Human Health Ambient Water Quality Criteria

Human Health Risk Assessment Branch/HECD/OST/OW

US Environmental Protection Agency

Virtual WQS Academy May 2023

Disclaimer

This presentation does not:

- Impose any binding requirements
- Determine the obligation of the regulated community
- Change or substitute for any statutory provision or regulatory requirement
- Change or substitute for any Agency policy or guidance
- Control in any case of conflict between this discussion and any statute, regulation, policy, or guidance

The views expressed in this presentation are those of the authors and do not necessarily represent the views or policies of the U.S. Environmental Protection Agency.

Outline

- 1. What are aquatic water quality criteria (AWQC)?
- How are health assessments interpreted and used?
 - Hazard identification
 - Dose response: Linear and non-linear for cancer and noncancer health effects
- 3. How is an exposure analysis conducted?
 - Identification of Target population
 - Defining exposure parameters for target population
 - Drinking water intake, fish consumption, bioaccumulation factor, relative source contribution
- 4. How is a human health criterion calculated?
 - Equations used to calculate AWQC

EPA Method for AWQC Development

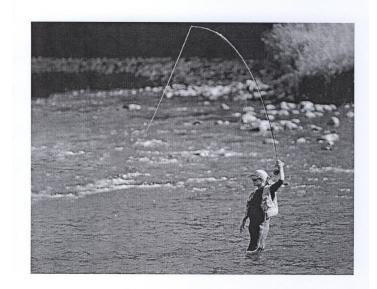


Office of Water
Office of Science and Technology
4304

EPA-822-B-00-00-October 2000

SEPA

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



Source: USEPA (2000a). Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health

- Describes EPA's recommended current methods for developing AWQC as required under Section 304(a) of the Clean Water Act (CWA).
 - States and authorized Tribes are required to adopt regulations which contain legally enforceable criteria
- Summarizes "state of the science" as of 2000
- Recommends approaches based on different chemical properties, exposure scenarios, and risk management policy decisions.

2015 Updated AWQC

Goals

- Incorporate the latest science on toxicity and exposure
- Increase transparency

Process

- May 2014: EPA published draft updated criteria for 94 chemicals
- August 2014: 90-day extended public comment period closed
- June 2015: EPA published final updated criteria for 94 chemicals based on peer reviewed studies and methods

Outcomes

- 94 of 116 chemicals were updated
- Publication of 94 criteria documents addressing chemical specific input values, assumptions, and calculations

Source: USEPA (2015a). <u>Human Health Ambient Water Quality Criteria</u>: 2015 Update Factsheet

What are AWQC?

- Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and drinking water, including incidental water consumption related to recreational activities.
- Water quality criteria can be referred to as
 - Ambient Water Quality Criteria (AWQC)
 - Human Health Criteria (HHC)
 - 304a Criteria

Source: USEPA (2000a). Section 1.1 Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health

AWQC Example: Chlorobenzene

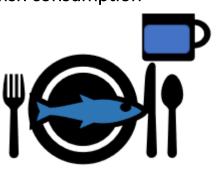
 $100 \mu g/L$

 $800 \mu g/L$

 $20 \mu g/L$

Water and Organism Criteria

Protects against histopathologic changes in the liver from exposure to chlorobenzene through drinking water and fish/shellfish consumption



Organism Only Criteria

Protects against histopathologic changes in the liver from exposure to chlorobenzene through fish/shellfish consumption only



Organoleptic Criteria

Controls undesirable taste and odor quality



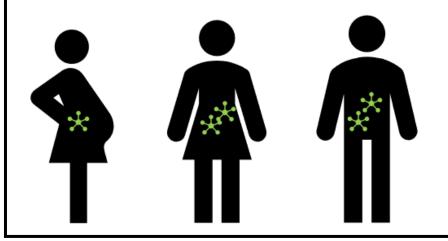




*Chlorobenzene is also regulated under the Safe Drinking Water Act, and therefore has a National Primary Drinking Water Regulation.

