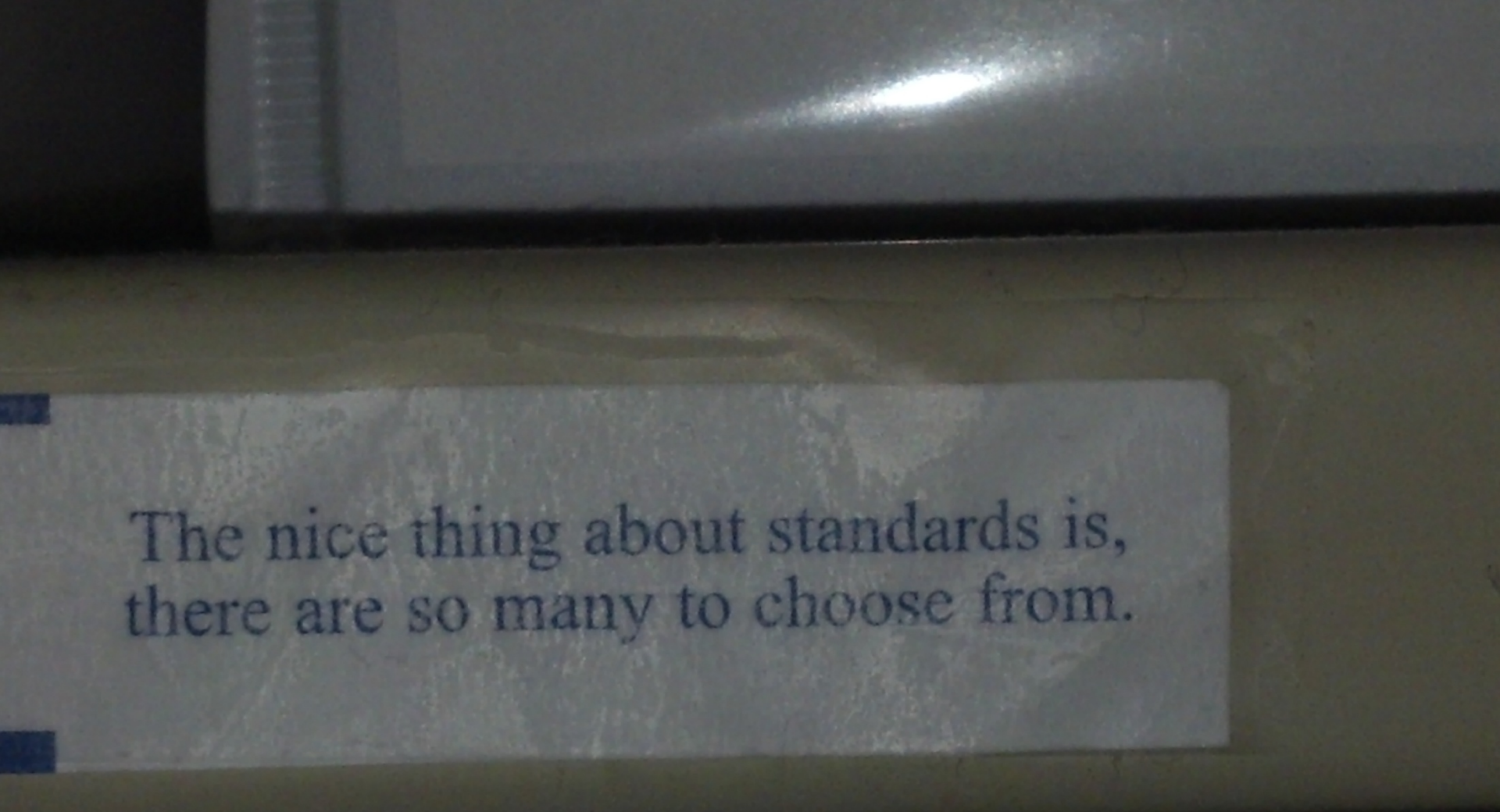
Identify Potential Receptors

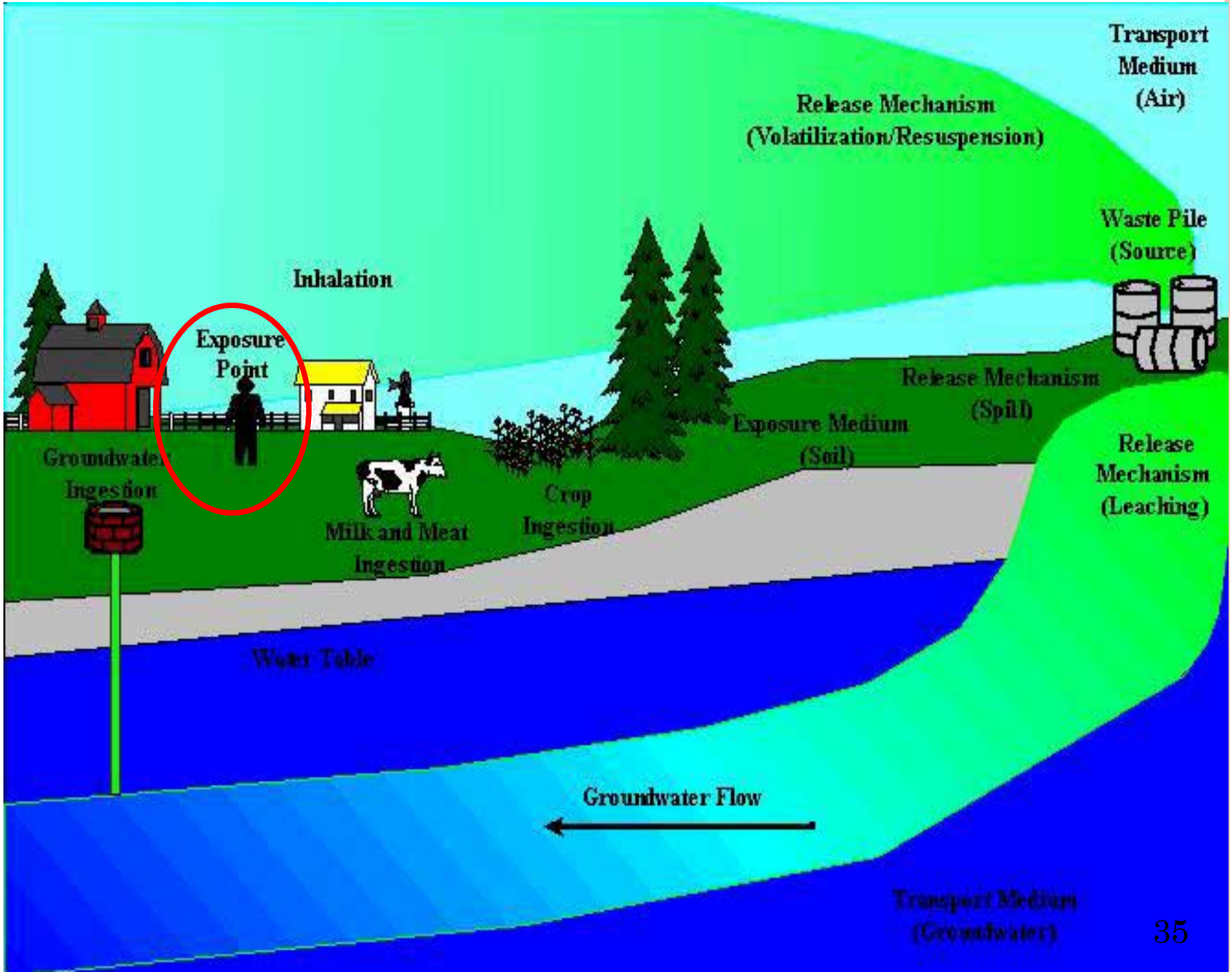
- **Residential?**
- **Commercial/Industrial?**
- **Recreational?**
- **Current, future or both?**

Next Step: Exposure Assessment!

