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# Human Health Ambient Water Quality Criteria (AWQC)

Water Quality Standards Academy

# Background

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- A Human Health AWQC is the highest concentration of a pollutant in water that is not expected to pose a significant risk to human health.
- EPA publishes two types of human health criteria:
  - Protection from ingesting water and aquatic organisms
  - Protection from ingesting aquatic organisms only

# Equations for Deriving AWQC

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- Noncancer Effects:

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

- Cancer Effects:
  - Nonlinear

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

- Cancer Effects:
  - Linear

$$AWQC = RSD \cdot \left( \frac{BW}{DI + \sum_{i=2}^4 (FI_i \cdot BAF_{i3})} \right)$$

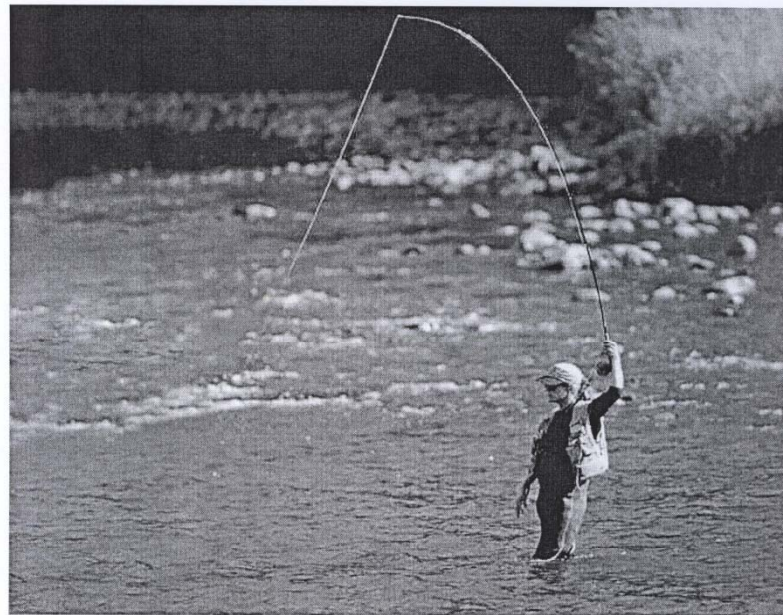
United States  
Environmental Protection  
Agency

Office of Water  
Office of Science and Technology  
4304

EPA-822-B-00-004  
October 2000



## Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)



[www.epa.gov/waterscience/criteria/humanhealth/method/index.html](http://www.epa.gov/waterscience/criteria/humanhealth/method/index.html)

3-13-2012

# Data Needs

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- Toxicity
  - Toxic effects and dose-response properties
  - Risk Specific Doses for linear carcinogens
  - Point of Departure (POD)/Uncertainty Factor (UF) for nonlinear carcinogens
  - Reference dose (RfD) for noncarcinogens
- Exposure
  - Relative Source Contribution (RSC)
  - Exposure parameters: body weight (BW) drinking water intake (DI) and Fish Intake (FI)

# Data Needs (contd.)

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- Bioaccumulation factors (BAFs)
  - Site-specific BAFs or National BAFs
    - Use of site-specific BAFs encouraged
  - Trophic level data on accumulation of chemical in fish or shellfish

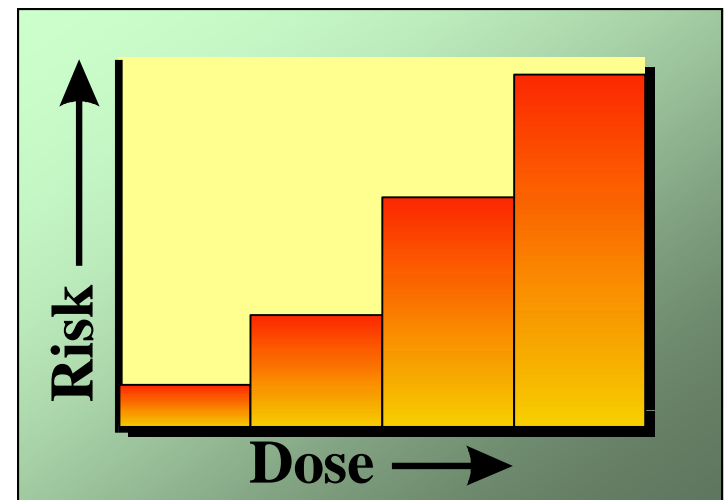
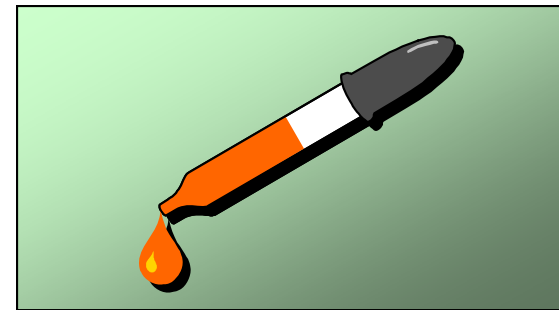
# Types Of Effects: Historical View

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- Cancer effects
  - Nonthreshold
  - Some risk at all doses
  - Linear response to dose
- Noncancer effects
  - Threshold
  - Acute, subchronic, or chronic
- Organoleptic effects
  - Taste, Odor, Color, etc.