Goal of AWQC

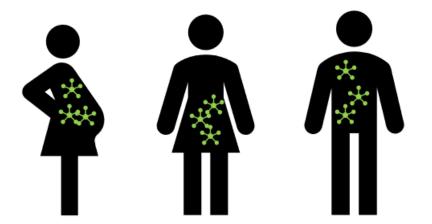
The concentration of the pollutant that the population is exposed to



Is less than or equal to



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



Example AWQC

1,1 Dichloroethylene

Water + Organism Criteria = $300 \mu g/L$

No adverse health effects are expected if the population is exposed to 1,1 dichloroethylene at concentrations \leq 300 µg/L.

Hexachlorobenzene*

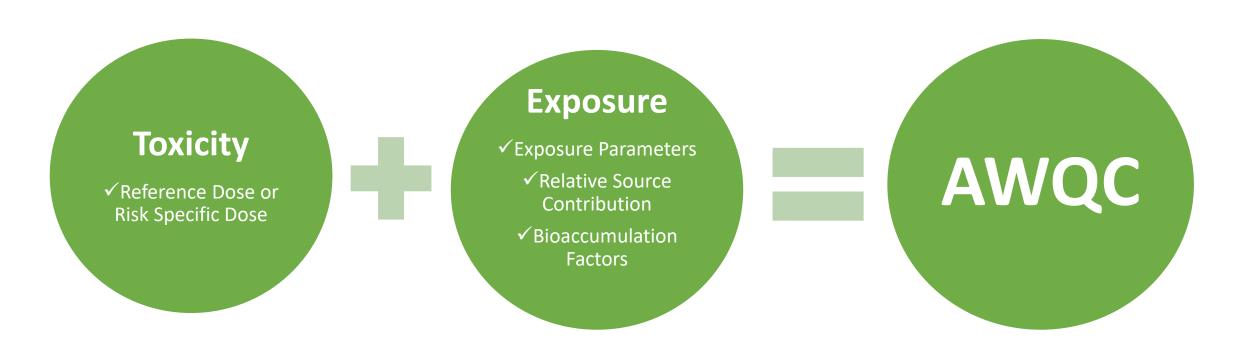
Water + Organism Criteria = $7.9 \times 10^{-5} \, \mu g/L$

There is potential for one additional cancer case per one million people due to exposure to hexachlorobenzene at concentrations

$$\leq$$
 7.9 x 10⁻⁵ µg/L.

^{*} This criterion is based on carcinogenicity of 10⁻⁶ risk.

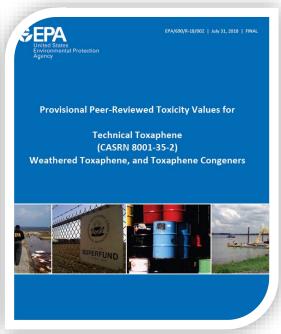
Required Information Input Values for Criteria Development



Learn About a Contaminant's Toxicity

Does the contaminant have publicly available Health Assessments?







Peer-reviewed health assessment sources include:

EPA Assessments

EPA considers *publicly available* assessments that have undergone *peer-review*.



Office of Water:

- Health Advisories, Criteria Documents, Health Effects Support Documents Office of Research and Development:
- Integrated Risk Information System assessments, Provisional Peer-Reviewed Toxicity
 Value Reports

Office of Pesticides

- Registration Eligibility Documents, Human Health Risk Assessments Office of Pollution Prevention and Toxics:
- Toxic Substance Control Act (TSCA) Risk Evaluations

