Human Health Ambient Water Quality Criteria

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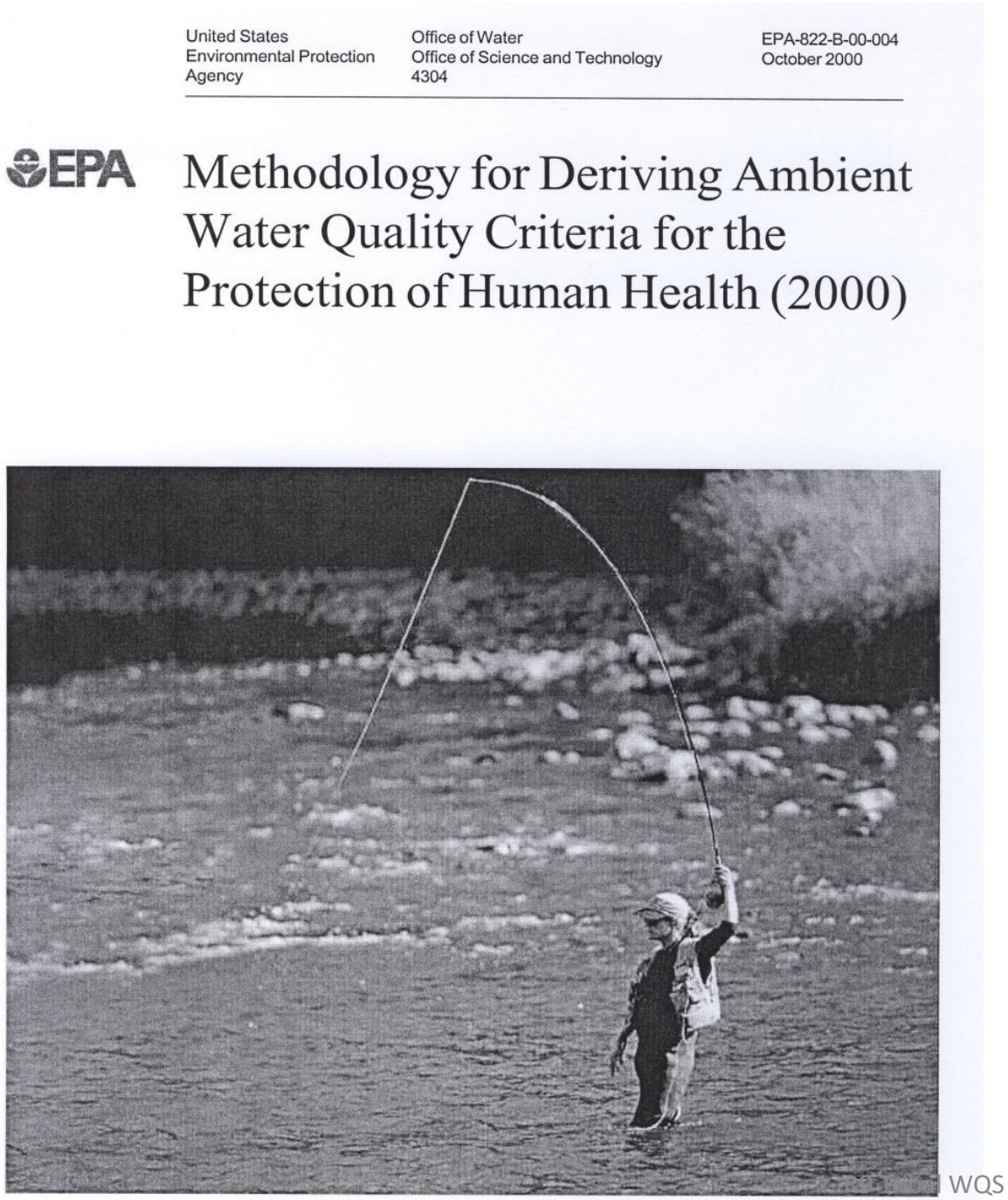


Methods for Human Health Criteria Development

https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics

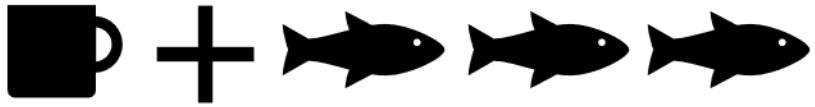
- 2000 Methodology describes the EPA's current methods for 304(a) human health criteria derivation.
- Document underwent significant internal, external, and White House review – was in development for ~10 years.
- Summarizes "state of the science" and recommends approaches given different chemical properties, exposure scenarios, and risk management policy decisions.

What are Human Health AWQC?

- The highest concentration of a pollutant in water that is not expected to pose a significant risk to human health through ingesting water and/or aquatic organisms over a lifetime of exposure

Water and Organism Criteria

- Considers exposure from drinking water uses and fish/shellfish consumption



Organism Only Criteria

- Only considers exposure from fish/shellfish consumption (no drinking water uses)

Organoleptic Criteria

- Considers taste, odor, color (not adverse health outcomes)

Goal of Human Health AWQC

The total dose of the compound that the population is exposed to

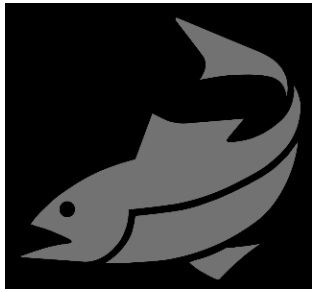
Is less than or equal to

$\leq$

The dose of the pollutant that is unlikely to cause adverse health effects *or* the dose that achieves the target risk level for the population

Derivation of Human Health Criteria

$$= \frac{\text{Toxicity Endpoints} \times \text{Weight}}{\text{Water} + \left(\text{Fish} \times \text{Bioaccumulation factors}\right)}$$



Required Information for Criteria Development

Exposure Factors

- **BW** = Adult Body Weight . EPA default is 80 Kg
- **DI** = Drinking water intake value. EPA default is 2.4 L/day (90th-ile of adults)
- **FI** = Fish Intake rate? EPA default is 22 g/day
- **BAF** = accumulation of toxin in fish/shellfish tissues?
- **RSC** = Relative Source Contribution (i.e., what percent comes from water and fish relative to air, food, or soil?) EPA default is 20%

Toxicity Factors

- **RfD** = Reference Dose for non- linear (threshold dose response curve)
- **RSD** = Risk-Specific Dose for linear dose response curve

Other Exposure Parameter Options to Consider

- Scenarios may exist where exposure parameters for specific population(s) or life-stages may be appropriate when deriving a criteria.
  - If the pollutant causes adverse effects in a specific population or life-stage
  - If a specific population or life-stage is likely to be highly exposed compared to the general population
- The EPA's **2011 Exposure Factors Handbook** and 2014 report "**Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)**" are good resources for bodyweight, drinking water intake rate, and fish consumption rate statistics.