# Nonthreshold Effects

- All Levels of exposure pose some probability of an adverse response
- Incremental risk levels can be calculated
- EPA targets a risk level of one in one million ( $10^{-6}$ )

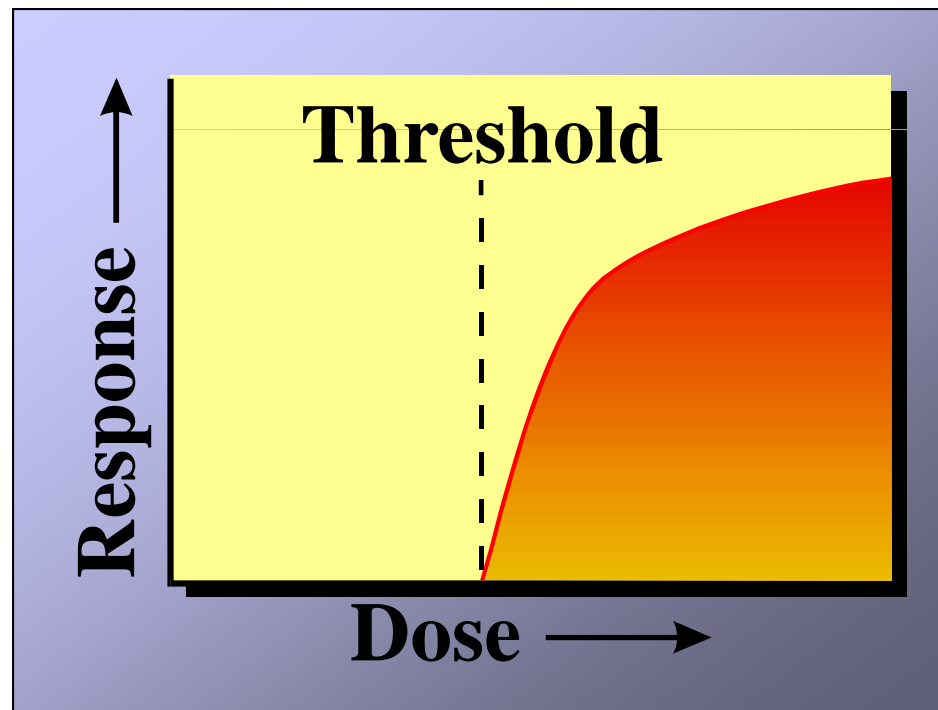




# Threshold Effects

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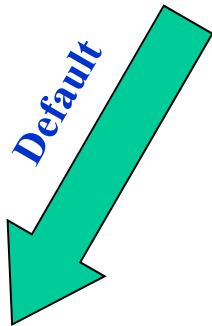
Exposures to some finite value are expected to be without adverse effect on human health



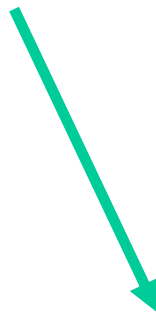
# Present View Of Toxicants

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**Carcinogens**



**Linear**



**Nonlinear**

**Noncarcinogens**



**Linear ?**

# Noncancer Dose-response Values\*

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## NONCANCER

- Reference Dose (RfD)
  - An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to humans (including sensitive subgroups) that is likely to be without an appreciable risk of adverse effects during a lifetime.

\* Risk values and complete toxicological assessments may be found on EPA's Integrated Risk Information System (IRIS) at [www.epa.gov/iris](http://www.epa.gov/iris)