Other Assessments



Agency for Toxic
Substances and Disease
Registry Toxicological
Profiles



Guidelines for Drinking
Water



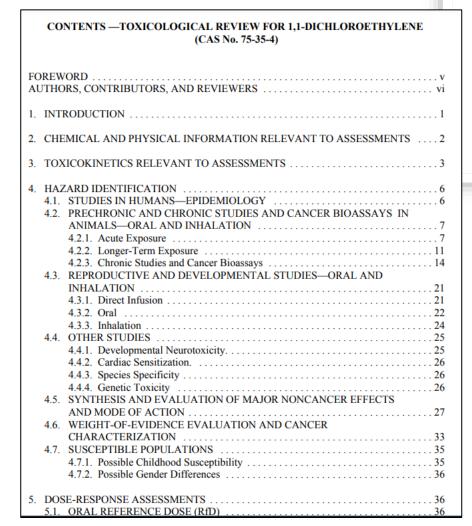
Drinking Water Guidelines



State assessments - e.g.,
CalEPA Public Health
Goals

Components of a Health Assessment

- Health assessments detail
 - Hazard (adverse health effects) and dose response for a given chemical.
 - dose-response information generally results in the development of toxicity values such as a Reference Dose (RfD) or Cancer Slope Factor (CSF)
 - Physical/chemical properties, fate and transport, use profiles, etc.



∲EPA

TOXICOLOGICAL REVIEW

OF

1,1-DICHLOROETHYLENE

(CAS No. 75-35-4)

In Support of Summary Information on the Integrated Risk Information System (IRIS)

June 2002

U.S. Environmental Protection Agency Washington, DC

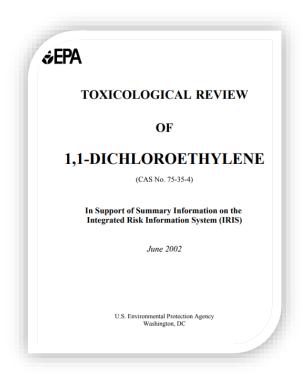
AWQC Example: 1,1 Dichloroethylene



Available Data Summarized in the Health Assessment

- Epidemiological study in 138 employees
 - no significant impact on hematology or clinical chemistry parameters (Ott et al., 1976)
- Acute study in rodents
 - increase in liver enzymes in serum (Jenkins et al., 1972)
- Chronic study in rats
 - liver toxicity (Quast et al., 1983)
- Chronic study in dogs
 - No adverse health effects observed (Quast et al., 1983)
- Developmental study in rats
 - No evidence of toxicity to dams or offspring (Murray et al., 1979)
- Carcinogenicity study in mice
 - Evidence of induction of kidney adenocarcinomas, however, data presented is insufficient (Speerschneider and Dekant, 1995; Amet et al., 1997; Cummings et al., 2000)

AWQC Example: 1,1 Dichloroethylene



The weight of evidence suggests that liver toxicity is the most sensitive effect (i.e. adverse effect seen at the lowest does)

Available Data Summarized in the Health Assessment

- Epidemiological study in 138 employees
 - no significant impact on hematology or clinical chemistry parameters (Ott et al., 1976)
- Acute study in rodents
 - increase in liver enzymes in serum (Jenkins et al., 1972)
- Chronic study in rats
 - liver toxicity (Quast et al., 1983)
- Chronic study in dogs
 - No adverse health effects observed (Quast et al., 1983)
- Developmental study in rats
 - No evidence of toxicity to dams or offspring (Murray et al., 1979)
- Carcinogenicity study in mice
 - Evidence of induction of kidney adenocarcinomas, however, data presented is insufficient (Speerschneider and Dekant, 1995; Amet et al., 1997; Cummings et al., 2000)

Hazard Identification: Qualitative Cancer Descriptors

- Assessments may assign qualitative cancer descriptors for evidence of human carcinogenic potential based on available cancer information
- 2005 EPA Cancer Guidelines replace the 1986 and 1999 guidelines.

