'TOXICOLOGY 101: BEHIND THE SCENES OF THE CALARP PROGRAM'

March 22, 2022

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A-3-22_ToxicologyCalARP_Riveles

24th California Unified Program Annual Training Conference

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Overview

I. Introduction to the role of OEHHA and CalARP
II. Introduction to Toxicological Principles
III. Introduction to Human Health Risk Assessment
IV. California Accidental Release Program Toxicology Review

I. Introduction to the Role of OEHHA in the California Accidental Release Program (CalARP)

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Introduction to CalARP

The purpose of the California Accidental Release Program (CalARP) is to prevent accidental release of substances that can cause serious harm to the public and environment, to minimize the damage if release does occur, to satisfy community right-to-know laws

CalARP and Toxicology

- OEHHA's Role
  - Periodically review CalARP chemical information
  - Keep up-to-date toxicology information on the CalARP chemicals
  - Updating information that contributes to Toxic Endpoint (TE) information

California Accidental Release Program

- This presentation does NOT cover:
  - How a chemical is added or removed from the list
  - How or why a Toxic Endpoint specifically has changed
  - Discussion of specific Toxic Endpoints or specific CALARP chemicals or scenarios
  - Discussion of CalARP program elements or specific program issues
  - This is not guidance on how to review information for CalARP or update a Toxic Endpoint

CalARP and Toxicology

- **Toxicology Updates to CalARP chemicals may include:**
  - Update of physical and chemical properties
  - Documentation of key studies, points of departure; time or dose adjustments; use of safety/uncertainty factors
  - Collect updated available info on Emergency and Occupational Exposure Values or other Health Guidance Values
  - Review of Inhalation Toxicology studies
  - Review of other relevant toxicological information

II. Introduction to Toxicological Principles

What is Toxicology?

"What is there that is not poison? All things are poison and nothing without poison. Solely the dose determines a thing is not a poison." Paracelsus

1500 AD

(from: Philosophia Magna Brickmann, Cologne, 1567)

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Toxicology

Study of adverse effects of chemical, physical, or biological agents on living organisms and the ecosystem

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Toxicology Basics

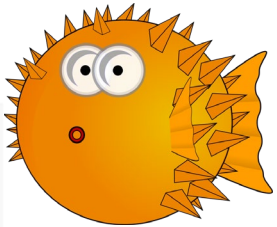
Three elements of toxicology:

1. Toxic agent
2. Biological system
3. Interaction between the toxic agent and the biological system

Toxicant vs. Toxin

Toxicant: Man-made substances producing adverse biological effects

Toxin: Small molecules produced by living organisms, includes poisons and venoms



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Exposure to Toxic Substances

1. Route of exposure: How a toxic substance gets in the body
    a. Inhalation
    b. Ingestion
    c. Dermal
    d. Injection

Exposure to Toxic Substances

2. Duration: Length of exposure
   Often dependent on study parameters

3. Frequency: How often one is exposed over time

Toxicology Terms: Dose and Effect

These factors determine the "dose" of the chemical:

- The extent of the effect is dependent upon the concentration of the active compound at the site of action over time
    - Some compounds may require bioactivation:
        - Where the parent compounds are converted to reactive metabolites by enzymes in the body

Back to the Field of Toxicology…

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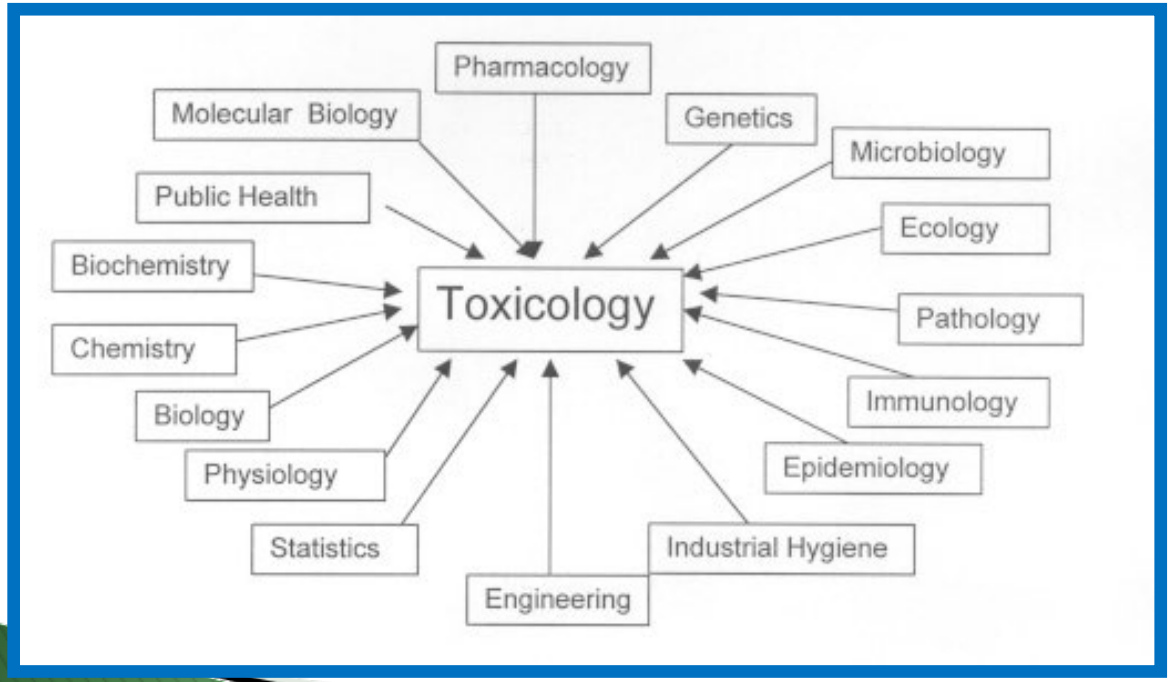
Toxicology is Multidisciplinary



[Toxicologist: Qualifications, Courses, Universities & Scope - Leverage Edu]

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Environmental Toxicology

Environmental Toxicology studies the effects of chemicals on man and the environment, it is the combination of toxicology and environmental chemistry

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Forensic Toxicologist

- The analysis of biological samples for the presence of toxins
- Works in a laboratory
- "Waiting for the Toxicology Results"

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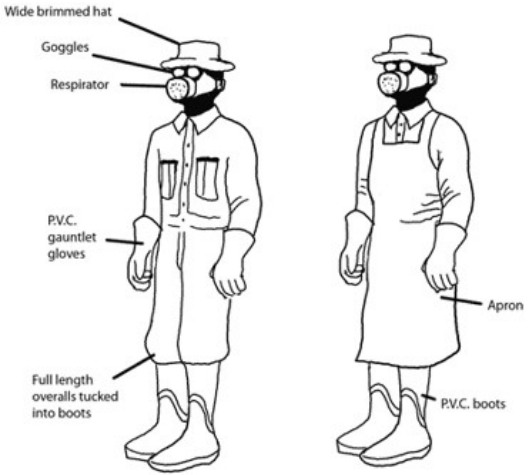
Industrial or Occupational Toxicologist