Questions?

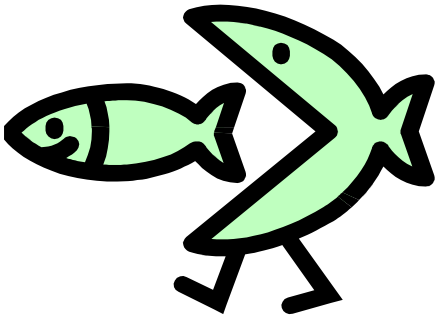
Exposure


The nice thing about standards is,
there are so many to choose from.


Transport Medium (Air)
Release Mechanism (Volatilization/Resuspension)
Waste Pile (Source)
Inhalation
Exposure Point
Release Mechanism (Spill)
Exposure Medium (Soil)
Release Mechanism (Leaching)
Groundwater Ingestion
Crop Ingestion
Milk and Meat Ingestion
Water Table
Groundwater Flow
Transport Medium (Groundwater)

Exposure Assessment

- Identifies and describes
  - Receptors to site related constituents
  - Pathways for exposure
  - Concentration and length of time of exposure
- Calculate the Average Daily Intake (Dose)
  - Each receptor
  - Each pathway
  - Each site-related constituent of concern



Expressed Mathematically

$$\text{Average Daily Dose (Intake)} = (\text{Chemical Concentration}) \frac{\left(\text{Ingestion Rate}\right)\left(\text{Exposure Duration}\right)\left(\text{Exposure Frequency}\right)}{\left(\text{Body Weight}\right)\left(\text{Averaging Time}\right)}$$

- Exposure factors
  - Terms used to calculate an average daily intake or "dose" per chemical per media per receptor for a specific exposure time
- Exposure factors vary per receptor

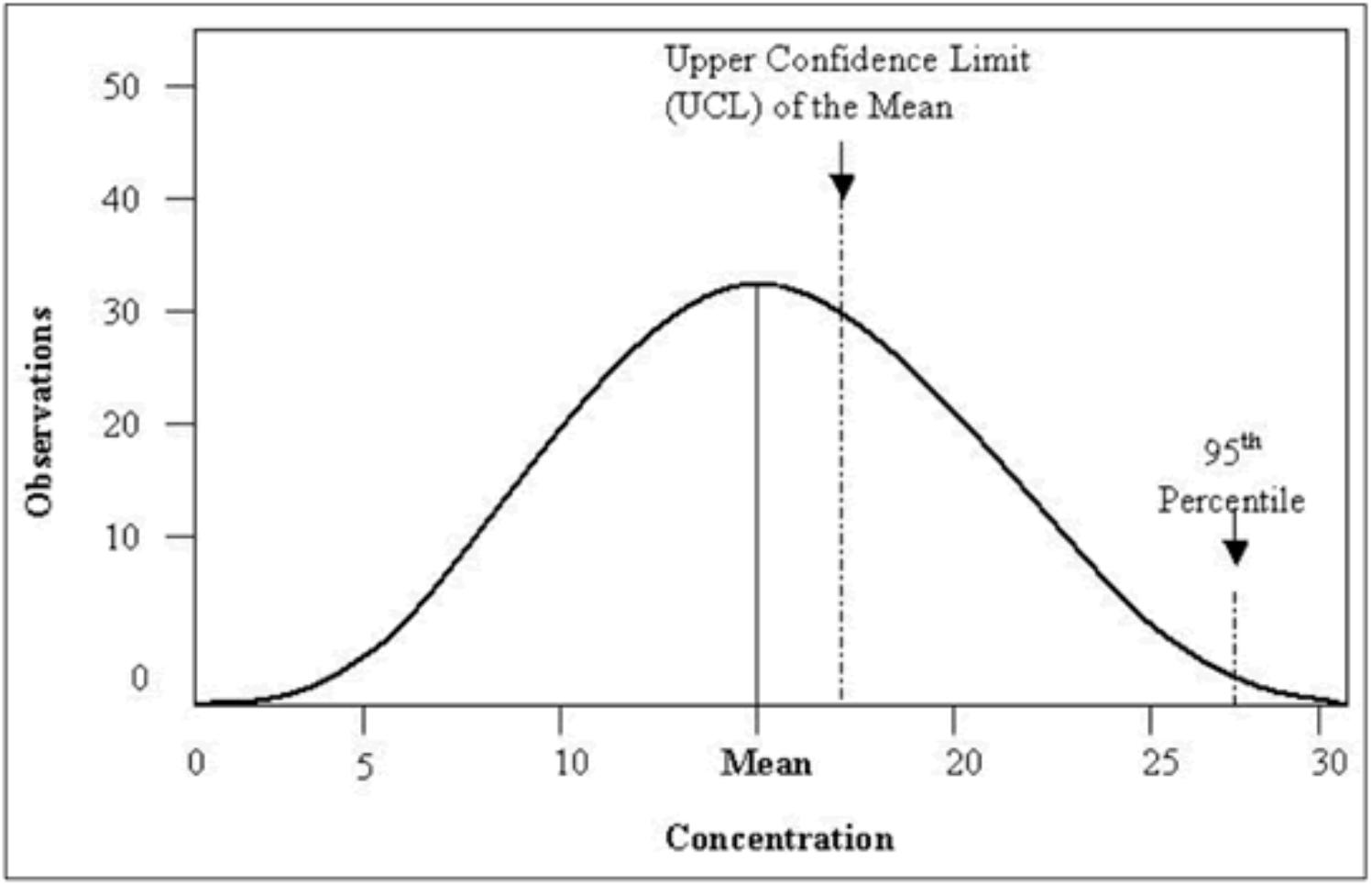
Exposure Factors

US EPA Exposure Factors Handbook, 2011
EPA/600/R-090/052F | September 2011 | www.epa.gov
http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf

- Exposure Duration (years)
- Exposure Frequency (days/year)
- Body Weight (kg)
- Soil Ingestion Rate (mg/day)
- Fraction Contaminated Soil
- Surface Area of exposed skin (cm^2)
- Soil Skin Adherence Factor (mg/cm^2)
- Exposure Time (hours/day)

A Bit of Statistics

- RME = Reasonable Maximum Exposure
- CTE = Central Tendency Exposure



Additions to the basic intake Equation…

- For example – physical properties of the site or media:
  - How much of the site is vegetated?
  - What is the density of the soil?
  - How much organic matter is in the soil?
  - How much can volatilize into air?
- All of these factors can affect the amount of contaminant that can be taken into the body (the daily dose)

RECEPTORS

Typical…

- Residential

  - children and adults
  - 350 days per year for 30 years
  - 24 hours a day, 7 days a week

- Commercial/Industrial

  - Adult workers (child visitors)
  - 250 days per year (typical work week) for 25 years
  - 8 hours a day, 5 days a week