# Noncancer Effects

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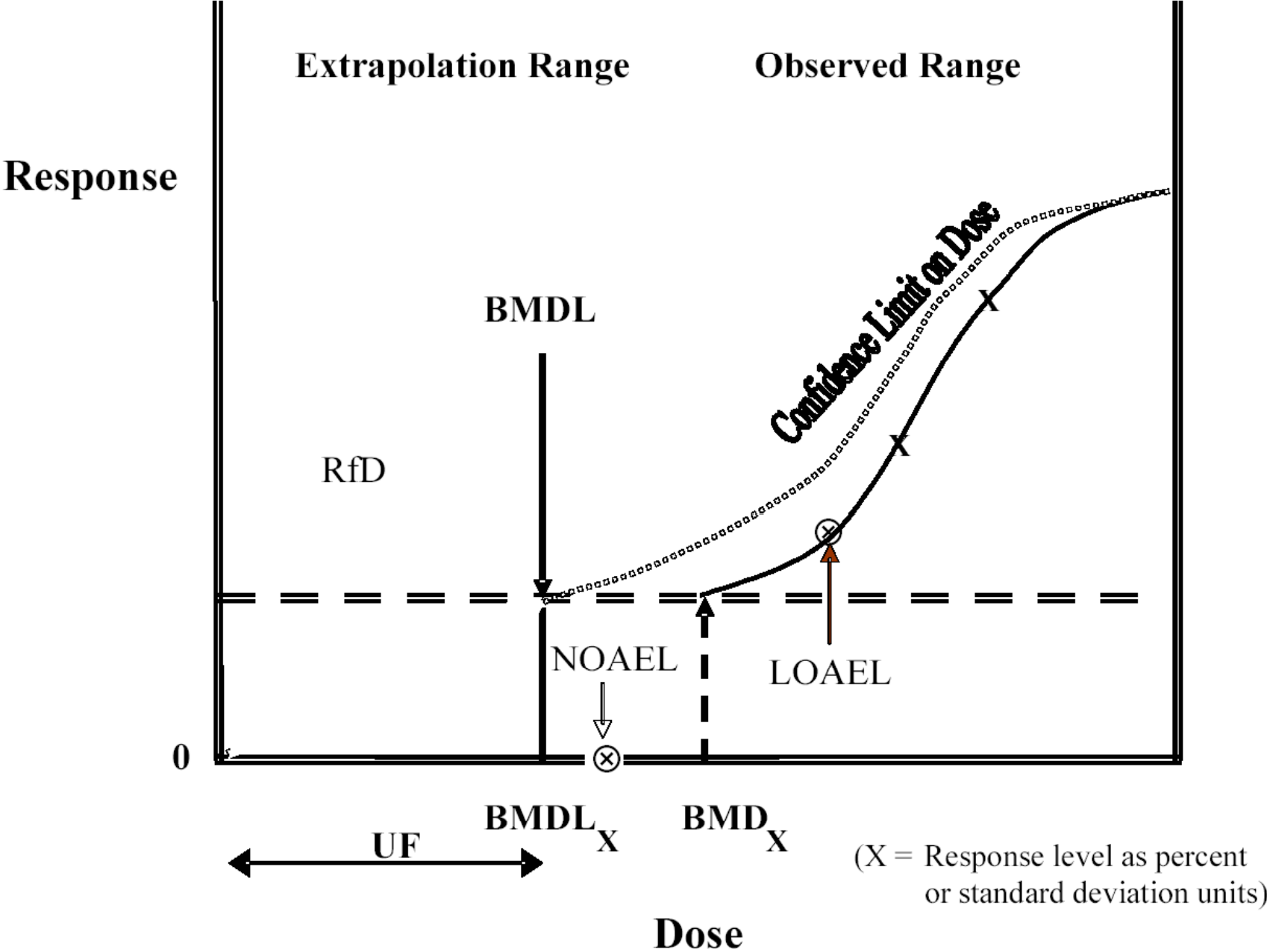
- RfD Derivation

RfD = Point of Departure divided by Uncertainty Factor (UF)

- Point of Departure

- No Observed Adverse Effect Level (NOAEL)
- Lowest Observed Adverse Effect Level (LOAEL)
- Benchmark Dose (BMD)

# Benchmark Dose Model



# Uncertainty Factors

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- Five areas of consideration
  - 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 an inadequate database ( $UF_D$ )
- Invoked as integers of 1, 3, 10
  - 3 is a half  $\log_{10}$
  - Value selected determined by the data available
  - Usually  $\leq 3,000$

# General Equation For Noncancer Effects

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$$AWQC = RfD \times RSC \times \left[ \frac{BW}{DI + (FI \times BAF)} \right]$$

**AWQC = Ambient Water Quality Criterion (mg/L)**

**RfD = Reference Dose (mg/kg-day)**

**RSC = Relative Source Contribution (% , to account for other sources of exposure)**

**BW = Human Body Weight (kg, 70 for average adult)**

**DI = Drinking Water Intake (L/day, 2 for average adult)**

**FI = Fish Intake (kg/day)**

**BAF = Bioaccumulation Factor (L/kg)**

# Carcinogen Dose-response Values\*

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- Risk Specific Dose (RSD) for linear carcinogens
  - RSD is the acceptable risk Level divided by the **Cancer Slope Factor**
  - EPA recommends  $10^{-6}$ , (one in a million chance of cancer), but accepts the  $10^{-5}$  risk level as long as highly exposed populations do not exceed  $10^{-4}$  risk level
- POD/UF approach for nonlinear carcinogens

\* Risk values and complete toxicological assessments may be found on EPA's Integrated Risk Information System (IRIS) at [www.epa.gov/iris](http://www.epa.gov/iris)