- Concerned with health effects from exposure to chemicals in the workplace



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Industrial Toxicology (alliedacademies.com)

Regulatory Toxicologist:

- Gathers and evaluates existing toxicological information to establish concentration-based standards of "safe" exposure
- Uses body of information to assess risk to human health and the environment

Looks like this

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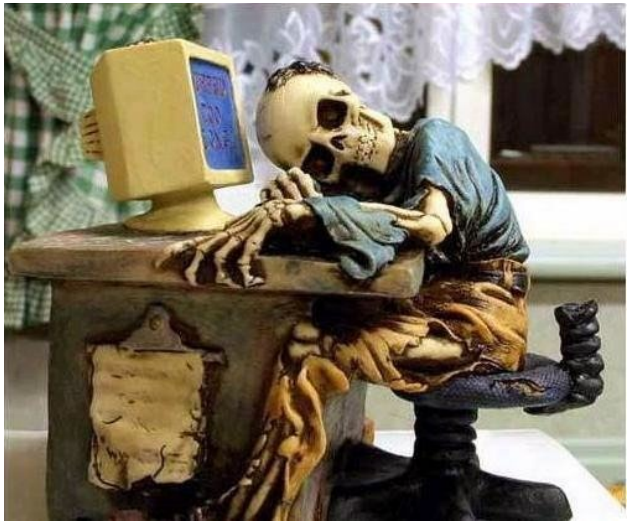
Working from home…

OR



Remember to…

III. Introduction to Human Health Risk Assessment

What is Risk?

The PROBABILITY that an adverse effect will result under specified conditions

Exposure + Hazard = RISK

What is Risk?

Exposure + Hazard = RISK

When Fonzie Jumped the Shark on 'Happy Days' | Mental Floss

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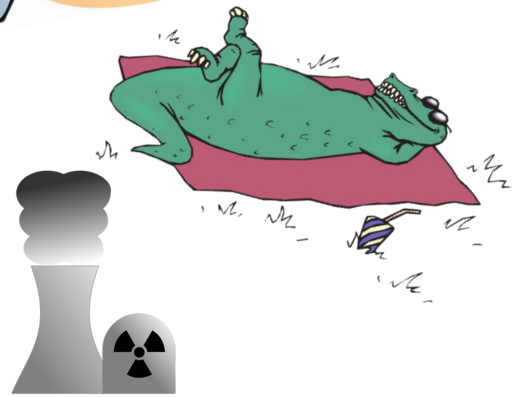
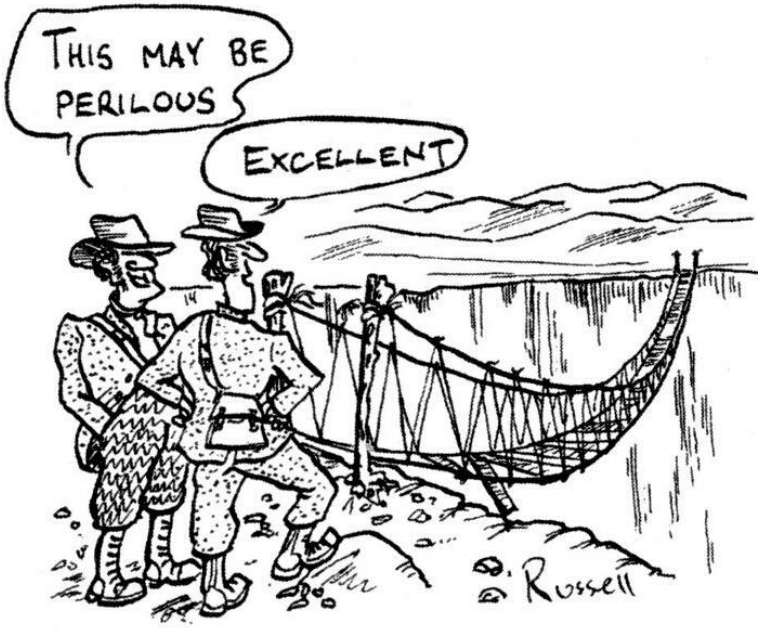
But what is an acceptable risk? = Risk Perception





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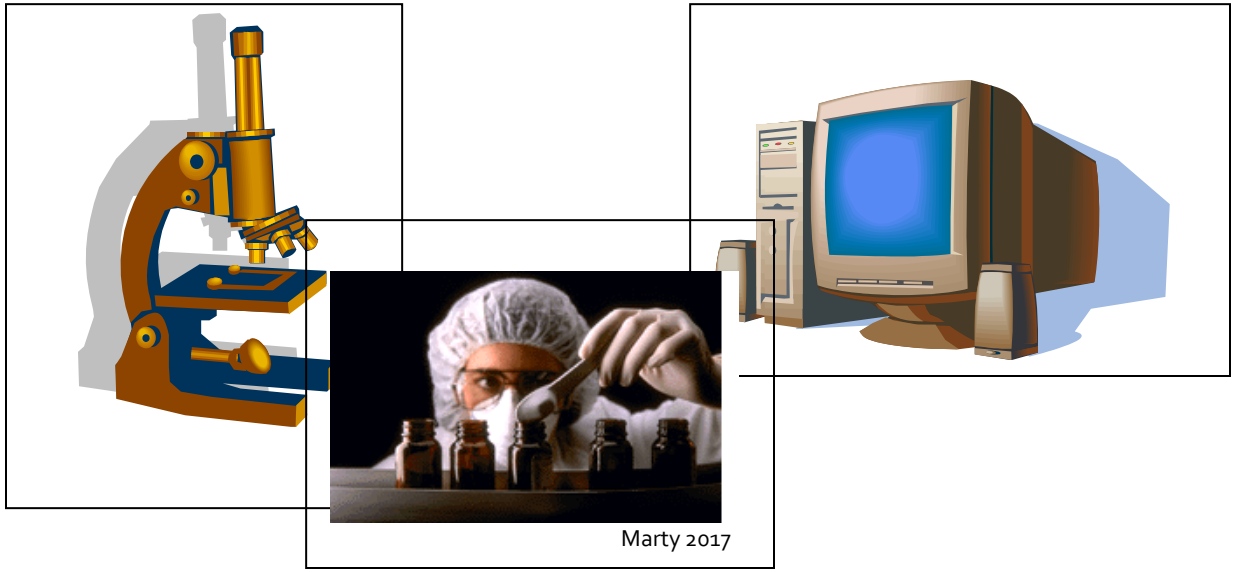
What is Health Risk Assessment?