2005 Cancer Descriptors

- Carcinogenic to humans
- Likely to be carcinogenic to humans
- Suggestive evidence of carcinogenic potential
- Inadequate information to assess carcinogenic potential
- Not likely to be a carcinogen

Helpful Guidance: USEPA (2005). Cancer Guidelines

AWQC Example: 1,1 Dichloroethylene

- Under the 1986 guidelines:
 - Group C, possible human carcinogen.
- Under the 1999 guidelines:
 - Suggestive evidence of carcinogenicity
- Under the 2005 guidelines:
 - Suggestive evidence of carcinogenic potential

Source: USEPA (2015c). <u>Update of Human</u> <u>Health Ambient Water Quality Criteria: 1,1</u> <u>Dichloroethylene</u>

Understanding Health Assessment Toxicity Conclusions

A pollutant typically has one prevailing dose-response pattern

Non-Linear or Threshold Dose-Response

Indicates that there is a dose below which no adverse effects were observed



Typical of non-cancer effects

Linear Dose-Response

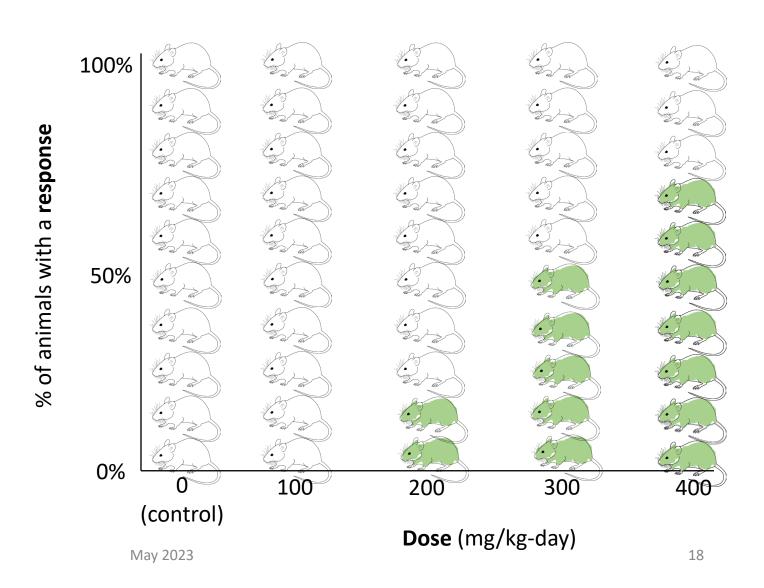
Assumes increased probability of effects at all levels of exposure



Typical of cancer effects

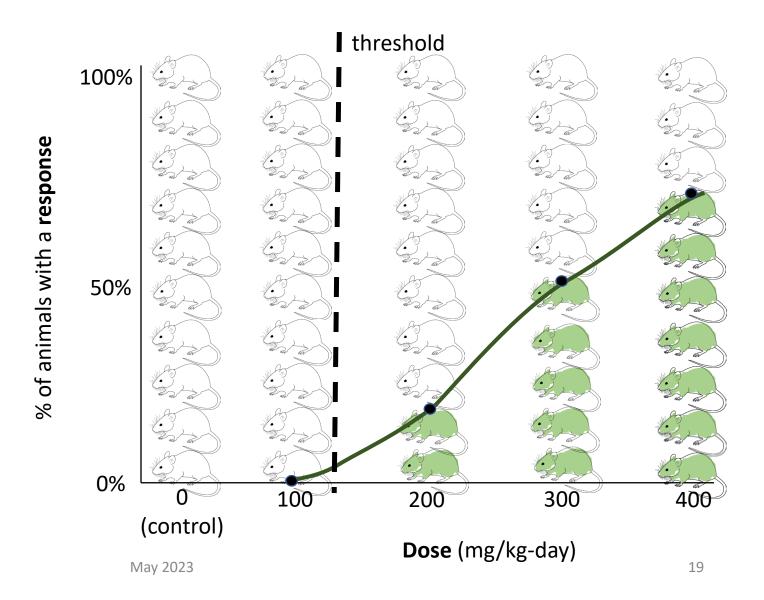
"Non-linear" or "Threshold" Dose-Response Curve

 In a hypothetical study, groups of 10 mice were exposed to Chemical A at 0, 100, 200, and 300, and 400 mg/kg/day.