RECEPTORS

Common…

- Construction/ Excavation

- Recreational

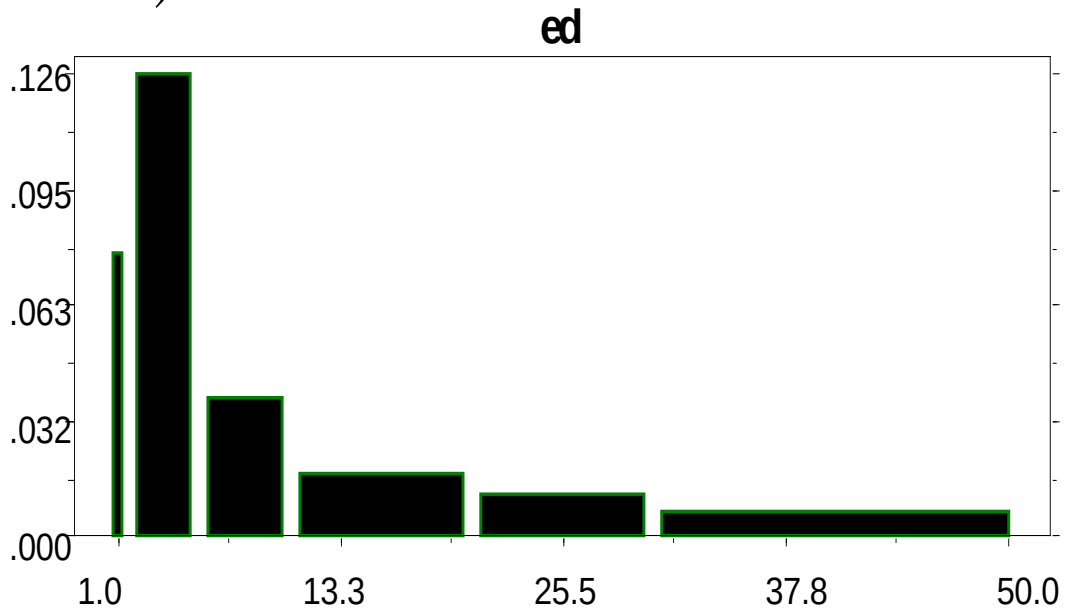
RECEPTORS

UNUSUAL…

Exposure Pathways

Is there only one way?

- Point Values
  - Assumes all residential receptors live in one home for 30 years..
- Distribution
  - Algorithm is run on an "iterative" basis…(VAP standards)



Equation Modifications

$$TC_{INH} = \frac{HQ \times AT}{\left(\frac{1}{RfC}\right) \times FI_{inh} \times ED \times EF \times \left[\left(\frac{1}{VF}\right) + \left(\frac{1}{PEF}\right)\right]}$$

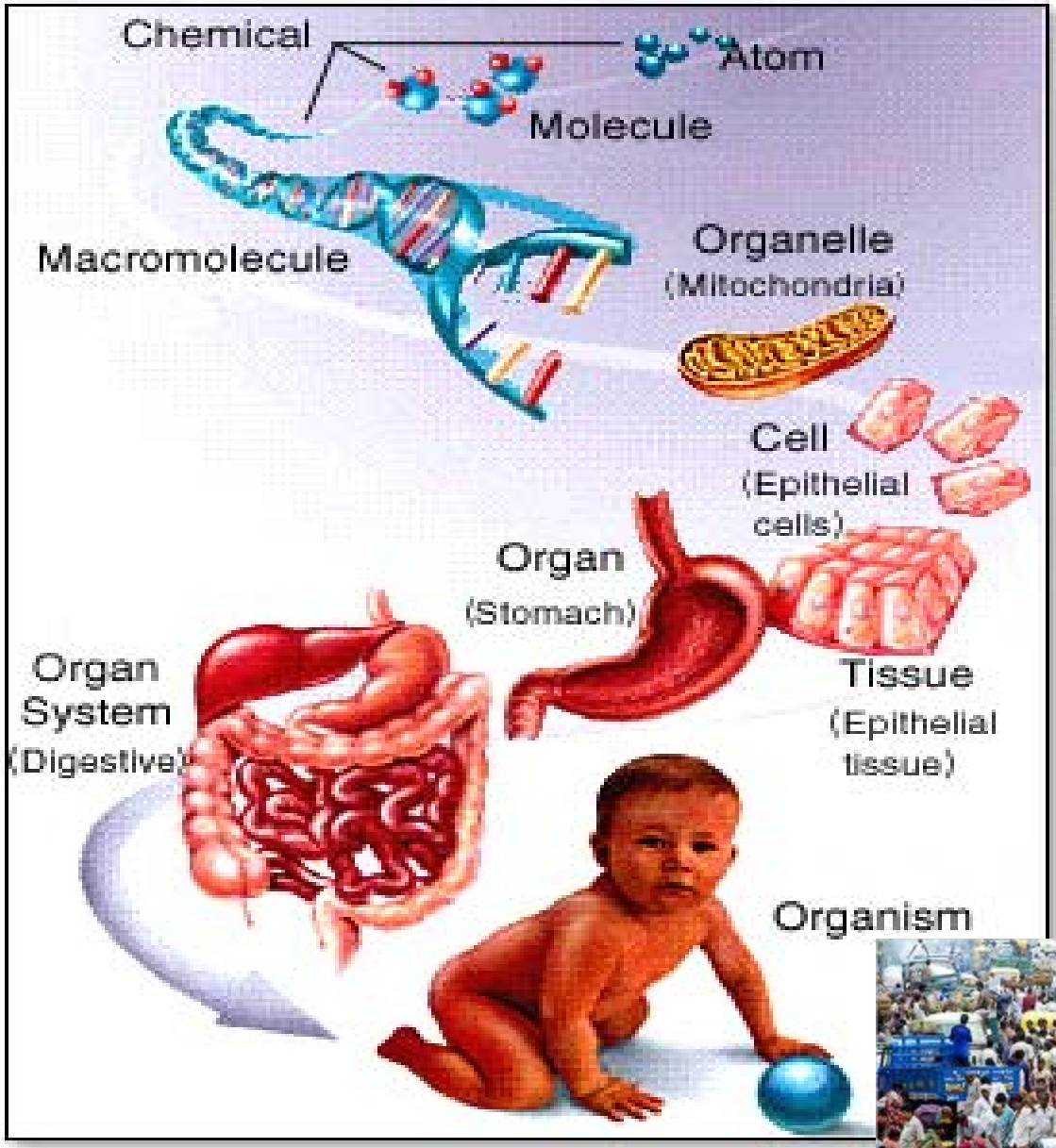
- TC_{INH} = Target Concentration for Inhalation Pathway (mg/kg)
- HQ = Target hazard quotient (HQ=1)
- AT = Averaging time (days) (specific to each exposure scenario for non-cancer endpoints)
- RfC = Inhalation reference concentration (Chemical specific)
- FI_{inh} = Fractional inhaled from contaminated source (unitless)
- EF = Exposure frequency (days/year) (specific to exposure scenario)
- ED = Exposure duration (years) (specific to exposure scenario)
- VF = Volatilization Factor (m^3/kg)
- PEF = Particulate Emission Factor (m^3/kg)