- The characterization of the potential adverse health effects of human exposures to environmental hazards (NAS 1983)

Perceptions of Risk Assessment Process



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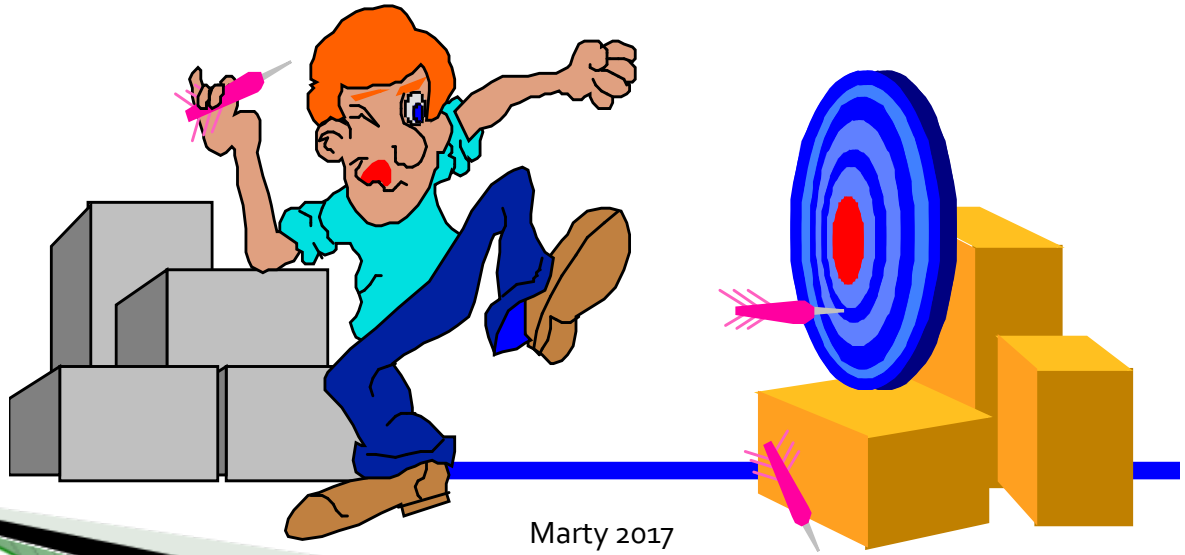
Reality of Risk Assessment Process



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Risk Assessment

What data are you using?

What's your key study?

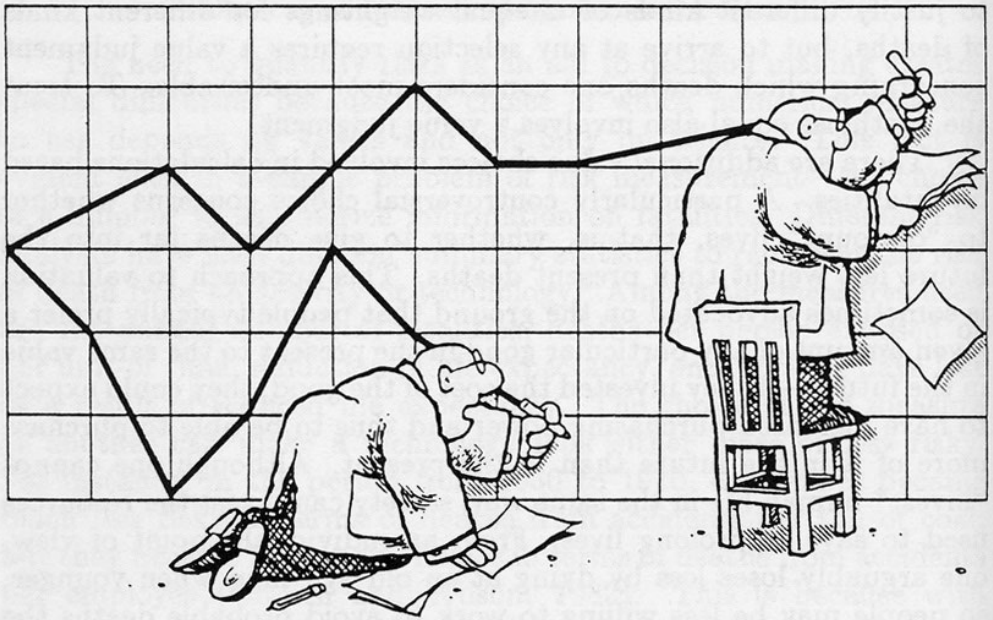

FIGURE 2.3 SOURCE: *National Wildlife Magazine*, August–September, 1984.
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Why Risk Assessment?

- Is there a problem with exposure to environmental chemical(s)?
- Need to characterize the nature and magnitude of health risks to humans
  - e.g., residents, workers, children
- Typically, only evaluating one chemical at a time

Common Types of Human Health Risk Assessment

- "Chemical-Specific Risk Assessments"
  - **Applies the 4 steps of Risk Assessment to a single chemical**
- "Site-specific risk assessment"
  - **Applies the 4 steps to specific locations or scenarios**
- Ecological Risk Assessment:
  - **Impacts and effects on environmental endpoints**

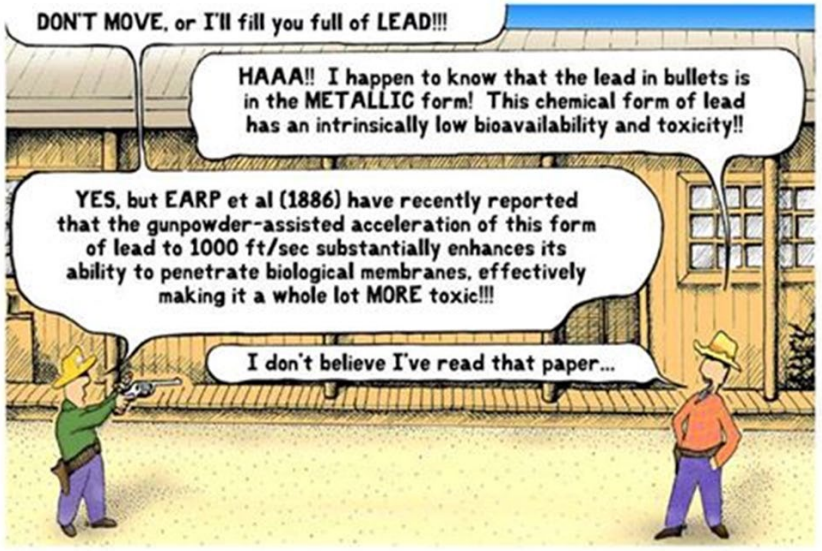
Steps of the Risk Assessment Process

1. Hazard Identification
2. Dose/Response analysis/assessment
3. Exposure assessment
4. Risk characterization

Step 1
Hazard Identification

Step 1: Hazard Identification

- The process of determining what adverse effects are caused by exposure to an agent
- Regulatory agencies typically do not conduct experiments to determine types of toxicity, but rather synthesize existing information



ENVIRONMENTAL TOXICOLOGIST IN THE WILD WEST

Hazard Identification

- Gathering and evaluating toxicological information about chemical in question
- What toxicological effects does the chemical cause?
- Is human data available?
- Is animal data adequate to allow extrapolation to possible human effects?