"Non-linear" or "Threshold" Dose-Response Curve

- In a hypothetical study, groups of 10 mice were exposed to Chemical A at 0, 100, 200, and 300, and 400 mg/kg/day.
- We can see that exposure at some doses do not result in adverse effects.
 - Threshold
 - there is a dose below which no adverse effects were observed



"Point of Departure" for Threshold Effects

Point of Departure (POD) is the dose in the toxicity study used to calculate the "protective" dose in humans.

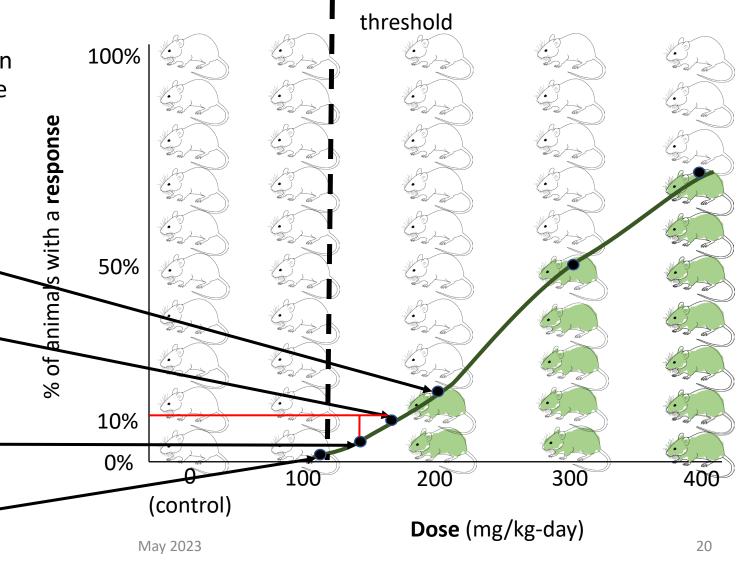
Possible PODs

LOAEL: lowest dose at which an adverse effect is observed

BMD: exposure level determined from a doseresponse model

BMDL: lower bound of confidence interval for BMD; corresponds to a pre-defined level of response (such as 5% or 10%) in excess of a control response

NOAEL: highest dose at which NO adverse effect is observed



Point of Departure (POD)

A point of departure (POD) is the dose in the toxicity study used to calculate the "protective" dose in humans. There are several different types of PODs:



Lowest observed adverse effect level (LOAEL) = lowest dose at which an adverse effect is observed



No observed adverse effect level (NOAEL) = highest dose at which no adverse effect is observed



Benchmark dose lower bound (BMDL) = lower bound of a confidence interval for a specific benchmark dose (BMD) which is a dose level corresponding to specific response levels, or benchmark responses, near the low end of the observable range of the data

Helpful Guidance: USEPA (2012). BMD Technical Guidance; USEPA (2023). BMD Tools

May 2023 21 Source: USEPA (2022). IRIS Glossary

Calculating a 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 study exposure duration (UF_s)

- Uncertainty due to use of a LOAEL (UF,)
- Uncertainty due to inadequate database (UF_D)



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

Helpful Guidance: EPA (2000b). <u>Technical</u>
Support Document Volume 1: Risk
Assessment



Example Uncertainty Factor Selection for AWQC

| Chemical | Selected Assessment | Critical Effect | POD | Uncertainty Factors | RfD |
|----------------------|---------------------|--|-------------------------------------|---|----------------|
| 1,1 Dichloroethylene | US EPA IRIS, 2002 | Liver toxicity in rats (chronic study) | $BMDL_{10} = 4.6 \text{ mg/kg-day}$ | TOTAL = 100 UF _H = 10 UF _A = 10 | 0.05 mg/kg-day |