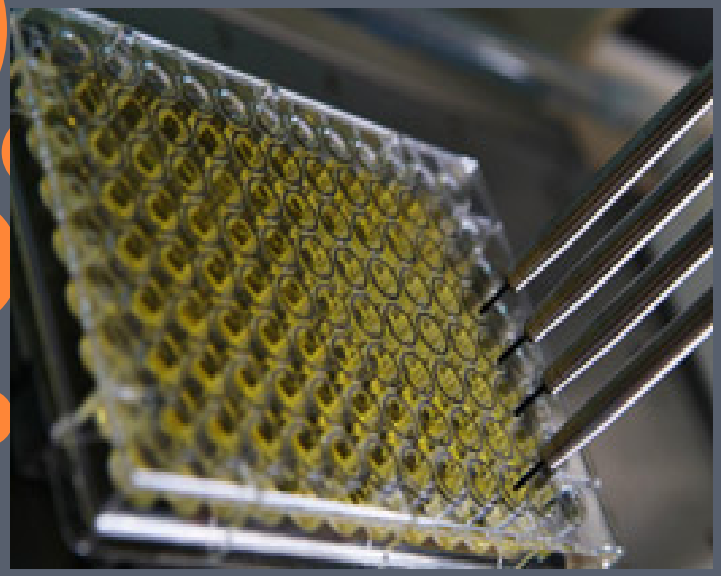
Even More Detail

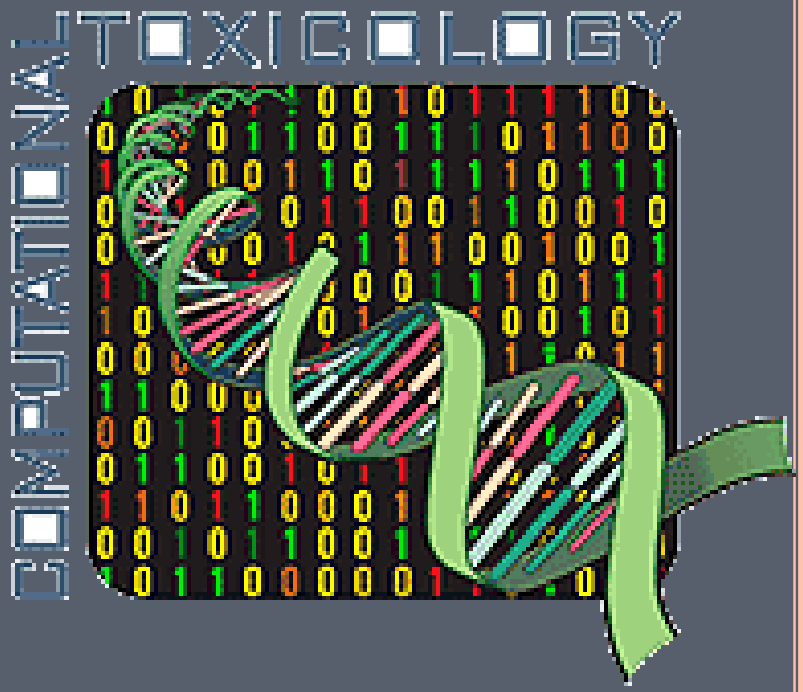
$$PEF = \frac{Q}{C} x \frac{3600}{0.036x(1-V)x(U_m \div U_t)^3 x F_x}$$

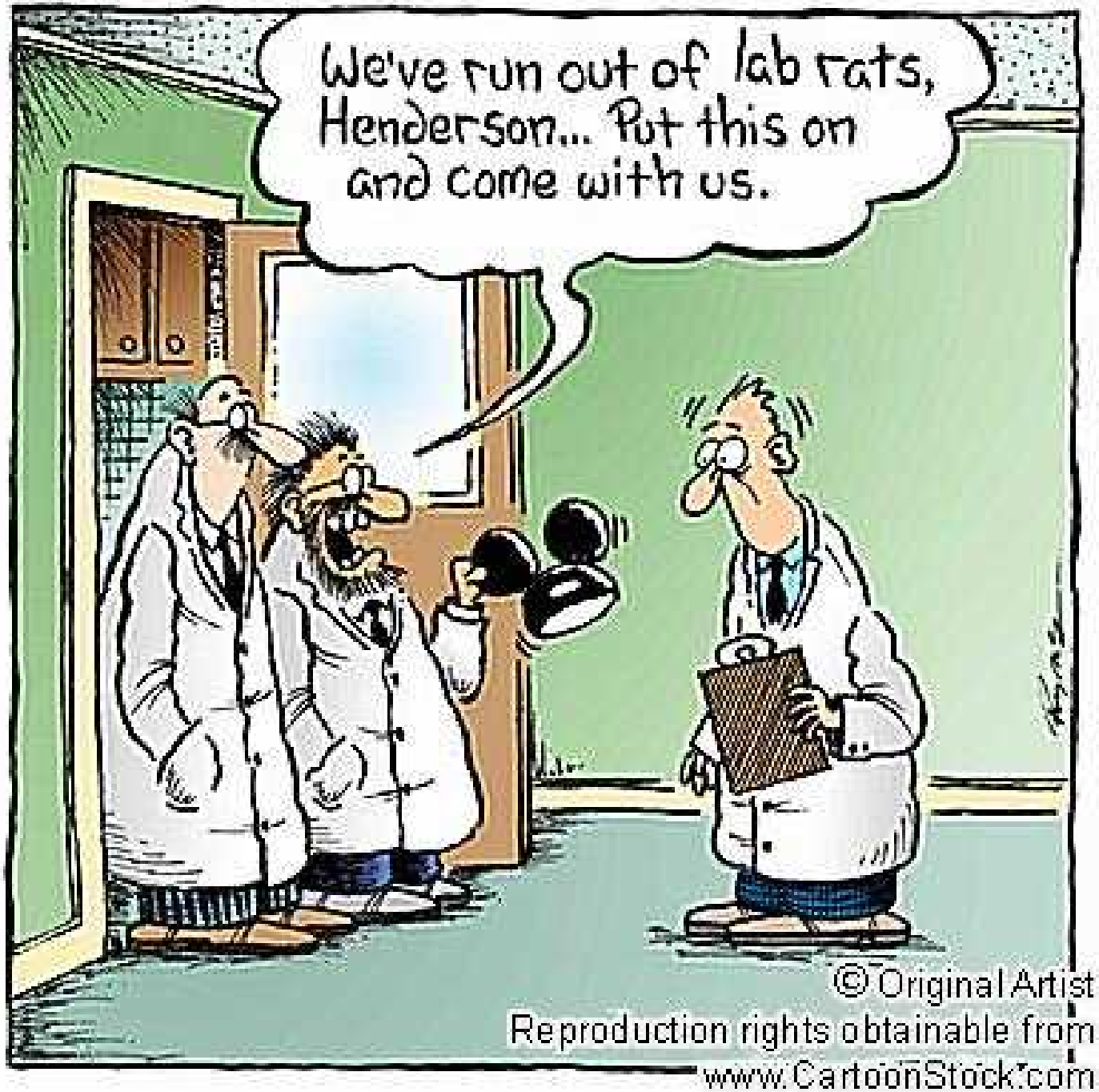
- Where:
  - PEF = Particulate Emission Factor (m^3/kg)
  - Q/C = Inverse of the mean concentration at center of square source (g/m^2-s per kg/m^3) (83.22, assuming a 0.5 acre area and Cleveland, Ohio)
  - V = Fraction of vegetative cover (unitless) (0.5)
  - U_m = Mean annual windspeed (m/s) (4.83, average Cleveland, Ohio)
  - U_t = Equivalent threshold value of windspeed at 7m (m/s) (11.32) [8]
  - F_x = Function dependent on U_m/U_t (unitless) (0.232)

Toxicity


Chemical
Atom
Molecule
Macromolecule
Organelle
(Mitochondria)
Cell
(Epithelial
cells)
Organ
(Stomach)
Tissue
(Epithelial
tissue)
Organ
System
(Digestive)
Organism




COMPUTATIONAL
TOXICOLOGY


We've run out of lab rats, Henderson... Put this on and come with us.
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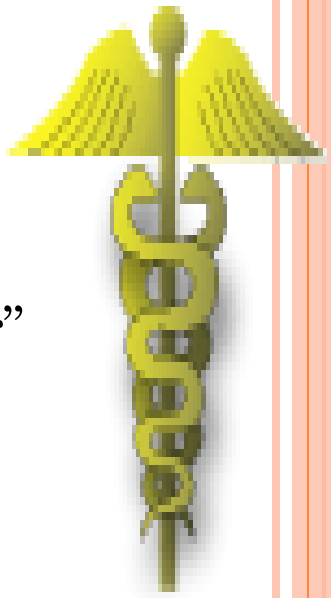
Toxicity Assessment

- Provides a summary of toxicity and potential effects from exposures
  - Toxicity Values are selected for risk calculations
- Two classifications for toxic effects
  - Carcinogenic
    - Exposure has potential to result in cancer
    - Toxicity values described by a “cancer slope factor”
  - Noncarcinogenic
    - Anything else
    - Exposure above a threshold level could result in adverse effect
    - Toxicity values described by a “reference dose”