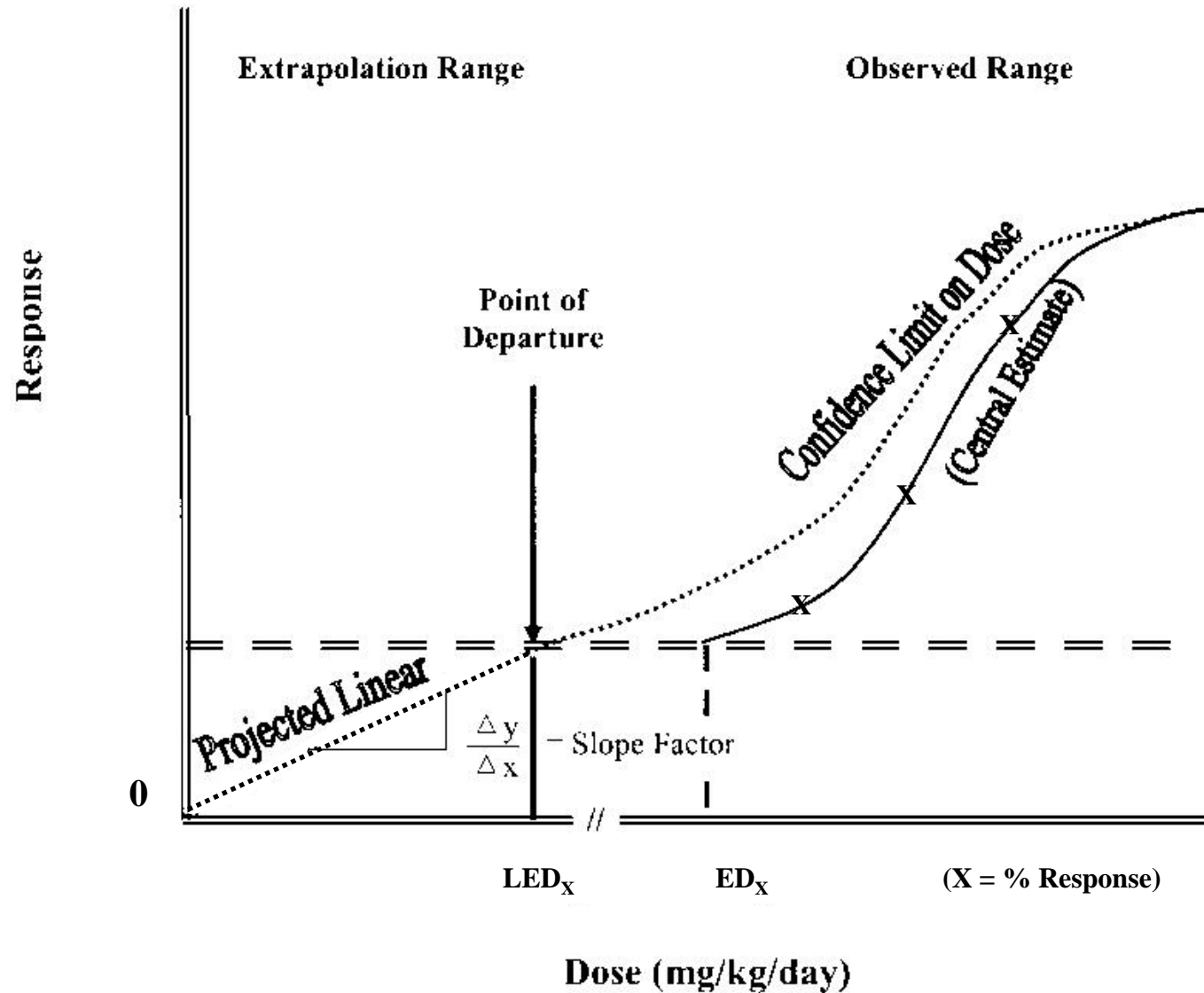


# Cancer Descriptors

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- Known human carcinogen
- Likely human carcinogen
  - Likely by all exposure routes
  - Likely at high doses but unlikely at low doses
    - Signifies a nonlinear mode of action
  - Likely by one route of exposure but not for other exposure routes
- Suggestive evidence of carcinogenicity
  - In most cases dose response will not be quantified for chemicals with this descriptor
- Unable to make a determination about possible carcinogenicity
- Not a carcinogen

# Dose-Response for Carcinogens: Linear



# General Equation For Linear Cancer Effects

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$$AWQC = RSD \times \left[ \frac{BW}{DI + (FI \times BAF)} \right]$$