Source: USEPA (2015c). <u>Update of Human Health Ambient Water Quality Criteria</u>: 1,1 <u>Dichloroethylene</u>

| Chemical | Selected Assessment | Critical Effect | POD | Uncertainty Factors | RfD |
|-------------------|---------------------|--|---------------------|---|-----------------|
| 2,4-dinitrophenol | US EPA IRIS, 1986 | Development of cataracts in humans (chronic study) | LOAEL = 2 mg/kg-day | TOTAL = 1000 $UF_{H} = 10$ $UF_{L} = 10$ $UF_{S} = 10$ | 0.002 mg/kg-day |

Source: USEPA (2015e). Update of Human Health Ambient Water Quality Criteria: 2,4-dinitrophenol

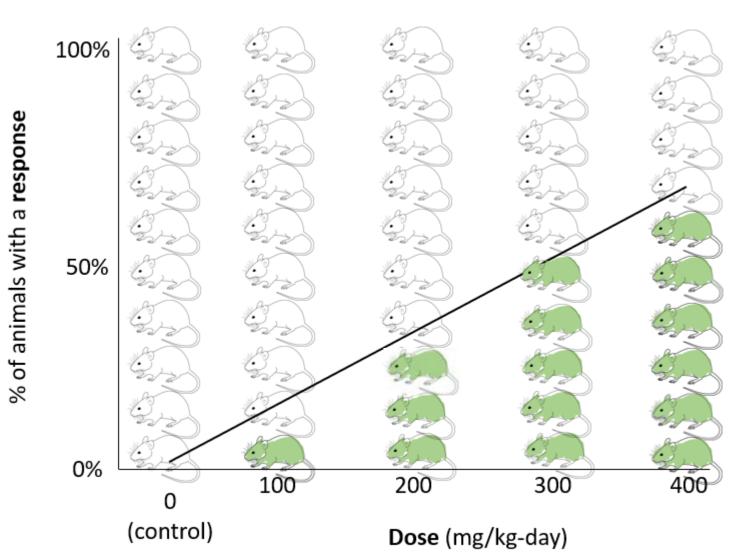
| Chemical | Selected Assessment | Critical Effect | POD | Uncertainty Factors | RfD |
|-----------------------|---------------------|---|-------------------------------|--|-------------|
| 1,1,1-trichloroethane | US EPA IRIS, 2007 | Reduced bodyweight in mice (subchronic study) | $BMDL_{10} = 2,155$ mg/kg-day | TOTAL = 1000 $UF_H = 10$ $UF_A = 10$ $UF_S = 3$ $UF_D = 3$ | 2 mg/kg-day |

Source: USEPA (2015f). <u>Update of Human Health Ambient Water Quality Criteria</u>: 1,1,1-trichloroethane

Linear Dose-Response Curve

- Assumes increased probability of effects at all levels of exposure (typically cancer)
- EPA targets a 1x10⁻⁶ cancer risk level (CRL)
 - One additional cancer case per one million people due to exposure to pollutant
 - Other cancer risk levels could be evaluated for consideration of risk management options and/or policy decisions

 - 1 case in 10,000 people
 1 case in 100,000 people
 1 case in 10 million people



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 or 10⁻⁶)