Steps in Hazard Identification

Conduct literature search of chemical (all data types)

Review data to understand health effect caused by the chemical

Use weight of evidence approach to identify toxic effects caused by chemical

Identify critical biological endpoints to focus risk assessment

Feed information into Dose-Response Assessment

Types of Information Used for Hazard Identification

- Human Studies
  - Epidemiological studies
  - Case reports (medical cases)
  - Clinical (In lab or clinic)
- Animal Studies
  - 90-day or lifetime studies
  - Special studies (e.g., developmental)
  - Acute exposure or repeated exposure studies
- *in vitro* assays
  - In a petri dish (studies cells and tissues)

Additional Types of Info used in Hazard ID

- Pharmacokinetic (toxico) studies: how your body handles the chemical
  - Absorption: how it gets in the body
  - Distribution: how it spreads in the body
  - Metabolism: how it changes in the body
  - Excretion: how it leaves the body
- Pharmacodynamic (toxico) information
  - How it interacts with cell receptors
- Mechanistic Info: (Mechanism of Action)
  - Exactly how it happens
- Molecular, Structural, and Cellular information

Epidemiological Studies

- Show association between an agent and a human disease
  - Prospective
  - Cohort
  - Case-Control
  - Clinical or Chamber Studies
- Occupational: Typically study worker exposure (e.g., asbestos, industry-specific)
- Can sometimes study general population exposures (e.g., arsenic, air pollution)

Epidemiological Studies (cont'd.)

- Sometimes difficult to detect an effect
  - If there is a small number of subjects in the study (in some case-control studies)
  - If the health effect is not specific (headache, nausea)
  - If hard to assess exposure
- Can sometimes combine multiple studies
  - Increase statistical power to detect an effect
  - Helpful in environmental epidemiology in particular

Animal Studies

- Hazard identification and risk assessments have largely relied on data from traditional animal toxicological studies
  - 2-year, chronic tox studies
  - High Cost
- National Toxicology Program (NTP) = Gold standard
  - Chronic studies generally use:
    - 50 rats or mice per gender per group
    - Control and 2-3 dose groups
    - Highest dose is maximally tolerated; lifetime ~2 years
    - Examined visually, clinically with histopathology at termination.

Acute Toxicity Studies

- Can be useful to identify hazards from high shorter-term exposures
- Usually have acute animal toxicity studies, a few occupational human studies are available
- Such studies involve airborne exposure to a chemical for short period of time and observation of the animals over a week or two, sometimes longer

Steps in Hazard Identification

Conduct literature search of chemical (all data types)

Review data to understand health effect caused by the chemical

Use weight of evidence approach to identify toxic effects caused by chemical

Identify critical biological endpoints to focus risk assessment

Feed information into Dose-Response Assessment

Types of Toxicological Endpoints - Noncancer

- Typically have toxicity data from animal studies measuring effects on specific organ systems
  - Need to consider all organ systems in hazard identification
  - Most sensitive effects
  - Occurring at lowest doses
  - Most sensitive species
  - Most sensitive life-stage

Cancer Hazard and Cancer Risk

Cancer hazard: a chemical that is capable of causing cancer

- Hazard identification
- Not a quantitative risk estimate

Cancer risk: a quantitative estimate of the risk of carcinogenic effects (cancer) from exposure to a cancer hazard

- Dose-response assessment and exposure assessment combined to get cancer risk
- "de minimus" risk expressed as excess cases of cancer
  - Example: One in a million

Steps in Hazard Identification

Conduct literature search of chemical (all data types)

Review data to understand health effect caused by the chemical

Use weight of evidence approach to identify toxic effects caused by chemical

Identify critical biological endpoints to focus risk assessment

Feed information into Dose-Response Assessment

Hazard Identification

- **Applying "weight of the evidence" evaluation** to identify the hazards.
  - Chemicals usually have multiple effects
  - Effects may be Acute or Chronic
  - And may include:
    - Carcinogenicity
    - Organ specific toxicity
    - Developmental/reproductive toxicity
    - Portal of entry effects (eye, nose, throat irritation)

Weight of Evidence

- GOAL:
  - Evaluate evidence for association between exposure and specific chemical's adverse effect
- Can be exposure from working an occupation
- General population exposure
- Experimental exposure (human or animal)

Characteristics

- **Strength of association**: Statistics
- **Temporality**: Does effect follow exposure
- **Consistency:** Across studies/populations
- **Biological plausibility**: Is it possible?
- **Specificity**: How specific is the effect?
- **Coherence with knowledge**: Does it agree with what we know?
- **Dose-response relationship**: Increasing effect with increasing dose?

Steps in Hazard Identification

Conduct literature search of chemical (all data types)

Review data to understand health effect caused by the chemical

Use weight of evidence approach to identify toxic effects caused by chemical

Identify critical biological endpoints to focus risk assessment

Feed information into Dose-Response Assessment

A Note About Choosing a Critical Biological Effect:

- Typically Risk Assessments look at the most sensitive critical effect
  - Occurring at lowest dose in the most sensitive species

- This may not hold true for chemical evaluation for:
  - CalARP
  - Emergency Response
  - Worst-Case-Scenario
  - Off-Site Consequence Analysis

Steps in Hazard Identification

Conduct literature search of chemical (all data types)

Review data to understand health effect caused by the chemical

Use weight of evidence approach to identify toxic effects caused by chemical

Identify critical biological endpoints to focus risk assessment

Feed information into Dose-Response Assessment

Step 2
Dose-Response Analysis

Dose-Response Analysis

- The process of quantifying the relationship between the exposure or dose of a chemical and the adverse effect
    - Based on toxicological or epidemiological studies
    - Most often only animal studies are available
    - Can evaluate multiple toxicological endpoints from several studies

Dose-Response Analysis

Often must extrapolate from animal studies with two important assumptions:

1. Threshold for non-cancer: a no-effect dose and lowest effect dose
2. No threshold for cancer: any amount can cause cancer

Points of Departure (POD) for Dose-Response Assessment

- Starting point of dose from study:
  - NOAEL: no observed adverse effect level
  - LOAEL: lowest observed adverse effect level
  - BMD – Benchmark Dose

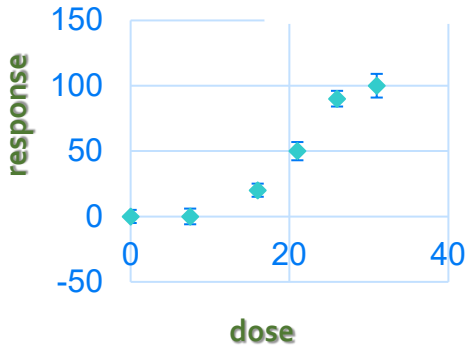
How Dose-Response is Generated

What's reported in a study:

- # Animals
- Dose groups
- Responses (+ effect)
- Table of average or "mean" responses and standard deviation or error
- Response values used to create a "dose" and "response" curve

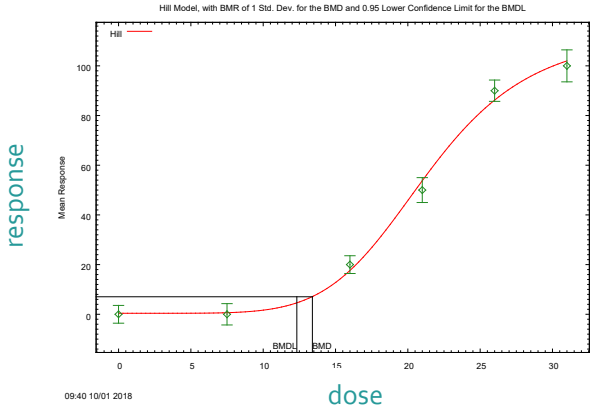
Dose	#	Mean	St dev
0	10	0	5
7.5	10	0	6
16	10	20	5
21	10	50*	7
26	10	90*	6
31	10	100*	9