**AWQC = Ambient Water Quality Criterion (mg/L)**

**RSD = Risk Specific Dose (mg/kg-day)**

**BW = Human Body Weight (kg, 70 for average adult)**

**DI = Drinking Water Intake (L/day, 2 for average adult)**

**FI = Fish Intake (kg/day)**

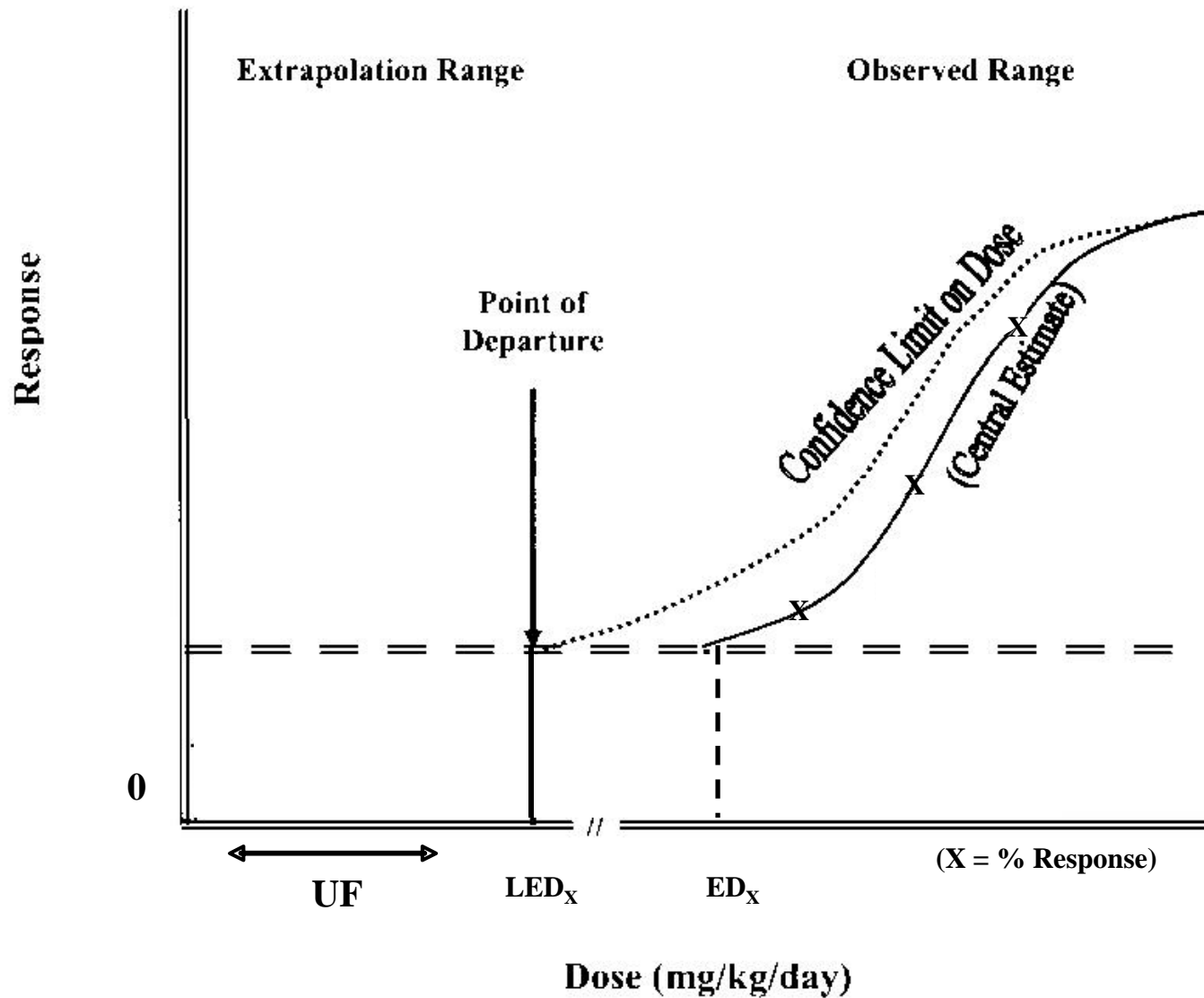
**BAF – Bioaccumulation Factor (L/kg)**

# Nonlinear Carcinogen

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- Must know the mode of action (MOA) to use this approach
- Mode of Action must support a zero slope at a dose of zero
  - Only possible for nonmutagenic chemicals
  - A MOA is "a sequence of key events starting with interaction of an agent with a cell, proceeding through functional and anatomical changes, and resulting in cancer formation." (U.S.EPA, 2005)
- Select the POD for quantification
  - A POD based on an event in the mode of action that occurs before tumors is preferred
    - Examples
      - cytotoxicity,
      - regenerative hyperplasia (tissue repair)
  - Comparable to RfD derivation

# Dose-Response for Carcinogens: Nonlinear



# General Equation For Nonlinear Cancer Effects

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$$AWQC = POD/UF \times RSC \times \left[ \frac{BW}{DI + (FI \times BAF)} \right]$$

**AWQC = Ambient Water Quality Criterion (mg/L)**

**POD/UF = Point of Departure/Uncertainty Factor (mg/kg-day)**

**RSC = Relative Source Contribution (to account for other sources of exposure)**

**BW = Human Body Weight (kg, 70 for average adult)**

**DI = Drinking Water Intake (L/day, 2 for average adult)**

**FI = Fish Intake (kg/day) = Bioaccumulation Factor (L/kg)**

**BAF = Bioaccumulation factor (L/kg)**

# Exposure Assessment

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- There are two primary exposure sources of concern for deriving human health water quality criteria.
  - Direct ingestion of drinking water
  - Consumption of fish/shellfish
- Other sources of exposure to a given contaminant are also considered when deriving criteria for non-carcinogens and non-linear carcinogens, as part of the Relative Source Contribution (RSC) analysis.

# Exposure Parameters and Protection Goals

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- EPA generally assumes daily exposure over the course of a lifetime.
- EPA generally assigns a mix of average values and high end values (e.g., 90<sup>th</sup> percentile) for exposure parameters such as ingestion rates and body weight.
- EPA's criteria are derived to protect the majority of the general population.



# EPA's Default Exposure Parameters

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

- BW = 70 kg; average adult body weight
- DI = 2 L/day; 90<sup>th</sup> percentile estimate
- FI = 17.5 g/day; 90<sup>th</sup> percentile estimate
- These parameters will be used by EPA for the national recommended water quality criteria when chronic health effects are of concern.

# Other Exposure Parameter Options

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- In special circumstances, when the basis of a health assessment is a developmental effect, EPA recommends the following parameter values:
  - Women of childbearing age (ages 15-44), when fetal developmental effects are the most sensitive health endpoint
    - BW = 67 Kg; average body weight
    - DI = 2 L/day; 90<sup>th</sup> percentile estimate
  - Children
    - BW = 30 Kg; ages 1-14
      - = 13 Kg; toddlers (ages 1-3)
      - = 7 Kg; infants
    - DI = 1 L/day for all three sub-categories, above