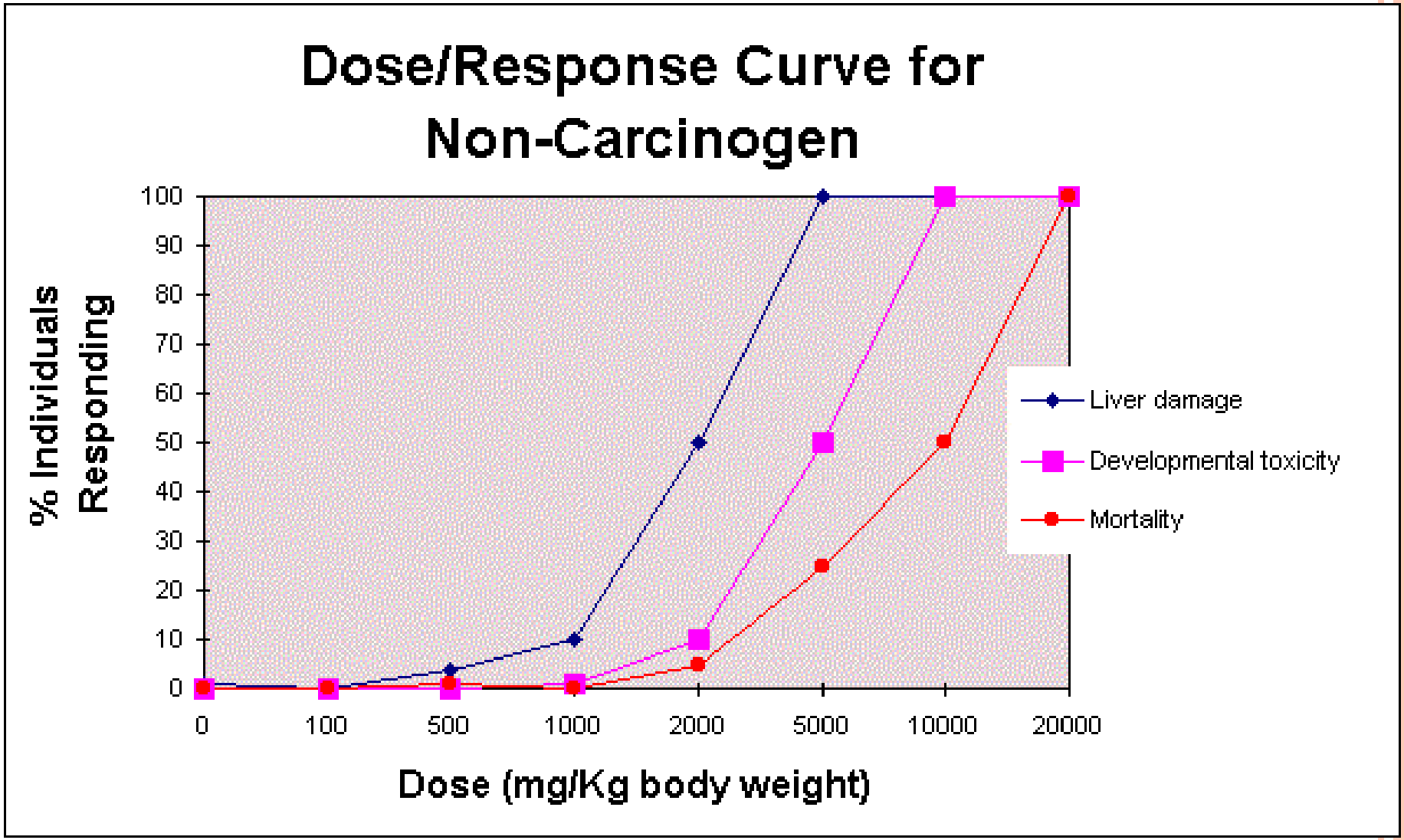
Major Factors Influencing Variation in Values

- Cancer Slope Factor (SF) and Reference Dose (RfD)
  - SF = expressed as risk per mg/kg per day
  - RfD = mg/kday
  - Different sources list different SFs and RfDs for same chemical
  - Typically different SF and RfD for each pathway (oral, inhalation, dermal)

Where do we get the numbers from?

- Ohio EPA follows US EPA recommendations:
  - Sources of Toxicity (hierarchy)
    - Tier 1" - IRIS – Integrated Risk Information System http://www.epa.gov/iris/
    - "Tier 2" – Provisional Peer Reviewed Toxicity Values (PPRTVs), Agency for Toxic Substances and Disease Registry (ASTDR), Cal EPA

Quantifying Non-Carcinogenic Risk – Less Is More

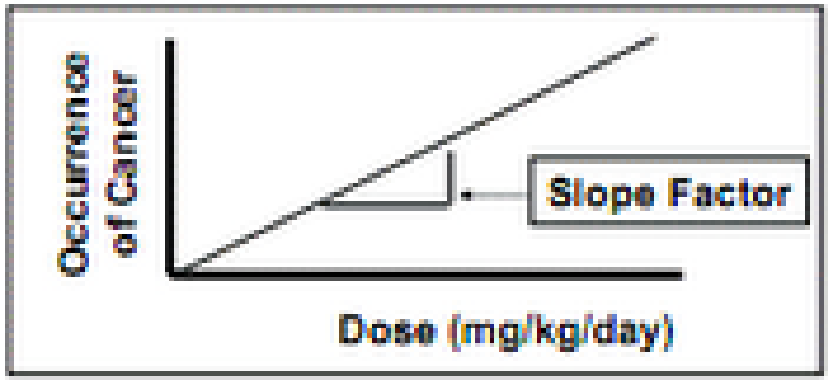


Quantifying Carcinogenic Risk

- Carcinogenic risk is an estimated probability of the receptors on the site developing cancer over a lifetime as a result of the exposure to the carcinogenic chemicals at the site
- It is assumed that carcinogens have an adverse health effect at any dose
- Slope factors are developed for chemicals that show sign of carcinogenicity in lab studies
- Slope factor compared to the exposure level at the site to determine the cancer risk