*P<0.05

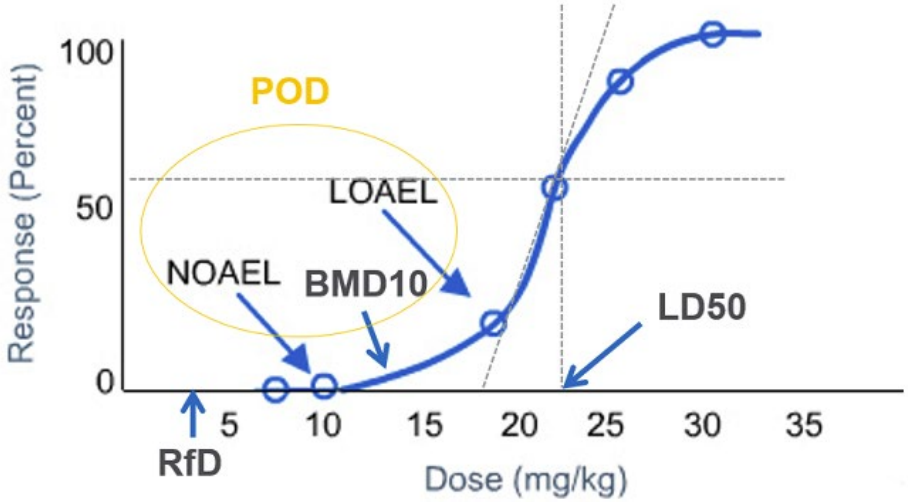


Task for Toxicologist:

- Analyze the data
- Comparing dose groups to control
- Use a modeling program.
  Benchmark Dose Response (BMDS) Modeling



POD types: NOAEL – LOAEL - BMDL



BMDL – The Benchmark Dose "lower confidence interval"

Uses statistical analysis of the whole dose-curve

vs.

Just comparing dose group to control group

Adjusting Study Duration

- Generally, use an acute study for acute value and chronic study for chronic value
  - Chronic exposures not appropriate for acute estimation
  - Acute exposures not appropriate for chronic estimation
  - Note: Can use a subchronic study for a chronic estimation but then need to use the Subchronic Uncertainty Factor (UFs)

Can't use long study for short-term value

Can't use short study for long-term value

Dose Adjustment

- Change from an administered dose to an internal dose
- Account for (Inter) animal to human variation
- Account for (Intra) variation between humans

Dose Adjustments

- Traditional method to adjust dose from animal model to human model:
  - Human Equivalent Concentration (HEC):
  - For inhalation uses surface area, minute volume, and relative ventilation rates of rodents versus humans. Still used in no PBPK model.
- Newer Method: Physiologically-based Pharmacokinetic Models (PBPK)
  - Derive a **dosimetric adjustment factor** (**DAF**) and can take into account differences between species including differences in absorption, distribution, metabolism, and excretion (ADME).
  - PBPK modeling can also model and predict responses in sensitive subpopulations (e.g., infants and children) if data are available

Time Adjustments

- Extrapolate from experimental exposure (number of hours and days in the study) to relevant exposure for Health Guidance Value)

Acute (1-hour) exposure:

- The study was conducted at: 6 hours per day for 3 days
- **Want to change to Acute 1-hour for one day**
- 6 hours / 1 hour X 3 days / 1 day = 6 X 3 = **18**

Example time adjustments for Chronic exposure:

- The study was conducted at: 6 hours per day for 5 days
- Want to change to Chronic 24 hours for 7 days
- 6 hours / 24 hours X 5 days / 7 days = **0.18**

Step 3: Exposure Assessment

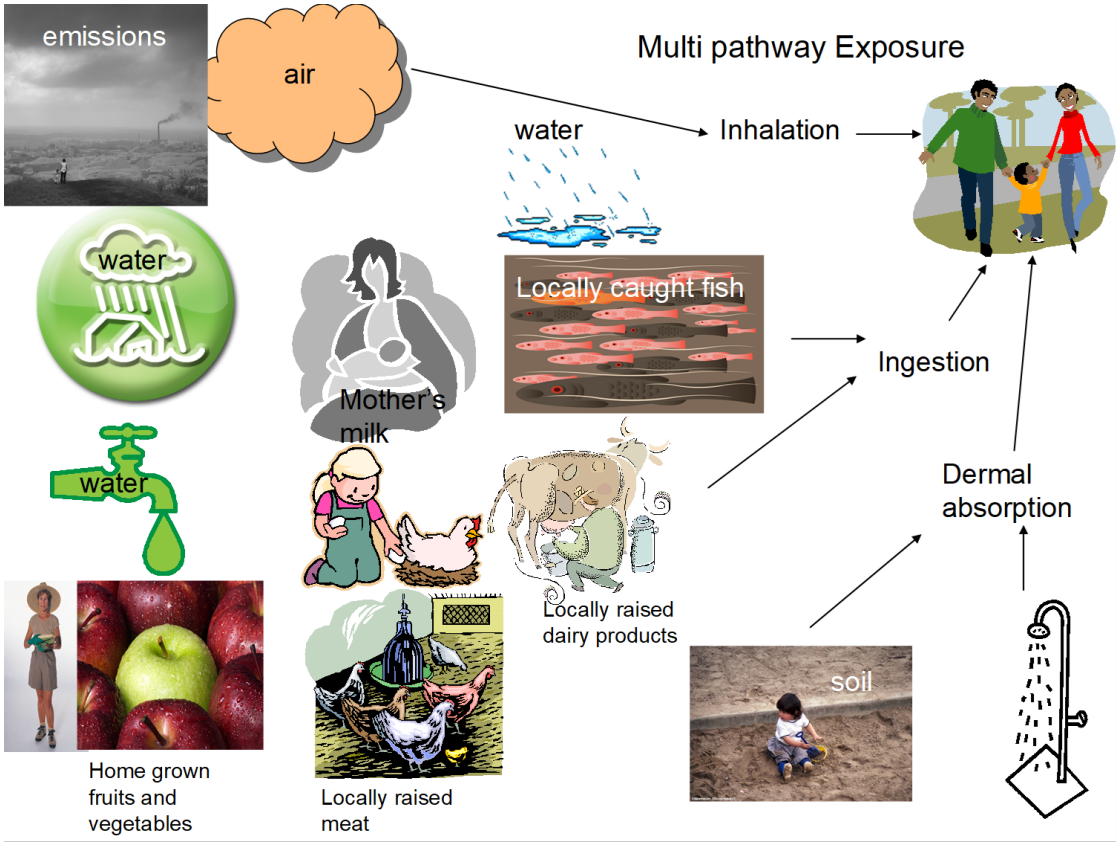
- The process of quantifying the amount of exposure to an environmental chemical humans receive from a single or multiple media

- Exposures are assessed for:
  - Maximum exposed individual
  - Average population exposure
  - Subsets of the population