# Additional Fish Intake Values

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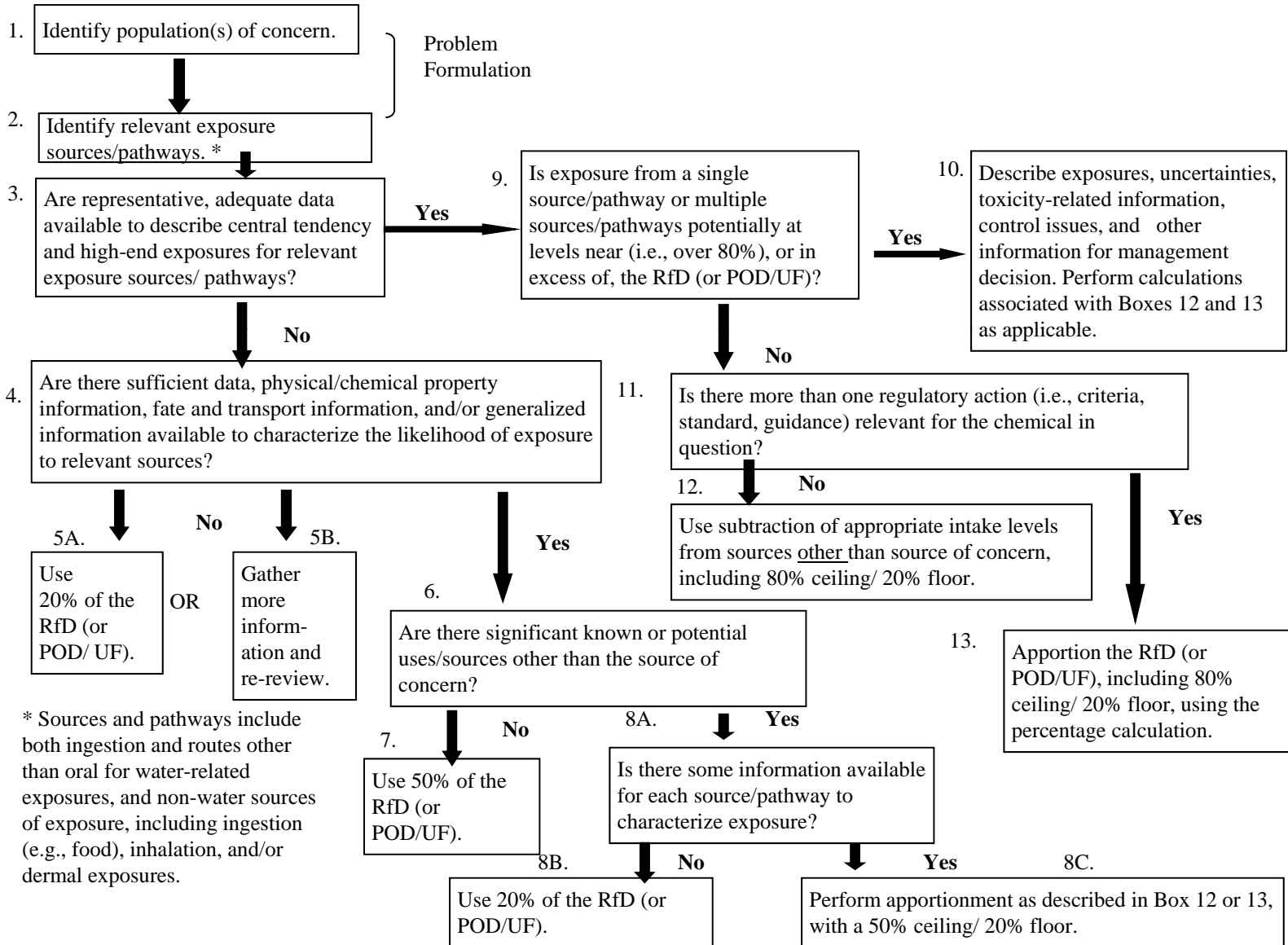
- For chronic health effects when targeting:
  - Recreational fishers = 17.5 g/day
    - Estimate of 90<sup>th</sup> percentile consumption of freshwater/estuarine fish/shellfish;
  - Subsistence fishers = 142.4 g/day
    - High-end estimate of consumption of freshwater/estuarine fish/shellfish.
- For developmental health effects when targeting:
  - Women of childbearing age (re: fetal effects) = 165.5 g/day
    - Estimate of 90<sup>th</sup> percentile meal size of freshwater/estuarine fish/shellfish;
  - Children (ages 1-14) = 156.3 g/day
    - Estimate of 90<sup>th</sup> percentile meal size of freshwater/estuarine fish/shellfish.

# Relative Source Contribution

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- Accounts for exposures from sources other than water and freshwater/estuarine fish and shellfish ingestion
  - Inhalation for airborne sources
  - Consumption of food
  - Consumption of marine aquatic organisms
- Not applied to linear carcinogens (i.e., those associated with a risk level)
- Expressed as a percentage of or subtracted from the RfD or nonlinear carcinogen depending on the circumstances