Examples of "target populations" include:

- **Pregnant women, lactating women, or women of childbearing age**

  Might be a good target population if the pollutant effects the fetus, newborn baby, or the female reproductive system
- **Children**

  Might be a good target population if effects involve growth and development, or if children are a highly exposed group (toddlers playing at a beach with contamination)
- **Subsistence fishers**

  Might be a good target population if there are subsistence fishers in the community, or if the toxin bioaccumulates dramatically in fish, such that the majority of exposure occurs through fish consumption

How Much Exposure Is Coming From Fish?

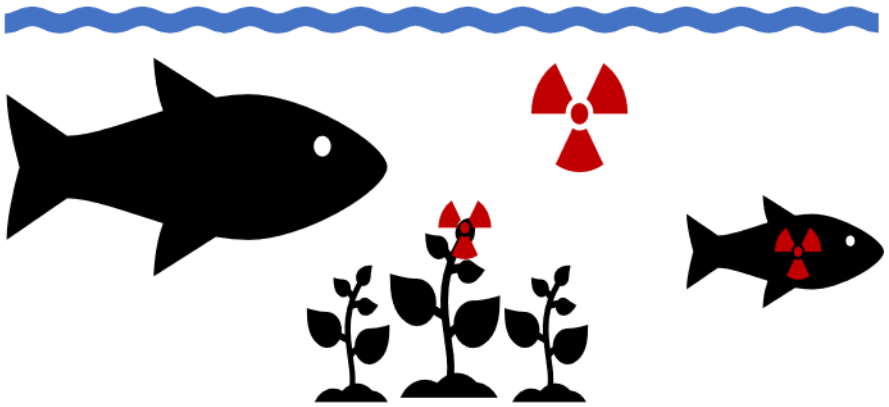
- We just talked about how many kg of fish and shellfish people consume, but how much of the pollutant is contained in that food?
- Bioaccumulation Factors (BAFs) translate the kilograms of fish consumed into liters of contaminated water that results in the same amount of exposure.

$$total\ exposure\ \left(\frac{L}{day}\right) = DI\ \left(\frac{L}{day}\right) + FCR\ \left(\frac{kg}{day}\right) * BAF\ (\frac{L}{kg})$$

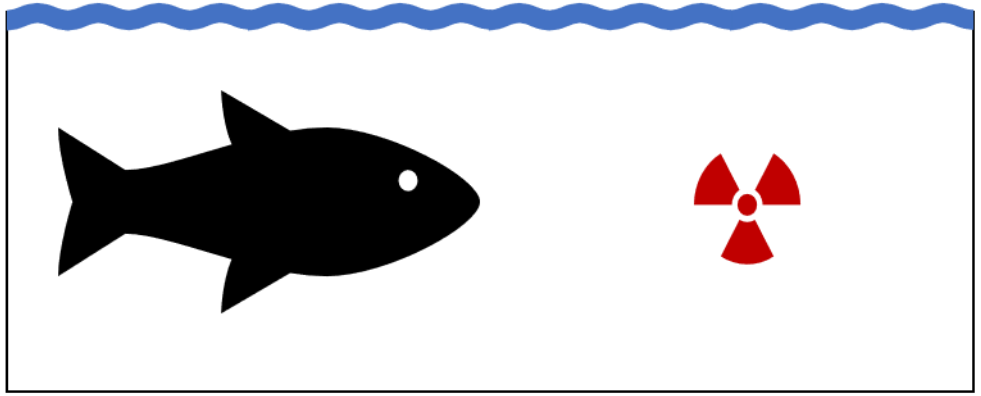
Estimating Bioaccumulation

$$Bioaccumulation = \frac{Concentration\ in\ fish\ tissue}{Concentration\ in\ water}$$