Exposure Assessment

- Single chemical
  (e.g., in a chemical-specific risk assessment, for example arsenic in drinking water), or
- Multiple chemicals
  (e.g., in a site-specific risk assessment where a facility emits many chemicals)

Multiple exposures contribute to exposure assessment



Exposure Assessment

- Routes of exposure
- Pathways of exposure
- Environmental media
- Measurements in media versus Models

In most site-specific risk assessments

- the amount of chemical in contaminated media is usually modeled but is occasionally measured
  - where the chemical is a more ubiquitous contaminant, we frequently have measurements in air or water to use to assess exposure

Exposure Assessment

How much contaminated media we take in is also necessary for exposure assessment

We research these **exposure variables** such as

Inhalation rate,

Soil ingestion rates, and

Consumption rates for:

Examples: Meat, Cow's milk, Mother's milk, Produce, Drinking water, and/or fish for the population of interest

Step 4: Risk Characterization

The process of combining the first three steps of risk assessment into a coherent picture describing the risks of exposure to the chemical(s) in question

- Combines dose-response and exposure assessment in a quantitative fashion and includes discussion of major uncertainties
  - Interspecies
  - Intraspecies
  - Subchronic
  - Data deficiencies
  - LOAEL to NOAEL

Susceptible Subpopulations

- Subpopulations of people exist due to differences in genetics, age, health, lifestyle, gender, etc
- Genetic polymorphisms
- Children have higher rates of asthma than adults
- Smaller airways mean bigger problem during bronchoconstriction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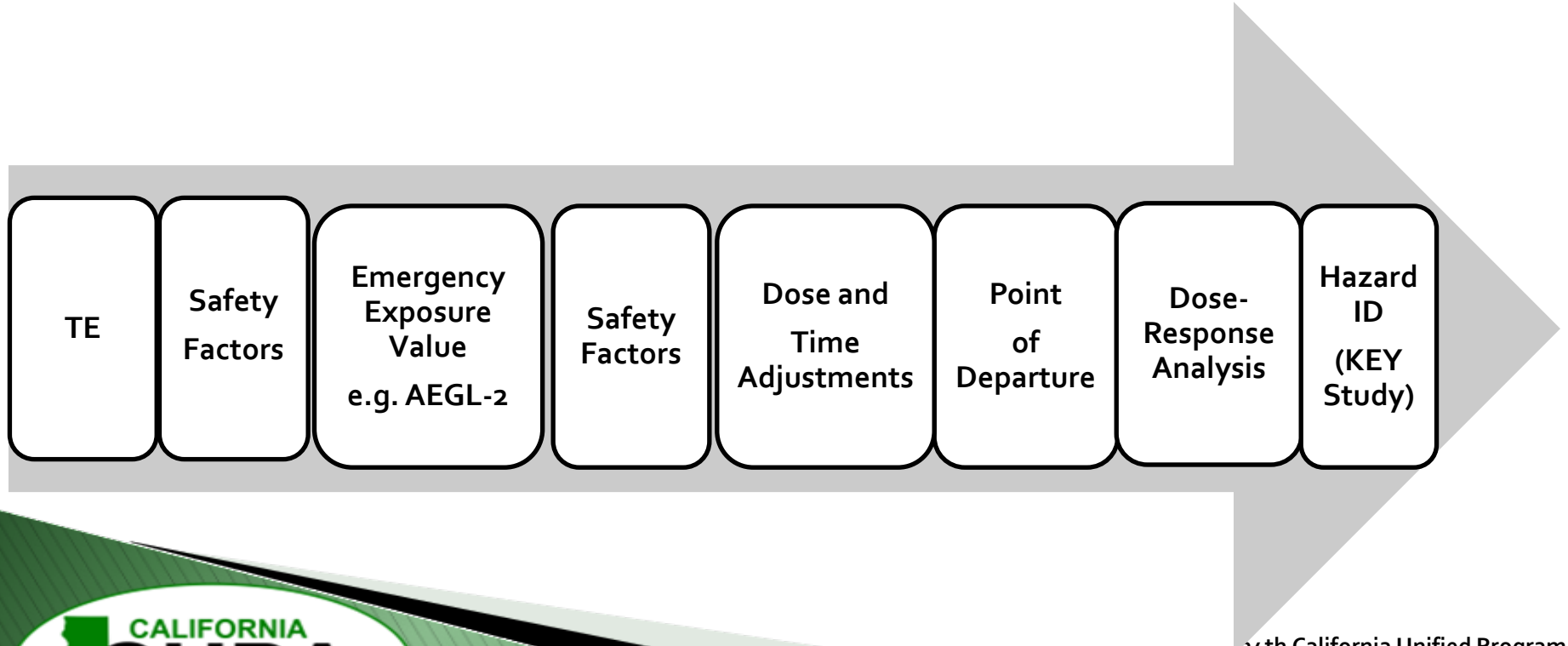
IV. California Accidental Release Program Toxicology Review

CalARP and Toxicology

- OEHHA's Role
  - Periodically review CalARP chemical information
  - Keep up-to-date toxicology information on the CalARP chemicals
  - Updating information that contributes to development of the Toxic Endpoint (TE) information

Roadmap to a Toxic Endpoint



Updating Information in CalARP and Comparison to Steps in Risk Assessment

Conduct literature search of chemical (all data types)

↓

Review data to understand health effects caused by the chemical

↓

Identify (acute) toxic effects caused by chemical

↓

Identify critical biological endpoints from Key Studies

↓

Identify POD from Dose-Response Assessment

Updating Information for CalARP Chemicals and Comparison to Steps in Risk Assessment

Understand time and dose adjustments

↓

Understand applied safety factors

↓

Assess Suitability of Each Exposure Value for Extrapolation to TE

↓

Determine value for POD for TE

↓

Add any additional safety factors

↓

Extrapolate to determine TE

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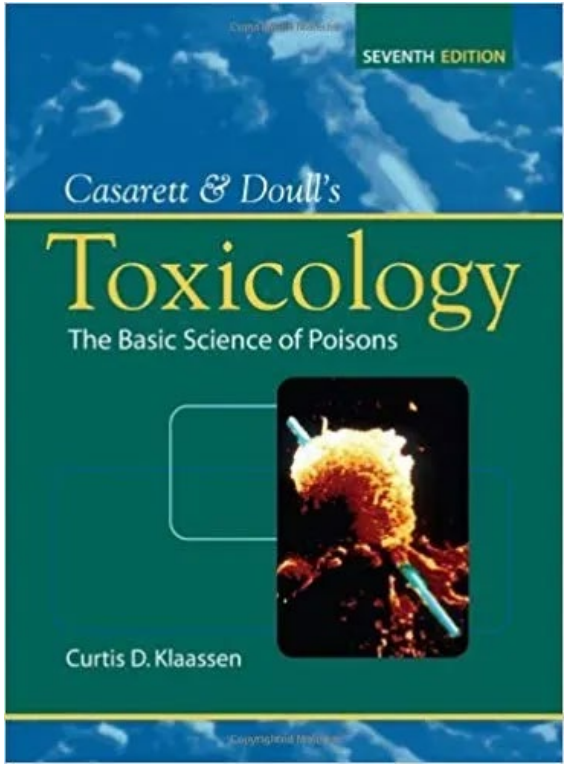
Like Hazard Identification