**Figure 4-1.**  
**Exposure Decision Tree for Defining Proposed RfD**  
**(or POD/UF) Apportionment**



# Bioaccumulation

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

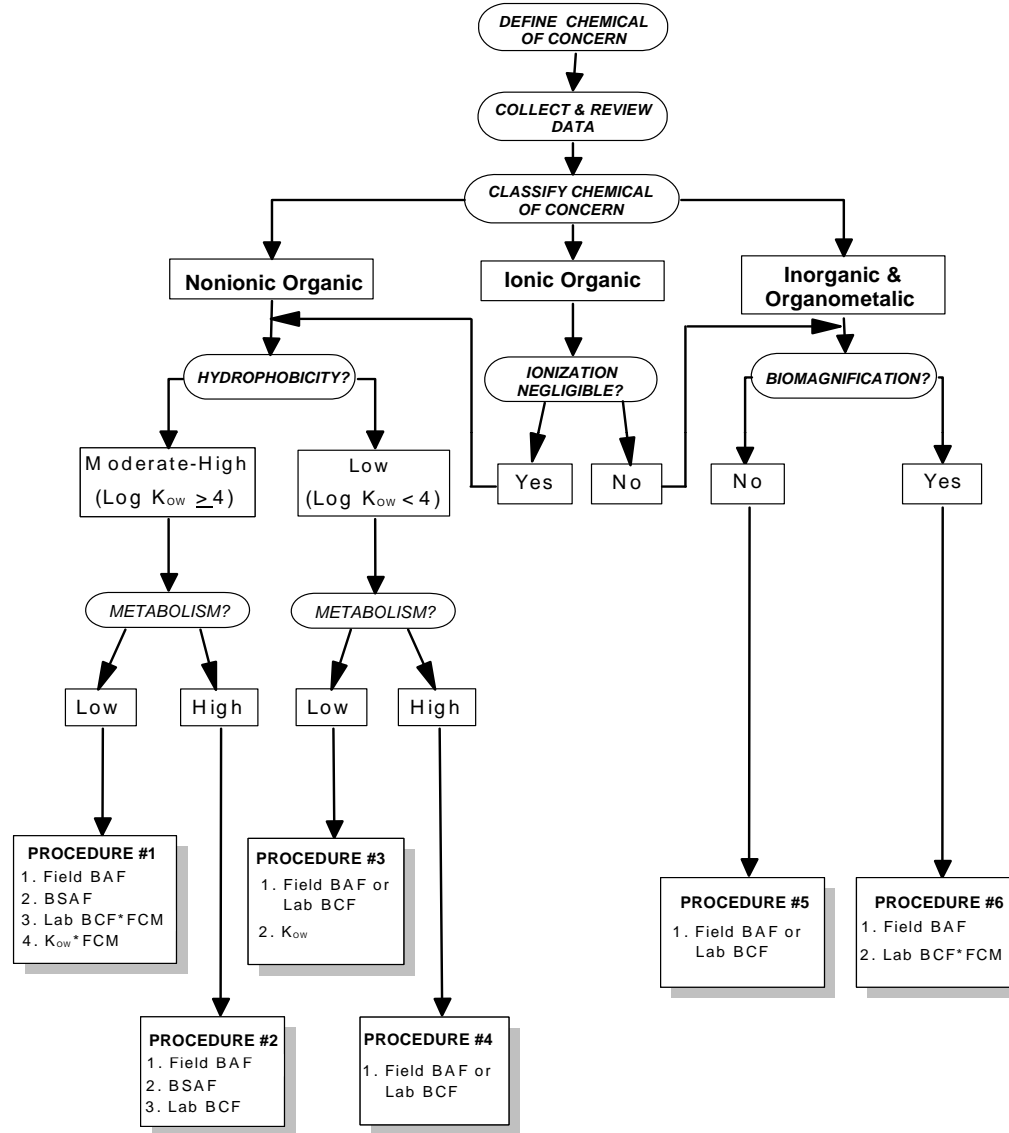
# Bioaccumulation Factors

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$$\text{BAF} = \frac{\text{Concentration in Tissue}}{\text{Concentration in Water}}$$

- A BAF reflects for uptake from all media exposures (water, food, sediment).
- A BCF reflects uptake from water only; and can substantially underestimate accumulation for highly hydrophobic chemicals.

Figure 5-1. Framework for Deriving a National BAF





# Methods for Deriving BAFs

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- Field-measured BAF (preferred for all chemicals)
- BAF from a Biota-Sediment Accumulation Factor (BSAF)
- BAF from a laboratory BCF\*
- BAF from chemical's Octanol-Water Partition Coefficient ( $K_{ow}$ )\*

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

# Baseline BAF

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**Field BAF, Field BSAF or Lab BCF**  
(Nonionic Organic Chemicals)

Normalize to the lipid content of species  
considering each trophic level

Convert the total water concentration to the  
freely dissolved concentration using the organic  
carbon content of the water

**Baseline BAF**

( $K_{ow}$  is equivalent to a baseline value)

Adjust to reflect National Default Organic  
Carbon and Trophic-Level Specific Lipid

**National BAF**

# Fish Tissue Criteria

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- HH AWQC Criteria can be expressed as a fish tissue concentration by dropping the Drinking Water Intake and BAF terms
  - Useful for pollutants where BAF is highly variable due to site-specific factors (e.g., Methylmercury)
  - Allows direct measurement of fish tissue for assessment purposes
  - Requires additional implementation procedures for deriving effluent limits

# Fish Consumption Advisories

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- The EPA Fish Consumption Advisory Program uses a methodology that differs from the AWQC program
  - Both programs use the same toxicological benchmarks (i.e., reference dose and risk specific dose)
- Fish tissue advisories are based on a characterization of measured concentrations in fish tissues from a specific waterbody
- Based on measured fish tissue concentrations and toxicity benchmarks, the allowable "fish meals per month" are calculated and communicated to populations at risk
- Additional information available at:

<http://www.epa.gov/waterscience/fish/advice/es.html>

# Question #1

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Which of the following is not a typical element of an assessment for deriving Section 304(a) criteria?