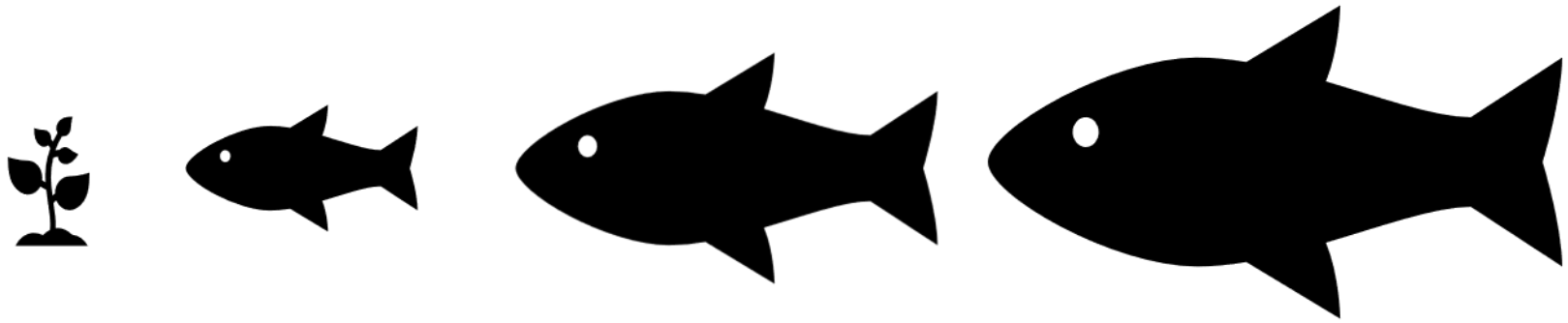
BAF: measurements in natural conditions



BCF: measurement in lab with only direct water exposure



Bioaccumulation and Trophic Levels



Trophic Level 2

BAF = 120 L/kg

Trophic Level 3

BAF = 200 L/kg

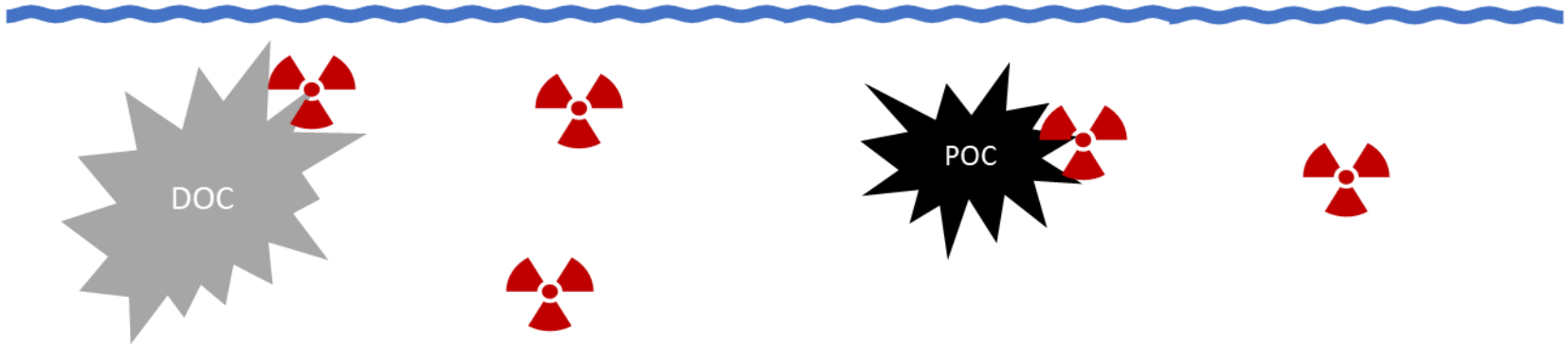
Trophic Level 4

BAF = 560 L/kg

$$\sum_{i=2}^{4} FI_i * BAF_i$$

Methods for Deriving BAFs

- The degree of bioaccumulation depends on the *bioavailable* concentration of the compound in water
  - Dissolved organic carbon (DOC) and particulate organic carbon (POC) concentrations correlate to the bioavailable fraction of the compound.
  - When compiling field BAF data from the literature for the 2015 HHC update, EPA recorded the POC and DOC concentrations at the location of the BAF sample so that BAF values could be compared across sites with differing biochemical conditions.
- States can derive **state and/or site-specific BAF values** from EPA's published baseline BAFs by using representative POC and DOC concentrations for their state.
- BCFs make no adjustments to control for natural conditions, like POC and DOC concentrations, that might lessen or heighten the bioaccumulation of the compound in the environment.



Methods for Deriving BAFs

- Field-measured BAF
  - National BAF an alternative
- BAF from a Biota-Sediment Accumulation Factor (BSAF)
  - Difficult to measure due to low solubility (e.g. PCBs)
- BAF from a laboratory BCF*
- Modeled BAF based on chemical and biological properties
- BAF from Octanol-Water Partition Coefficient (K_{ow})*

* with or without a Food Chain Multiplier (FCM), depending on biomagnification potential

Derivation of Human Health Criteria

$$= \frac{\text{Toxicity Endpoints} \times \text{Weight}}{\text{Water} + (\text{Fish} \times \text{Bioaccumulation factors})}$$

Health Toxicity Endpoints

- Generally speaking, a pollutant has one of the following dose-response patterns:

Linear Dose-Response

All doses pose an increased probability of an adverse effect – the dose response curve is linear

- Typical for *cancer* effects
- Some non-carcinogens have a linear dose-response

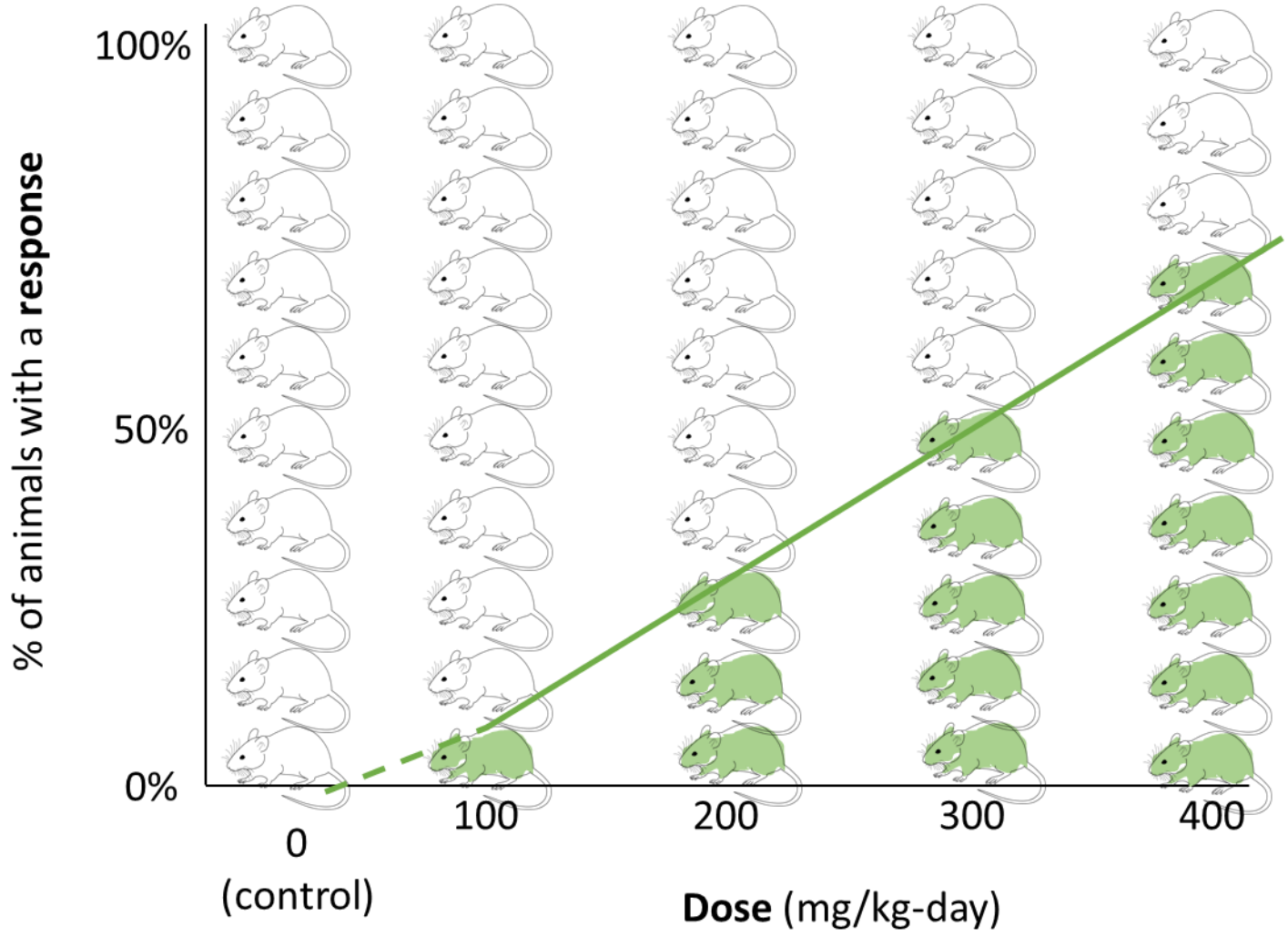
Non-Linear Dose-Response

Threshold response observed: in the available toxicity studies, there was a dose below which no adverse effects were observed