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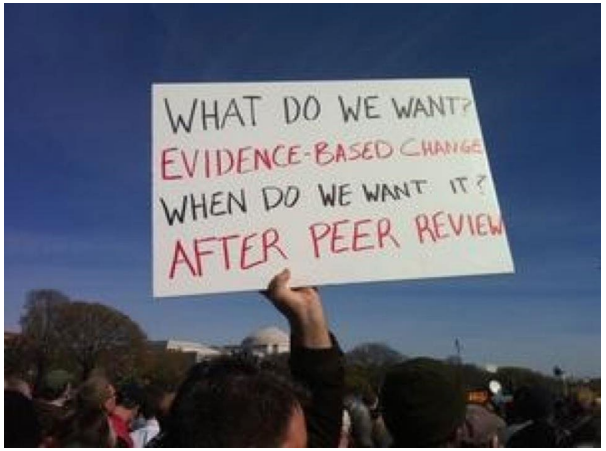
Literature Search

- Hazard Substances Data Bank in PubChem for Scientific Literature
  - https://pubchem.ncbi.nlm.nih.gov/source/11933
- National Institute for Occupational Safety and Health
- CAMEO Chemicals
- Other Government websites
  - United States Environmental Protection Agency
  - United States Department of Energy
- Systemic Reviews



Types of Information- Updates may include:

- Physical Chemical Properties
- Documentation of key studies and points of departure; time and dose adjustments; use of safety/uncertainty factors
- Updates to Emergency and Occupational Exposure Values
- Review of Inhalation Toxicology studies (mostly acute studies)
- Review of other relevant Toxicological Information

Physical and Chemical Properties

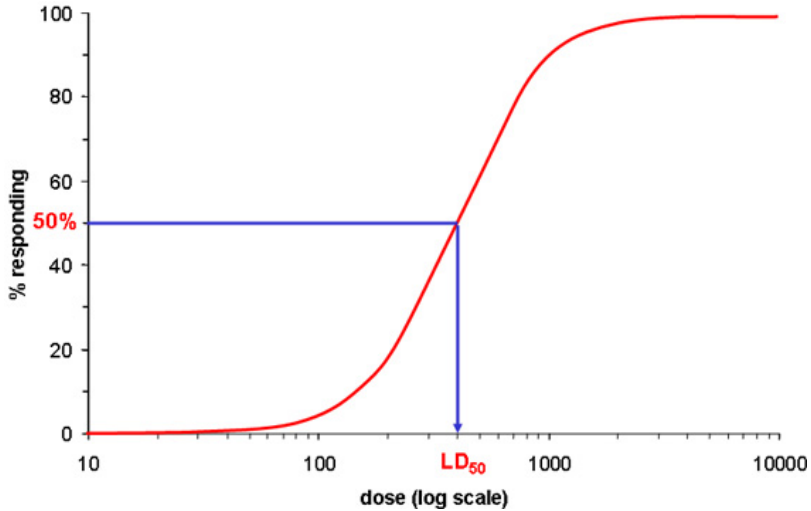
- Description
- Molecular Formula
- Molecular Weight
- Boiling Point
- Freezing Point
- Solubility
- Vapor Pressure
- Ionization Potential
- Density

Acute Inhalation Toxicity Studies

- Can be useful to identify hazards from high shorter-term exposures
- Acute animal toxicity studies, occupational human studies, or chamber studies
- Short-term airborne exposure
- In few circumstances can extrapolate from other routes of exposure

Lethal Dose-50 (LD50) Studies

- Dose at which a substance causes death in 50% of the tested subjects
- Multiple Species
  - Sensitivity
  - Dose-groups



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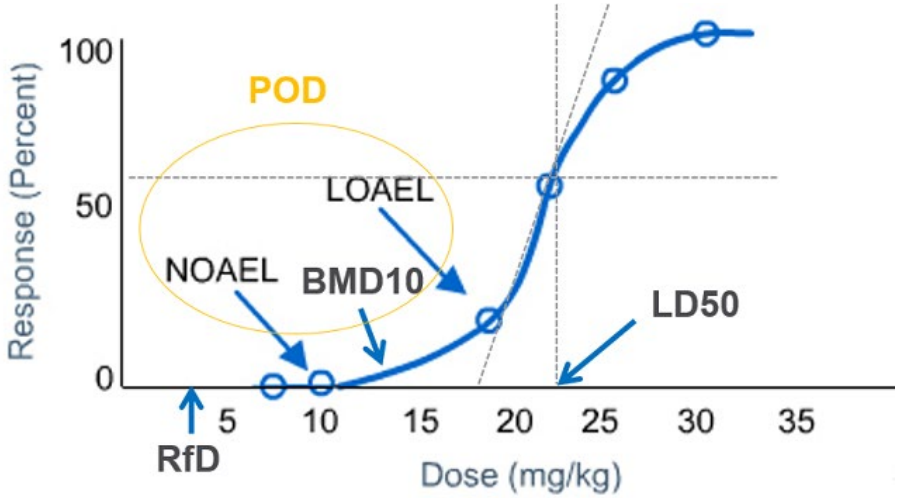
Looking for a New Key Study and D/R Info

- Relevant dose groups: three or more is best
- Relevant species: most sensitive
- Best or Appropriate POD
- Multiple Species
  - Sensitivity
  - Dose-groups



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So many Exposure Values, so little time…

AEGLS

TEELS

WEEL

ERPGS

IDLH

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Determination of Key Studies from Existing Emergency Exposure Values

- Look-up documentation for each exposure value
- Assess how exposure value was calculated
- Consider appropriate level AEGL-1, AEGL-2, AEGL-3
- Determination suitability for use
- Add any additional supporting information

Exposure Values

Emergency Exposure Value	Acronym	Developed by
Acute Exposure Guideline Level	AEGL	United States Environmental Protection Agency
Emergency Response Planning Guideline	ERPG	American Industrial Hygiene Association
Immediately Dangerous to Life and Health	IDLH	National Institute of Occupational Safety & Health
Temporary Emergency Exposure Level	TEEL	United States Department of Energy
Workplace Environmental Exposure Level	WEEL	Toxicology Excellence for Risk Assessment

Emergency Exposure Levels

- Acute Exposure Guideline Level (AEGL, U.S. Environmental Protection Agency)
- Emergency Response Planning Guideline (ERPG, American Industrial Hygiene Association)
- Immediately Dangerous to Life and Health (IDLH, National Institute for Occupational Safety and Health)
- Temporary Emergency Exposure Level (TEEL, U.S. Department of Energy)
- Workplace Environmental Exposure Level (WEEL, American Industrial Hygiene Association)

Emergency Exposure Values

- **AEGL:**
  - Describe human health effects from once-in-a-lifetime, or rare, exposure to airborne chemicals
  - Used by emergency responders when dealing with chemical spills or other catastrophic exposures
- **ERPG**
  - Estimates the concentrations at which most people will begin to experience health effects if they are exposed to a hazardous airborne chemical for 1 hour