Quantifying Carcinogenic Risk

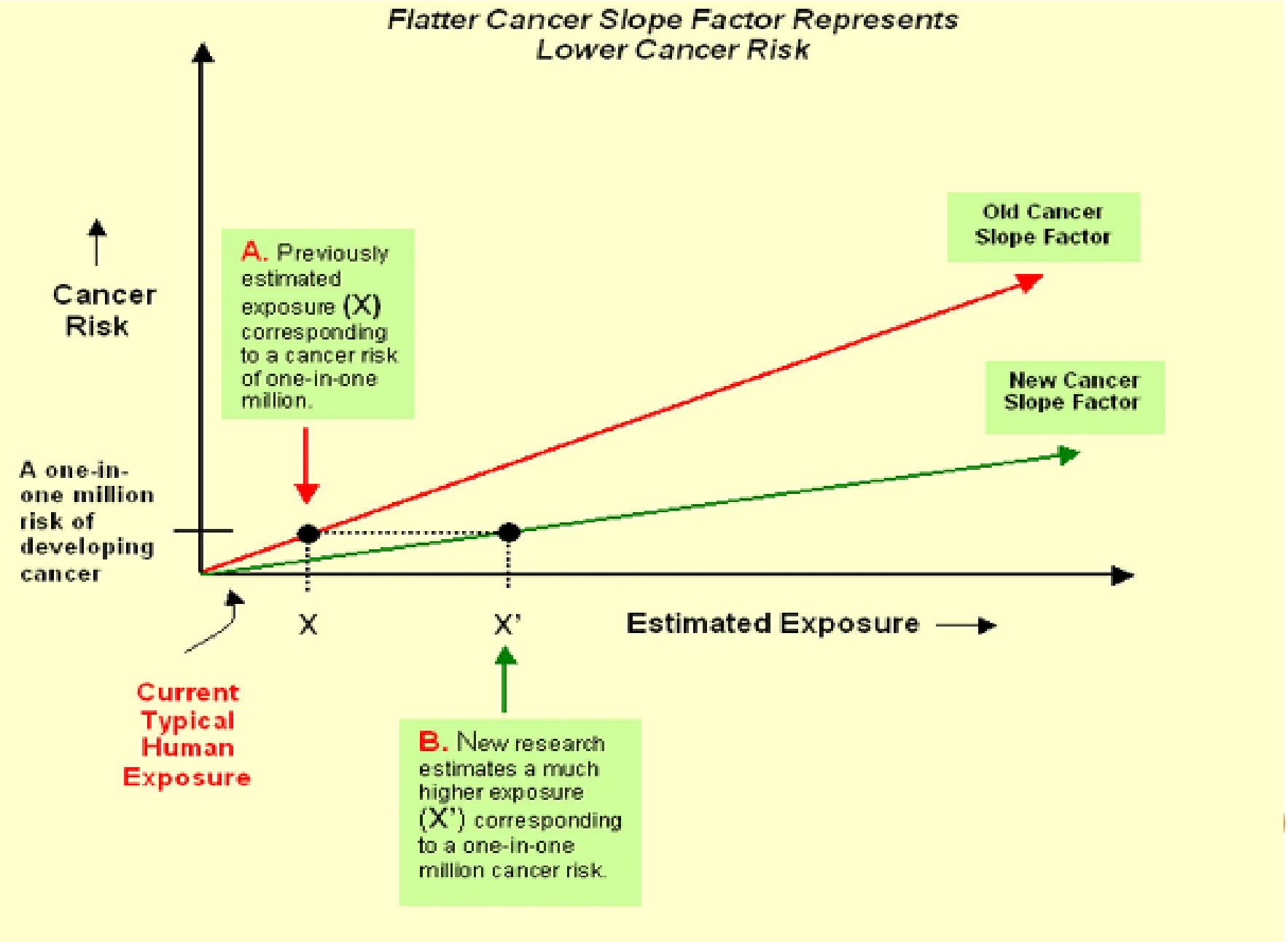
Carcinogenic Dose-Response Curve



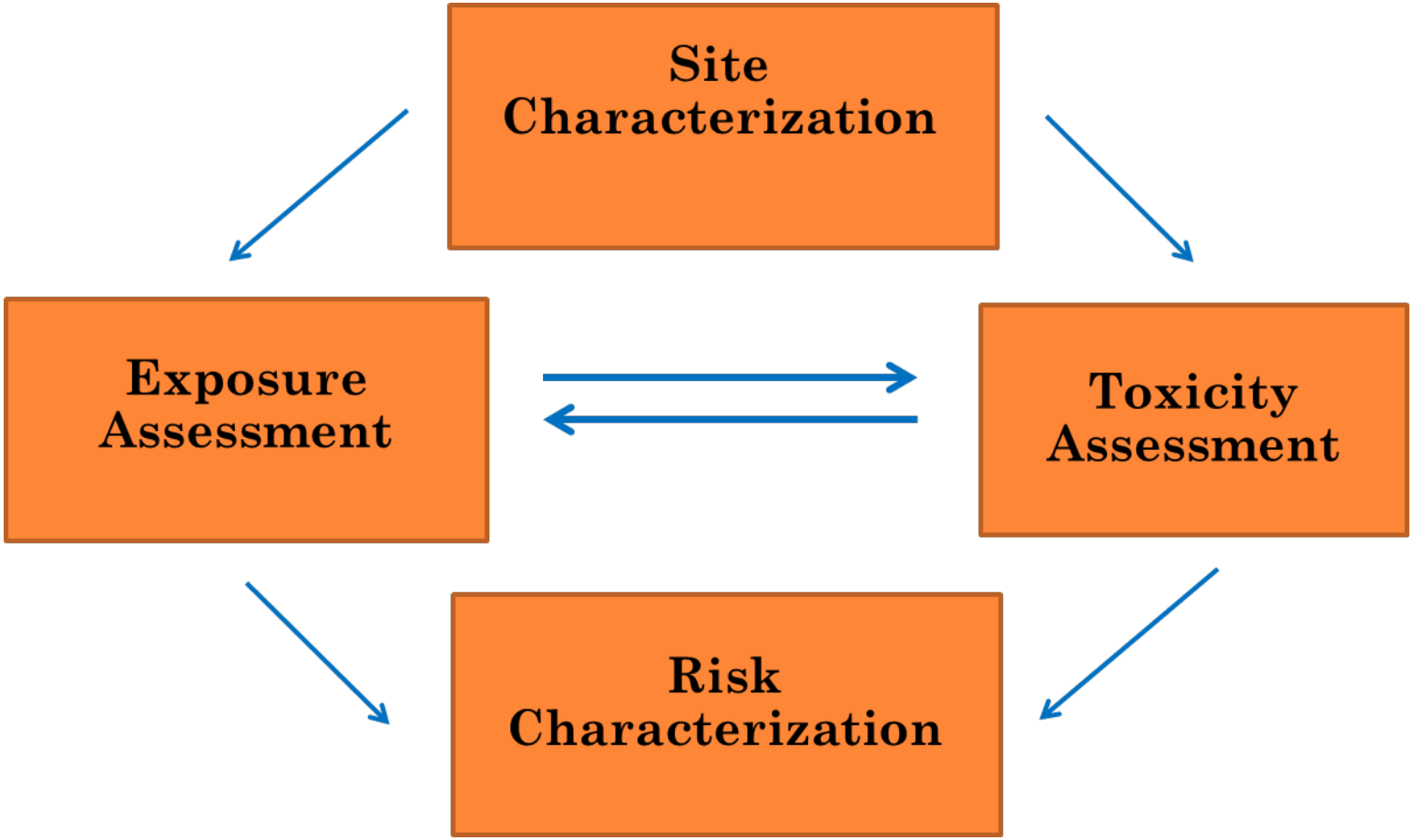
Slope Factor = Risk / Dose

SLOPE FACTOR: Derivation is based on the assumption that every dose poses a risk; there is no safe dose.

More is More…..


Flatter Cancer Slope Factor Represents
Lower Cancer Risk
Cancer Risk
A. Previously estimated exposure (X) corresponding to a cancer risk of one-in-one million.
Old Cancer Slope Factor
New Cancer Slope Factor
A one-in-one million risk of developing cancer
X
X'
Estimated Exposure
Current Typical Human Exposure
B. New research estimates a much higher exposure (X') corresponding to a one-in-one million cancer risk.

SUMMARY


Site Characterization
Exposure Assessment
Toxicity Assessment
Risk Characterization