- Typical for *noncancer* effects
- Some carcinogens have a nonlinear dose-response

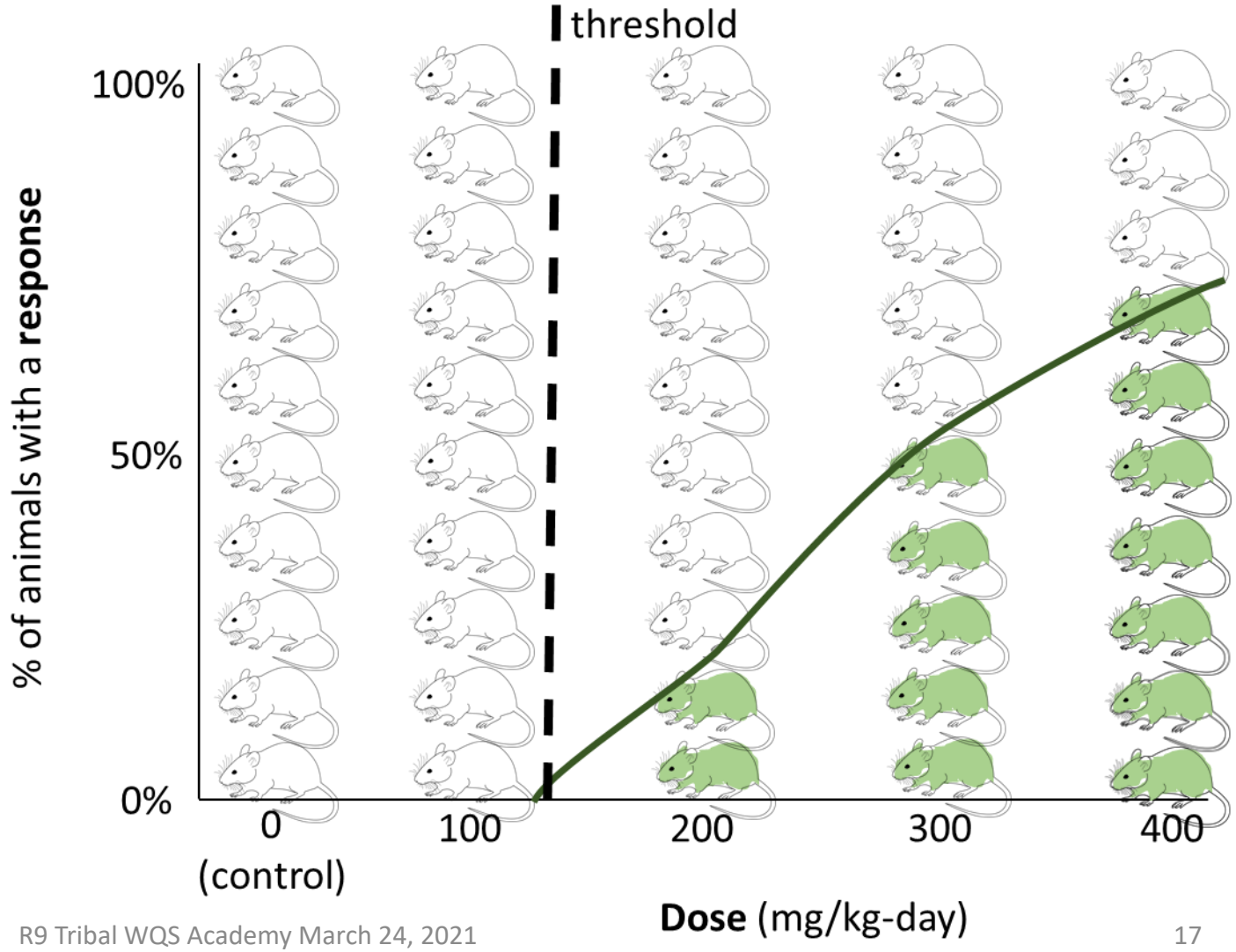
Linear Dose-Response Curve

- All levels of exposure pose some increased probability of effects (cancer).
- EPA targets a cancer risk level (CRL) of one additional cancer cases per one million people due to exposure to the pollutant.
- Other target cancer risk levels (1 case in 100,000 people, 1 in 10,000, 1 in 10 million) could be targeted – this is a risk management or policy decision.



“Non-linear” or “Threshold” Dose-Response Curve

- There are doses that do not result in adverse effects in the available studies.