Emergency Exposure Values

- **IDLH:**
  - Characterize high-risk exposure concentrations and conditions and are used as a component of respirator selection criteria
- **WEEL:**
  - Provide air concentrations intended to protect most workers from adverse health effects related to occupational chemical exposures
- **TEEL:**
  - Designed to predict the response of members of the general public to different concentrations of a chemical during an emergency response incident

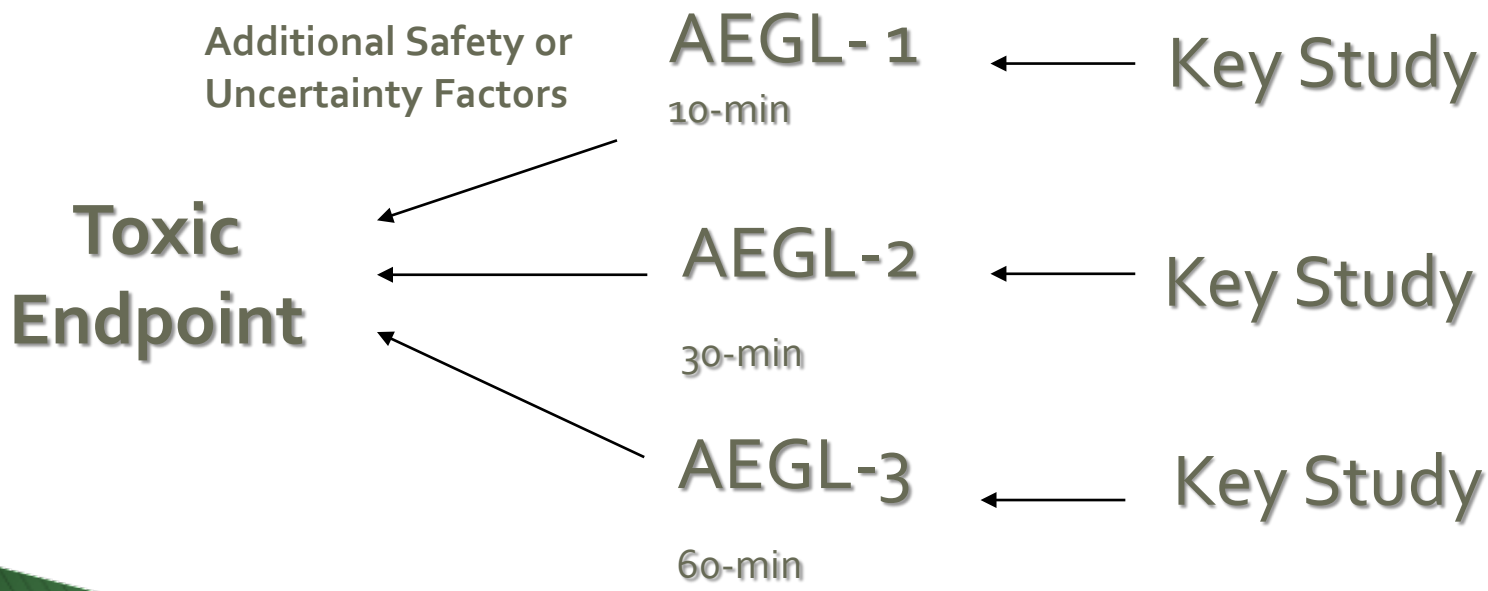
Occupational Values

- NIOSH Reference Exposure Limit (REL)
- U.S. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PEL)
- American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV)

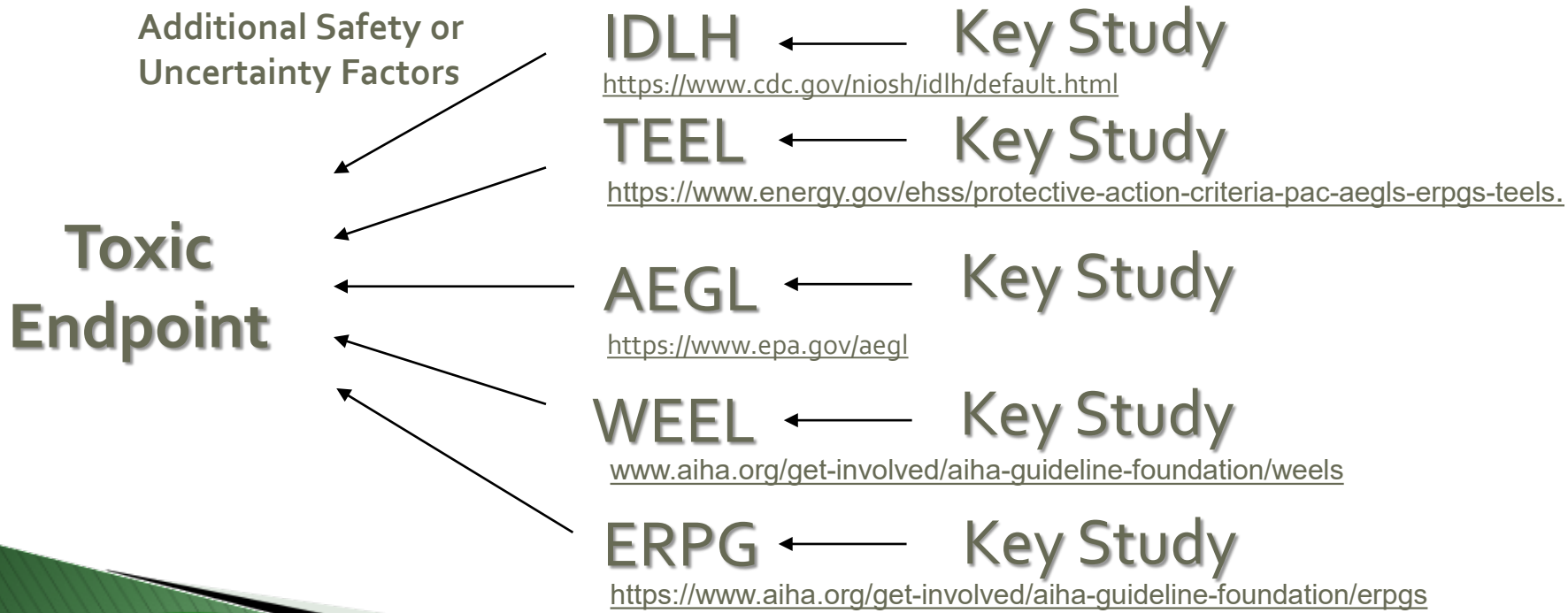
Occupational Exposure Values

Occupational Exposure Value	Acronym	Developed by
Occupational Exposure Limits	OEL	European Chemicals Agency
NIOSH Reference Exposure Value	REL	National Institute of Occupational Safety & Health
Permissible Exposure Limits	PEL	U.S. Occupational Safety and Health Administration
Threshold Limit Values	TLV	American Conference of Governmental Industrial Hygienists

Updating Toxic Endpoint Information



CalARP Toxic Endpoint Information



What we Covered Today

- Basics of Toxicology
- Human Health Risk Assessment Process
- Steps of Risk Assessment
- How information for CalARP chemicals is updated

Questions?

Interested in a course in Advanced Risk Assessment techniques for next year?

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Thank you!