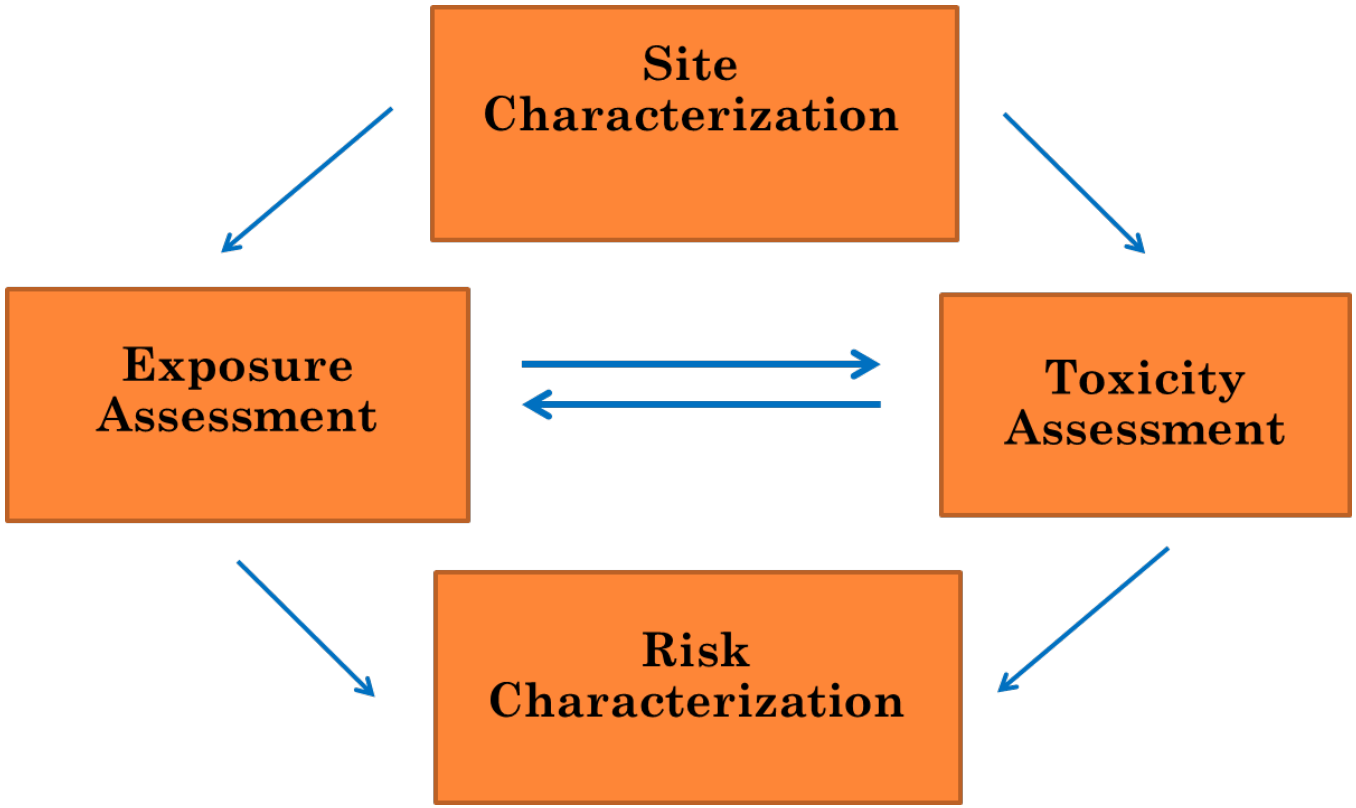
Questions?

Thank You

Risk Characterization

The Final Step in a Risk Assessment

What is Risk Characterization?



In Risk Characterization, the information from Site Characterization, Exposure Assessment, and Toxicity Assessment are summarized and integrated into quantitative and qualitative expressions of risk.

Risk Characterization

Components of the risk characterization process:

- Review outputs from toxicity and exposure assessments
- Quantify risks from individual chemicals
- Determine individual pathway risk by quantifying risks from multiple chemicals
- Combine risks across exposure pathways
- Summarize and present results qualitatively and quantitatively

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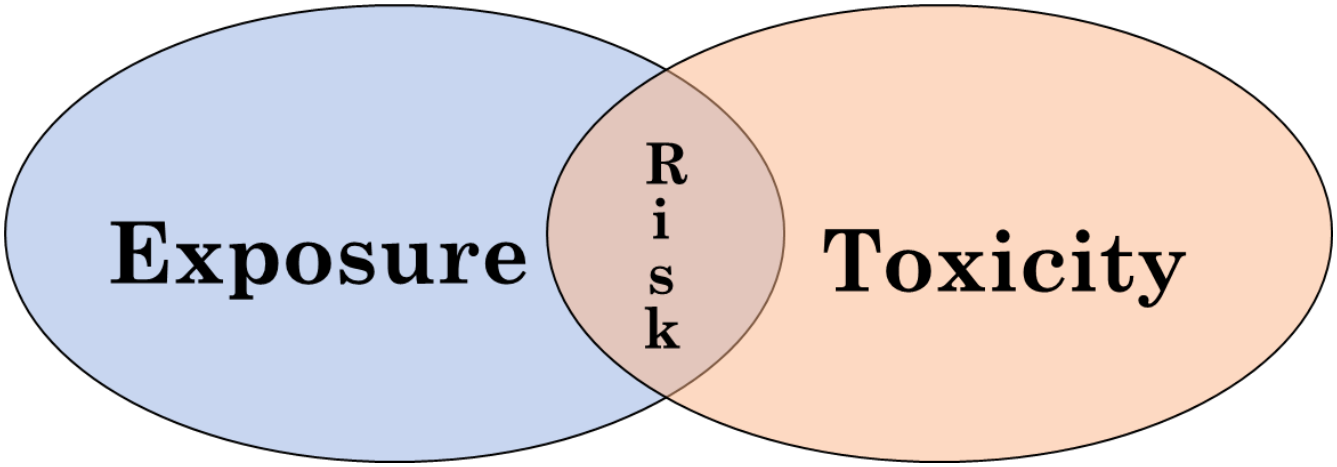
Review Toxicity and Exposure Assessment Outputs

- The first component in risk characterization is to gather, review, compare, and organize the outputs of the exposure and toxicity assessments
  - Exposure duration, frequency, and magnitude
  - Pathways and receptors
  - Toxicity values



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Quantify Risks from Individual Chemicals

- Risk calculated for each chemical utilizing exposure and toxicity data
- Risk expressed in numerical form
- Non-carcinogenic hazard and carcinogenic risk

Quantifying Non-Carcinogenic Hazard

- Non-carcinogenic effects are evaluated by comparing an exposure level (dose) with the toxicity value
- Expressed as a hazard quotient
- The hazard quotient assumes that there is a level of exposure below which it is unlikely to experience an adverse non-carcinogenic health effect

Quantifying Non-Carcinogenic Hazard

- The hazard quotient (HQ) is the ratio of the exposure level at a site to the reference dose

$$\textbf{HQ} = \frac{\textbf{site exposure (i.e., ADD)}}{\textbf{reference dose}}$$

- Hazard quotient values are variable, with values less than and equal to 1 generally considered indicative of acceptable hazard

1 ÷ 2.1 = × 0.5 +

Quantifying Carcinogenic Risk

- The potential for carcinogenic risk is expressed by estimating the probability of cancer incidence in a population of individuals for a specific lifetime (excess lifetime cancer risk, ELCR)
- Utilizing receptor exposure levels and chemical toxicity data

Cancer risk = exposure (ADD) x tox data (SF)

- Cancer risk expressed as a unitless probability of an individual in a population developing cancer over a lifetime

Quantifying Carcinogenic Risk

Number and how it reads in various scientific notations			
0.1	1x10-1	1.0E-1	One in ten
0.01	1x10-2	1.0E-2	One in a hundred
0.001	1x10-3	1.0E-3	One in a thousand
0.0001	1x10-4	1.0E-4	One in ten thousand
0.00001	1x10-5	1.0E-5	One in a hundred thousand
0.000001	1x10-6	1.0E-6	One in a million
0.000000001	1x10-9	1.0E-9	One in a billion

Risk Characterization

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- Review outputs from toxicity and exposure assessments
- Quantify risks from individual chemicals
- **Determine individual pathway risk by quantifying risks from multiple chemicals**
- Combine risks across exposure pathways
- Summarize and present results qualitatively and quantitatively

Determine individual pathway risk by quantifying risks from multiple chemicals

Determine cumulative risk of each exposure pathway by adding risk from each individual chemical in that pathway

Total Pathway Risk

Chemical A $Risk_{NC}$

Chemical A $Risk_{C}$

Chemical B $Risk_{C}$

Chemical B $Risk_{NC}$

C Risk

NC Risk

Risk Characterization

Components of the risk characterization process:

- Review outputs from toxicity and exposure assessments
- Quantify risks from individual chemicals
- Determine individual pathway risk by quantifying risks from multiple chemicals
- **Combine risks across exposure pathways**
- Summarize and present results qualitatively and quantitatively

Combine risks across exposure pathways

Non-Carcinogenic Hazard		**Carcinogenic Risk**	
Soil direct contact =	0.2	Soil direct contact =	3x10^-6
Indoor air =	0.1	Indoor air =	4x10^-6
Total non-carcinogenic hazard at site (HQ)=	0.3	Total carcinogenic risk at site (ELCR) =	7x10^-6

Compared calculated risk values to applicable risk goals

Risk Characterization

Components of the risk characterization process:

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- Quantify risks from individual chemicals
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- **Summarize and present results qualitatively and quantitatively**

Results Summarization and presentation

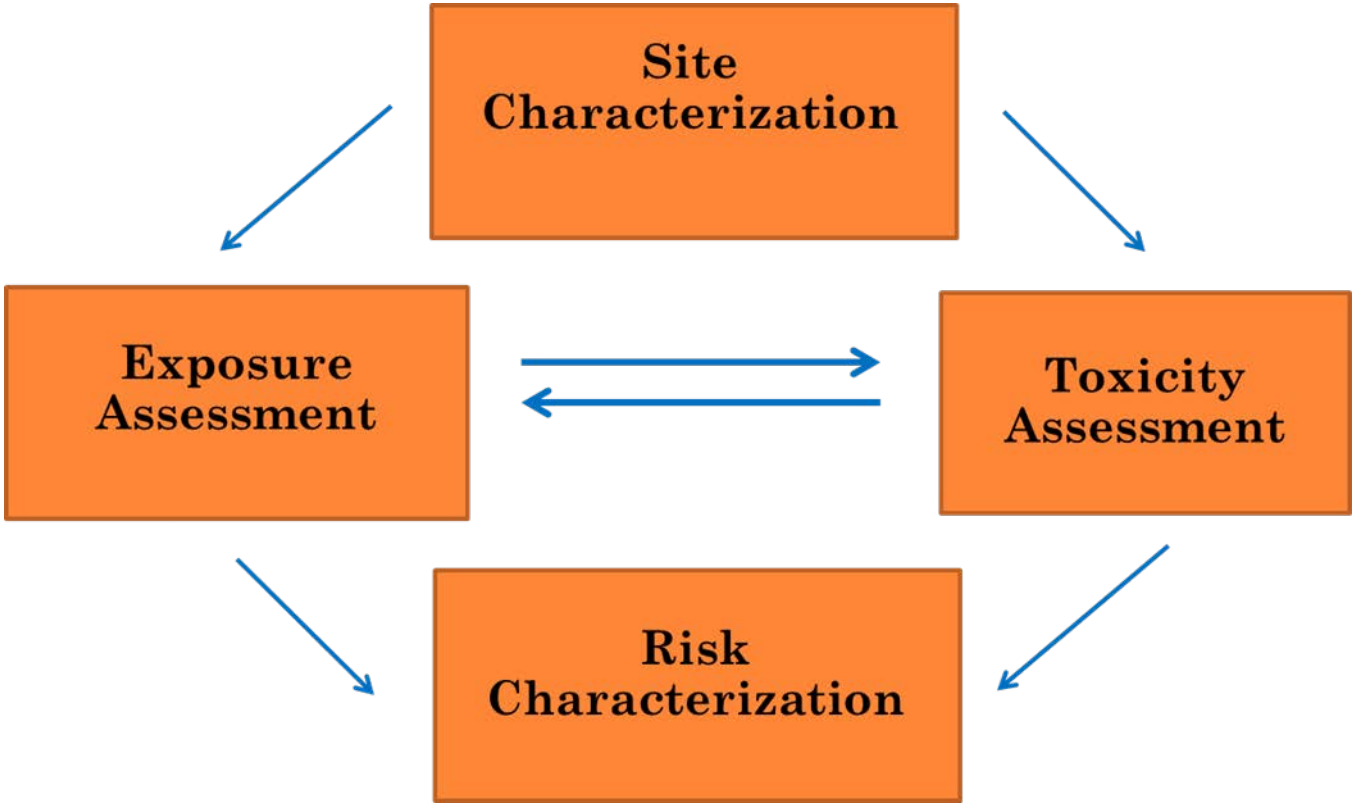
- Quantitative AND qualitative presentation- very important to provide discussion along with the HQ and ELCR values
- Places the numerical estimates of risk in the context of what is known and what is not known about the situation, and in the context of decisions to be made about selection of remedies
- A risk characterization cannot be considered complete unless the numerical expression of risk are accompanied by explanatory text interpreting and qualifying the results

Risk Characterization "Sum up"

- Review outputs from toxicity and exposure assessments
- Quantify risks from individual chemicals
- Determine individual pathway risk by quantifying risks from multiple chemicals
- Combine risks across exposure pathways
- Summarize and present results qualitatively and quantitatively

At the conclusion of the risk characterization, the results will highlight the potential sources of risk at a site so that these sources may be dealt with effectively in the remedial process

Thank you!



Questions?

And Finally

What does this mean?

So now what do we know? How can we use it?

- We know what and how much is affecting who and how, and we can compare that with what we have decided is acceptable

- Remember the risk goal for carcinogenic risk?
  - 1 E^{-5} or 0.00001 or 1 in 100,000

- And the Hazard Index of 1?
- We, well not really we, more like US EPA and history, have decided these are acceptable.

So now what do we know? How can we use it?

- We can decide that remediation is necessary or not
- We can engineer ways that will intercept these risks and hazards or contain them
- We can monitor concentrations to insure risks are not increasing or are lessening
- We can inform the nearby public of hazards or concerns
- We can compare one site to another

Risk Management

- Public concerns, response, interaction
- Cost/Benefit
- Available Engineering and Technology
- Possible future uses

Site Characterization Goals

- Sometimes referred to Data Collection and Evaluation/analysis

- Gather available information
- Collect data based on some sort of sampling and analysis plan
- Determine nature and extent of contamination
- Different programs have variations on the nature and extent of contamination and "site" or property
- Superfund/Remedial Response sites, full nature and extent
- VAP focuses more on releases/history and identified areas

- List of Chemicals and actual or potential receptors

The CSM structure

- What exposure scenarios (*e.g.*, residential, recreational, commercial)
- Current and future risks (reuse plan, professional judgment)
- Where contamination is or may be
- Who is exposed (which receptors)
- Which exposure media (*e.g.*, soil, ground water, sediment) (where located)
- How exposed (exposure route) (*e.g.*, inhalation, ingestion, direct contact)

Exposure Assessment

- Identifies and describes
  - Receptors to site related constituents
  - Pathways for exposure
  - Concentration and length of time of exposure

- Calculate the Average Daily Intake (Dose)
  - Each receptor
  - Each pathway
  - Each site-related constituent of concern

Toxicity Assessment

- Provides a summary of toxicity and potential effects from exposures
  - Toxicity Values are selected for risk calculations
- Two classifications for toxic effects
  - Carcinogenic
    - Exposure has potential to result in cancer
    - Toxicity values described by a “cancer slope factor”
  - Noncarcinogenic
    - Anything else
    - Exposure above a threshold level could result in adverse effect
    - Toxicity values described by a “reference dose”

Risk Characterization "Sum up"

- Review outputs from toxicity and exposure assessments
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At the conclusion of the risk characterization, the results will highlight the potential sources of risk at a site so that these sources may be dealt with effectively in the remedial process

Risk Management

- Public concerns, response, interaction
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- Available Engineering and Technology
- Possible future uses

Continued Reading

- http://www.epa.gov/risk/
- http://www.epa.ohio.gov/portals/30/vap/docs/fvapsupportDoc.pdf

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