Toxicity Endpoints for Human Health Criteria

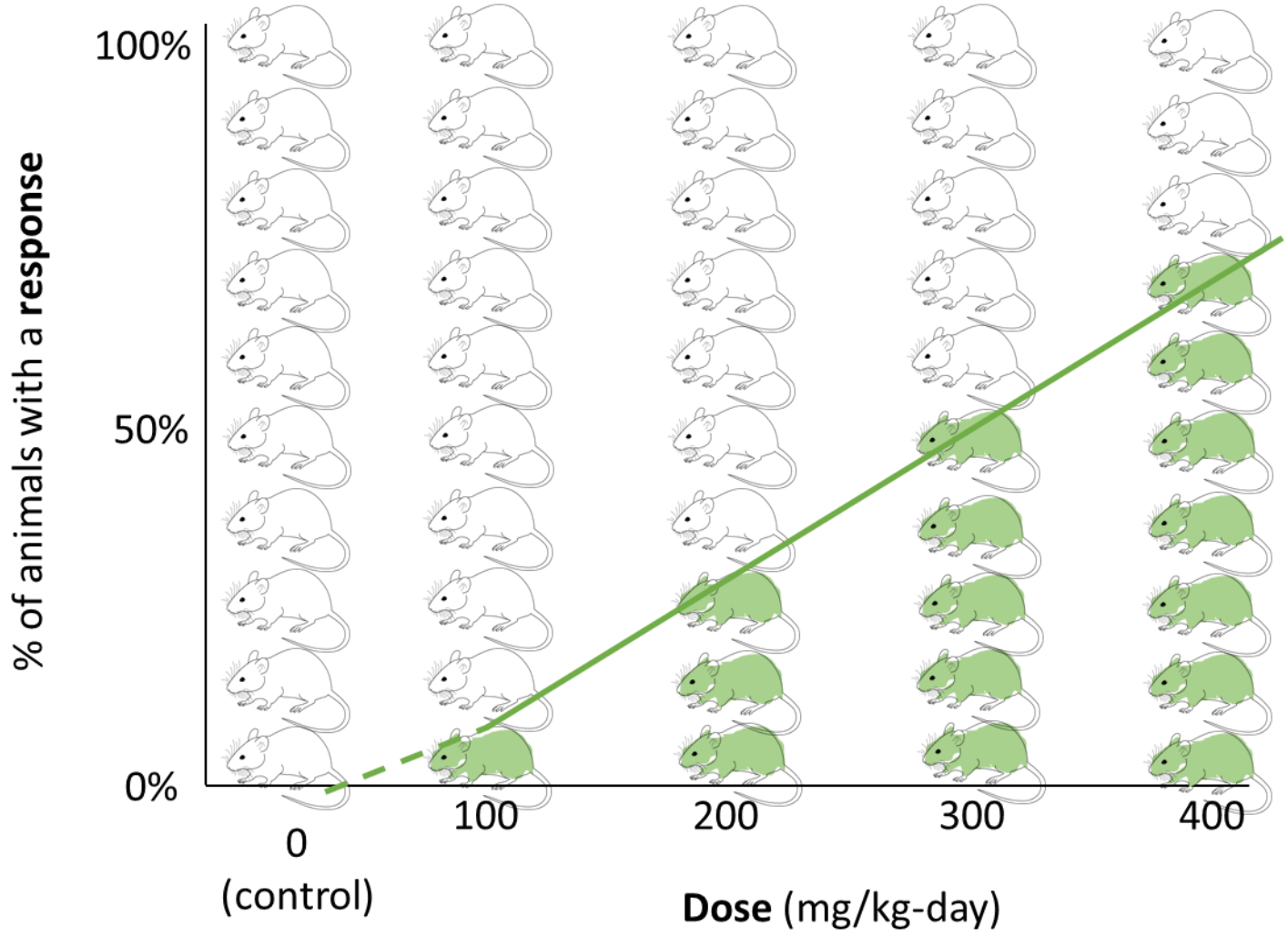
- For linear dose response = Risk Specific Dose (RSD)
  - Risk Specific Dose = Cancer Risk Level / **Cancer Slope Factor**
- For threshold response = Reference Dose (RfD)
  - Reference Dose = **Point of Departure** / Uncertainty Factor

Sources of health assessments include:

- EPA Office of Water (Health Advisories, Health Effects Support Documents)
- EPA Office of Research and Development (Integrated Risk Information System assessments, Provisional Peer-Reviewed Toxicity Value Reports)
- EPA Office of Pesticides (Registration Eligibility Documents, Human Health Risk Assessments)
- CDC Agency for Toxic Substances and Disease Registry (Toxicity Profiles)
- Health Canada (Guidelines for Drinking Water)
- World Health Organization (Drinking Water Guidelines)
- State assessments (such as CalEPA Public Health Goals)

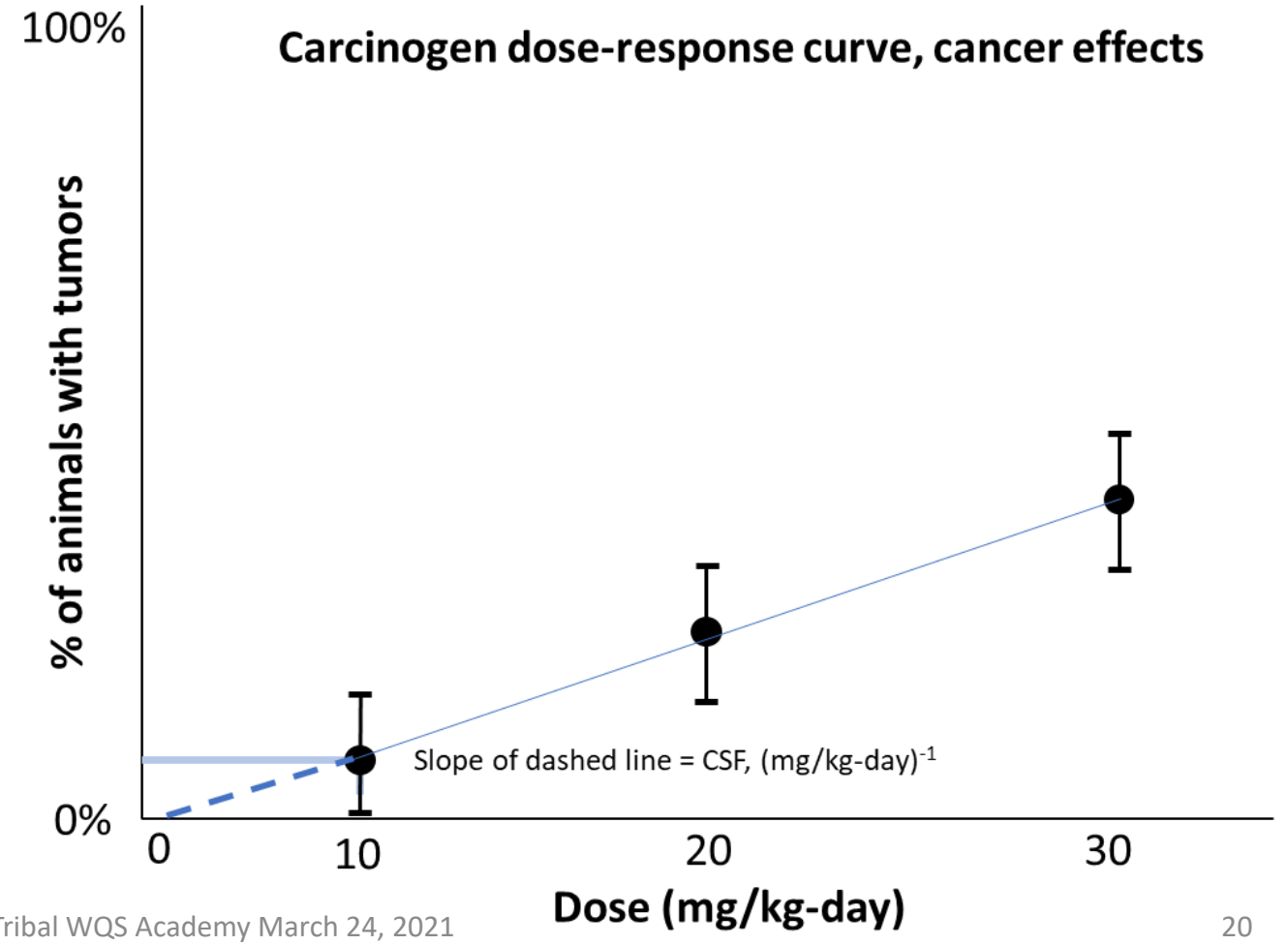
Carcinogens: Calculating a Risk-Specific Dose (RSD)