- a. exposure
- b. treatment technologies
- c. bioaccumulation
- d. toxicity
- e. criterion formulation

# Question #1

---

Which of the following is not a typical element of an assessment for deriving Section 304(a) criteria?

- a. exposure
- b. treatment technologies
- c. bioaccumulation
- d. toxicity
- e. criterion formulation

*b. The other four elements are usually part of an assessment for developing or revising Section 304(a) criteria. Consideration of treatment technologies is not part of the criteria derivation process. Section 304(a) criteria are based solely on human health and do not reflect consideration of economic impacts or technological feasibility.*

## Question #2

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*True or False?*

*Section 304(a)(1) criteria are regulatory limits  
States are required to adopt.*

# Question #2

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*True or False?*

*Section 304(a)(1) criteria are regulatory limits States are required to adopt.*

*False. These criteria are not Federal regulations; however, they are sometimes used by the States and Tribes to establish standards. They present scientific data and guidance on the environmental effect of pollutants, which can be useful to derive regulatory requirements.*



# Question #3

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*True or False?*

*Health assessments may include data and information on cancer effects, noncancer effects, and organoleptic effects.*

# Question #3

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*True or False?*

*Health assessments may include data and information on cancer effects, noncancer effects, and organoleptic effects.*

*True. The review of health effects data and relevant information may address carcinogenic endpoints, noncancer endpoints, and/or undesirable taste and odor (organoleptic) effects imparted by a chemical to ambient water.*

# Question #4

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*True or False?*

*The RfD is a threshold value below which noncarcinogenic toxic effects are unlikely to occur.*

# Question #4

---

*True or False?*

*The RfD is a threshold value below which noncarcinogenic toxic effects are unlikely to occur.*

*True. RfD is the reference dose or the daily estimated exposure to a human population that is not likely to cause deleterious effects over a lifetime. The RfD is expressed as milligrams of toxicant per kilogram of human body weight per day (mg/kg/day).*

# Question #5

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*The Carcinogenic Potency Slope factor is \_\_\_\_\_:*

- a. RL
- b. RfD
- c. BCF
- d. CSF or  $q1^*$
- e. BAF

# Question #5

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*The Carcinogenic Potency Slope factor is \_\_\_:*

- a. RL
- b. RfD
- c. BCF
- d. CSF or q1\*
- e. BAF

*d. CSF or SF is the more recent abbreviation for the cancer slope factor. Older assessments use the q1\* designation. The CSF is a number that provides an indication of the potential a chemical has to cause cancer in humans. The number is derived from animal studies or epidemiological data on human exposures and use of a linear extrapolation model. The CSF is expressed in units of (mg/kg/day)<sup>-1</sup>.*

## Question #6

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*The process of uptake and accumulation of a chemical through the food chain and water is called?*

- a. Food Chain Multiplier
- b. Bioaccumulation
- c. Bioconcentration
- d. RfD
- e. RSC

# Question #6

---

*The process of uptake and accumulation of a chemical through the food chain and water is called?*

- a. Food Chain Multiplier
- b. Bioaccumulation
- c. Bioconcentration
- d. RfD
- e. RSC

*b. Bioaccumulation. Bioconcentration considers only uptake of a contaminant through exposure to water*



# Question #7

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Which of the following is a method of accounting for multiple sources of exposure when developing human health criteria?

- a. RfD
- b. RfC
- c. RSC
- d. RSD
- e. BAF

# Question #7

---

Which of the following is a method of accounting for multiple sources of exposure when developing human health criteria?

- a. RfD
- b. RfC
- c. RSC
- d. RSD
- e. BAF

*c. RSC. The Relative Source Contribution (RSC) method of considering other exposures (e.g. non-fish dietary intakes, air, soil) determines the RSC factor used in the criteria calculations, which ensures that each criterion is protective of all likely or anticipated exposure, sources/routes relevant to the chemical.*

## Question #8

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*An electronic online data base of the U.S. EPA accepted source for RfD values is \_\_\_\_\_ .*

- a. BAF*
- b. BCF*
- c. RfD*
- d. IRIS*
- e. CSF*

# Question #8

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*An electronic online data base of the U.S. EPA accepted source for RfD values is \_\_\_\_\_ .*

- a. BAF*
- b. BCF*
- c. RfD*
- d. IRIS*
- e. CSF*

*d. The Integrated Risk Information System (IRIS) is an electronic online data base of the U.S. EPA that provides chemical-specific risk information on the relationship between chemical exposure and estimated human health effects.*

# Question #9

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*True or False?*

*Section 304(a) criteria are always expressed as chemical concentrations in the water column (e.g., as a mg/L value).*

# Question #9

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*True or False?*

*Section 304(a) criteria are always expressed as chemical concentrations in the water column (e.g., as a mg/L value).*

*False. Although most current Section 304(a) criteria are expressed as water column values, the criteria may also be expressed as fish tissue concentrations (e.g., the methylmercury criterion). The fish tissue values are very useful when bioaccumulation is highly variable and they allow for direct measurement when assessing compliance monitoring.*