- All levels of exposure pose some increased probability of effects (cancer).
- EPA targets a cancer risk level (CRL) = 1 in 1,000,000
- Calculate Cancer Slope Factor (CSF)
- RSD = CRL/CSF



Understanding the Cancer Slope Factor (CSF)

- Cancer Slope Factor = the value that expresses the incremental increased risk of cancer incidence from a lifetime exposure to a pollutant



Risk-Specific Dose (RSD)

The RSD is the dose at which the population meets the targeted cancer risk level (e.g., 1 case in 1 million)

$$\textbf{Risk Specific Dose (RSD)} = \frac{\textbf{Cancer Risk Level (CRL)}}{\textbf{Cancer Slope Factor (CSF)}}$$

Key passages from 2000 Methodology on the Cancer Risk Level:

- "With the 2000 Methodology, EPA will publish its national 304(a) water quality criteria at the 10^{-6} risk level, which EPA considers appropriate for the general population."
- "EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport-fishers or subsistence fishers) does not exceed the 10^{-4} level."

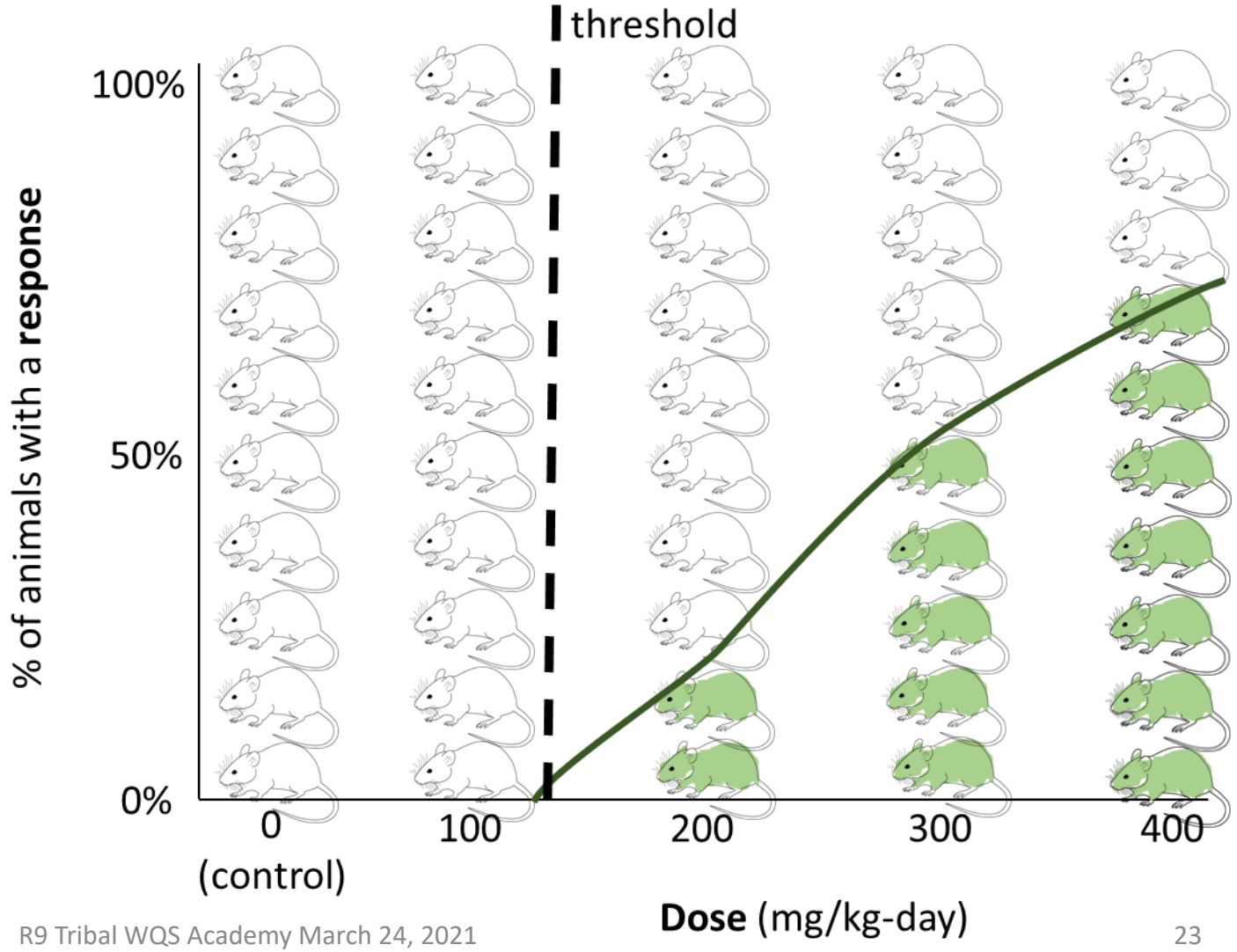
Calculating a criteria for a Carcinogen

$$AWQC = RSD * \left(\frac{BW}{DI + \sum_{i=2}^{4} FI_i * BAF_i} \right)$$

What about chemicals the don’t cause cancer?

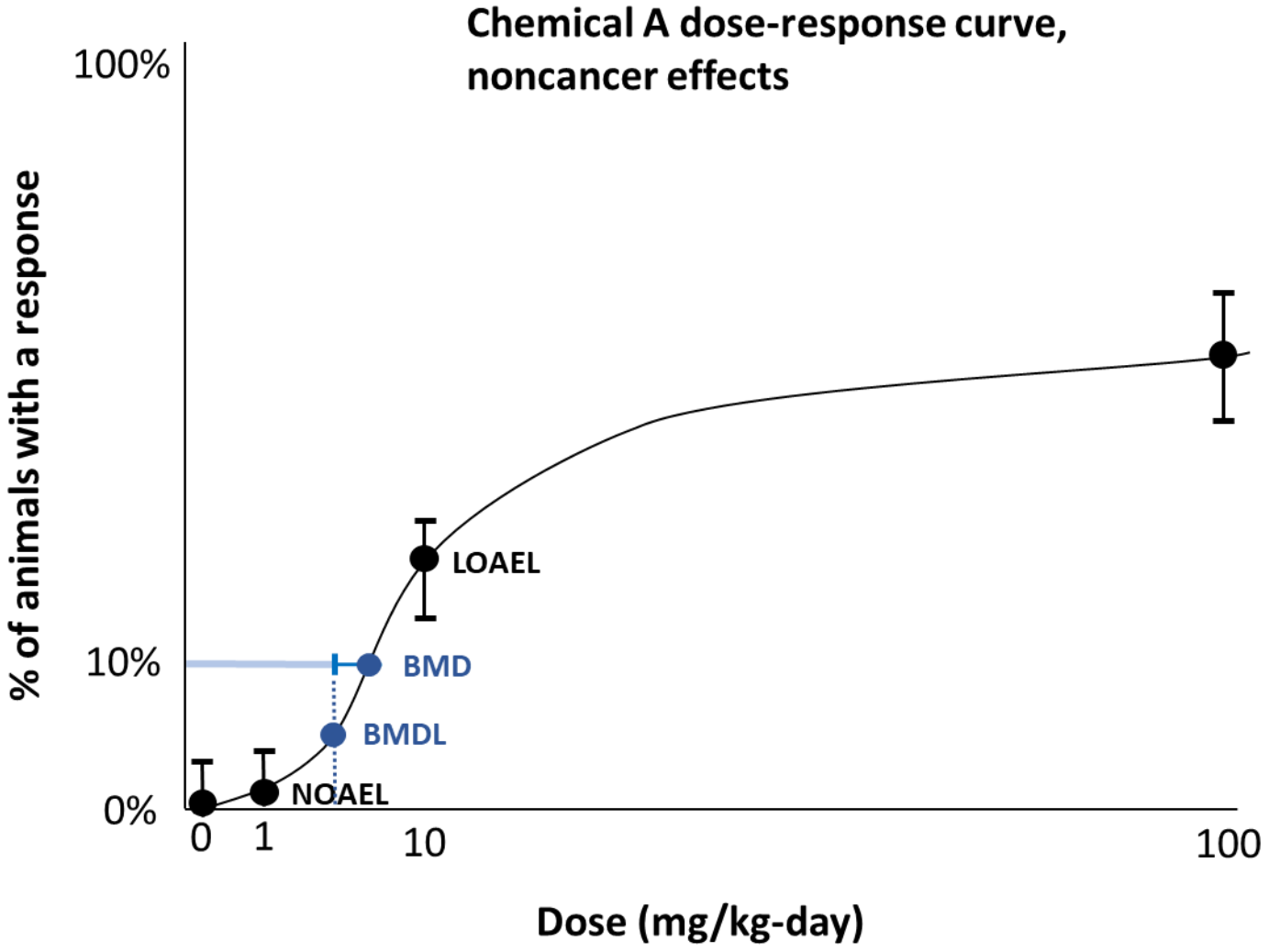
“Non-linear” or “Threshold” Dose-Response Curve

- There are doses that do not result in adverse effects in the available studies.
- Calculating a Point of Departure (POD)
- Developing Uncertainty Factors (UFs)
- Reference Dose = POD/UFs



Understanding the POD Chosen for Chemical A

- Lowest Observed Adverse Effect Level (LOAEL); the lowest dose at which adverse effects are occuring in the animals.
- No Observed Adverse Effect Level (NOAEL); the dose at which there are not adverse effects occuring in the animals.
- Benchmark Dose (BMD); computer modeled dose that defines the dose that causes a pre-defined response rate (e.g., 10%) in a toxicity study.
- Benchmark Dose Lower Bound (BMDL); the lower confidence bound of the BMD.



Reference Dose (RfD) from the POD using Uncertainty Factors (UFs)

- **Reference Dose = POD / UF_{Total}**
  - *A reference dose is an estimate of the amount of a chemical a person can ingest daily over a lifetime (chronic RfD) or less (subchronic RfD) that is unlikely to lead to adverse health effects.*
- Five areas of uncertainty
  - Intraspecies variation (UF_H) 
  - Interspecies variation (UF_A) 
  - Uncertainty due to the duration of study (UF_S) 
  - Uncertainty due to use of a LOAEL (UF_L) 
  - Uncertainty due to an inadequate database (UF_D) 

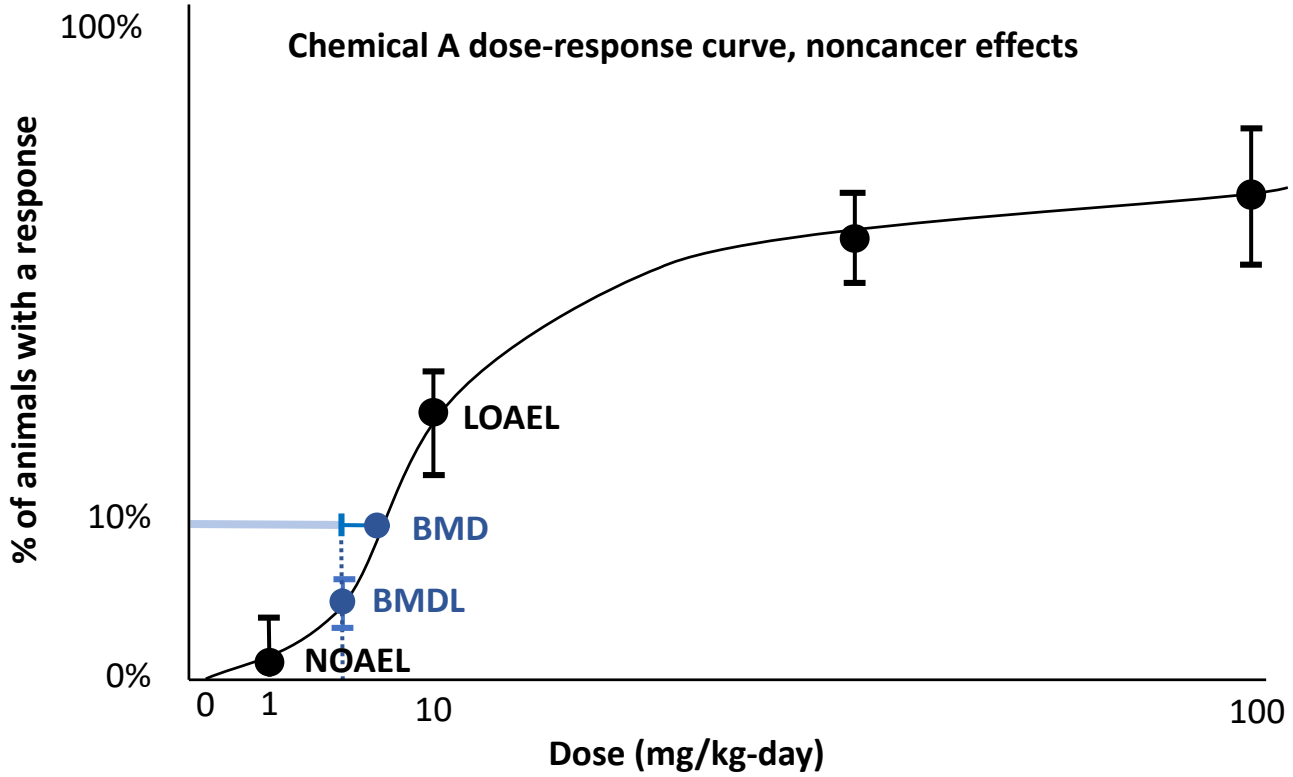
$$UF_{Total} = UF_H \times UF_A \times UF_S \times UF_L \times UF_D$$

- UF can be assigned either 1, 3, or 10
- EPA policy is that the maximum total UF = 3000

Example Calculation of the Reference Dose (Rfd)

- Selecting the POD
  - $BMDL_{10}$ = 5 mg/kg-day
- Choosing Uncertainty Factors
  - **UF_H** = 10
  - **UF_A** = 10
  - **UF_D** = 3
- Calculating the RfD
  - RfD = $\frac{\text{5 mg/kg-day}}{300}$

RfD= **0.02 mg/kg-day**



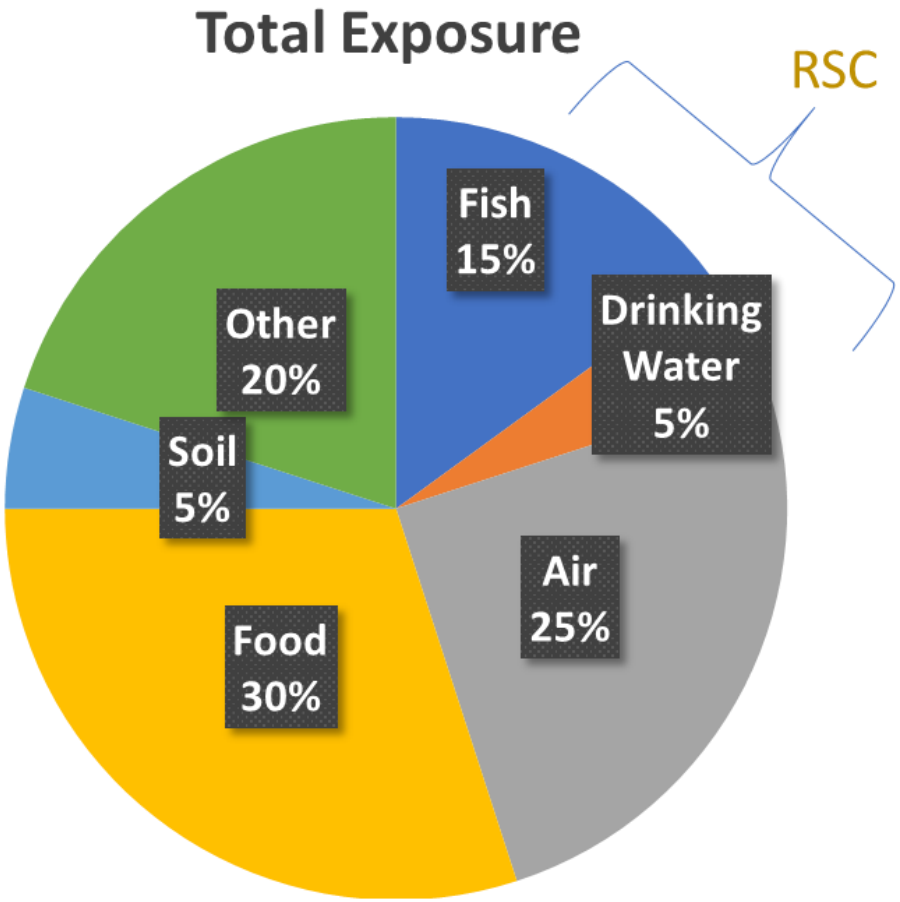
Calculating a Criteria for a Threshold Contaminant

$$AWQC = RfD * RSC * \left(\frac{BW}{DI + \sum_{i=2}^{4} FI_i * BAF_i} \right)$$

Hey! What's an RSC?

Understanding the Relative Source Contribution (RSC)

- The RSC is the percentage of your total exposure to the pollutant coming from drinking water and eating fish and shellfish.
  - EPA uses the decision tree for RSC's in the 2000 methodology when making decisions about the RSC.
  - Generally, EPA selects an RSC of 20%, unless there are quantitative data on all sources of exposure that could be used to calculate a % RSC.
- Other sources of exposure could include:
  - Inhalation from ambient air
  - Consumption of food (especially locally-grown and prepared)
  - Consumption of soil or dust



Formula for calculating criteria for linear contaminant

$$AWQC = RSD * \left(\frac{BW}{DI + \sum_{i=2}^{4} FI_i * BAF_i} \right)$$

Formula for calculating criteria for non-linear contaminant

$$AWQC = RfD * RSC * \left(\frac{BW}{DI + \sum_{i=2}^{4} FI_i * BAF_i} \right)$$

An Example calculation of a threshold criterion Input Variables

- **RfD = 0.02 mg/kg-day**
- **BW = 80 kg**
- **DI = 2.4 L/day**
- **FI**
  - **TL 2 = 7.6 g/day**
  - **TL 3 = 8.6 g/day**
  - **TL 4 = 5.1 g/day**
- **BAF**
  - **TL 2 = 120 g/day**
  - **TL 3 = 200 g/day**
  - **TL 4 = 560 g/day**

Example Calculation of the Threshold Criterion

$$\mathrm{AWQC} = \mathrm{RfD} * \mathrm{RSC}* \left(\frac{\mathrm{BW}}{\mathrm{DI}+\sum_{i=2}^{4} \mathrm{FI_i}*\mathrm{BAF_i}}\right)$$

$$\text{Chemical A AWQC} = \mathbf{0.02}\,\frac{\mathbf{mg}}{\mathbf{kg-day}} * \mathbf{20\%} * \frac{\mathbf{80\ kg}}{\mathbf{2.4}\,\frac{\mathbf{L}}{\mathbf{day}} + (\mathbf{0.0076}\,\frac{\mathbf{kg}}{\mathbf{day}} * \mathbf{120}\,\frac{\mathbf{L}}{\mathbf{kg}} + \mathbf{0.0086}\,\frac{\mathbf{kg}}{\mathbf{day}} * \mathbf{200}\,\frac{\mathbf{L}}{\mathbf{kg}} + \mathbf{0.0051}\,\frac{\mathbf{kg}}{\mathbf{day}} * \mathbf{560}\,\frac{\mathbf{L}}{\mathbf{kg}})}$$

$$\text{Chemical A AWQC} = 0.04\text{mg/L}$$

Demonstration of Human Health Calculator

https://www.epa.gov/wqs-tech/water-quality-standards-tools-tribes