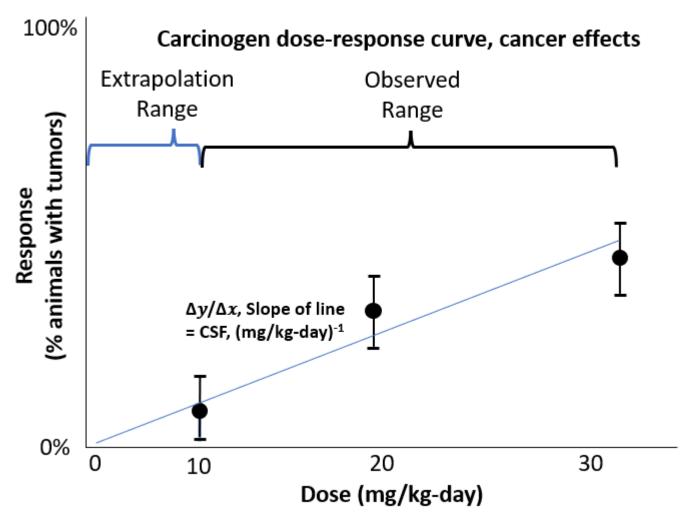
Risk Specific Dose (RSD)= $\frac{\text{Cancer Risk Level (CRL)}}{\text{Cancer Slope Factor (CSF)}}$

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."

Understanding the Cancer Slope Factor (CSF)

- Cancer Slope Factor
 - Measures incidence of cancer relative to dose over a lifetime exposure to a carcinogen
 - Used to derive the riskspecific dose
 - Derived similarly to a noncancer BMD



Example Risk Specific Dose Calculations

| Chemical | Selected Assessment | Critical Effect | Cancer Slope Factor | Cancer Risk Level | RSD |
|-------------------|------------------------|--|------------------------|----------------------|------------------------|
| Hexachlorobenzene | EPA OPP RED, 2008 | Development of hepatocellular carcinomas in rats | 1.02 per mg/kg- day | 1 x 10 ⁻⁶ | 9.8 x 10 ⁻⁷ |

Hexachlorobenzene is classified as B2, "probably human carcinogen" based on the 1996 Proposed Guidelines for Carcinogen Risk Assessment. **Source:** USEPA (2015d). <u>Update of Human Health Ambient Water Quality Criteria: Hexachlorobenzene</u>

| Chemical | Selected Assessment | Critical Effect | Cancer Slope Factor | Cancer Risk Level | RSD |
|------------------------|------------------------|--|--------------------------|----------------------|------------------------|
| 1,2- Dichloroethane | Health Canada, 2015 | Development of mammary tumors in female rats | 0.0033 per mg/kg- day | 1 x 10 ⁻⁶ | 3.0 x 10 ⁻⁴ |

^{1,2} Dichloroethane is classified as B2, "probably human carcinogen" based on the 1986 EPA Guidelines for Carcinogen Risk Assessment. **Source:** USEPA (2015g). Update of Human Health Ambient Water Quality Criteria: 1,2-Dichloroethane

Required Information for Criteria Development



Exposure Information for Criteria Development

- How much exposure to a pollutant could occur from direct ingestion of the drinking water?
- What is the drinking water intake value? (DI)
- How much exposure could occur from eating fish and shellfish?
- What is the Fish Intake rate? (FI)
- How much does this compound accumulate in fish/shellfish tissue (bioaccumulation factor)? (BAF)
- How much exposure could occur from other sources (e.g., air, diet, soil, dust)?
- What is the relative source contribution? (RSC)
- Are any life stages or populations either more highly exposed or more sensitive to exposure compared to the general population?

Exposure parameters for adults in the general population used in AWQC

- Body Weight (BW)
 - 80 kg; average adult body weight
- Drinking Water Intake (DI)
 - 2.4 L/day; 90th percentile per capita consumption rate
- Fish Intake (FI) for trophic level (TL)
 - TL 2 (first order consumers) = 7.6 g/day
 - TL 3 (intermediate predators)= 8.6 g/day
 - TL 4 (top predators) = 5.1 g/day

See USEPA (2019). <u>Chapter 3 (2019) of EPA's Exposure Factors Handbook</u> and USEPA (2014) report "<u>Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)</u>" for BW, DI, and fish consumption rate statistics

Other Exposure Parameters to Consider

Parameters for specific life stages or population(s) may sometimes be appropriate when deriving criteria.

- If a pollutant causes adverse effects in a specific population or life stage
 - Pregnant women, lactating women, or women of childbearing age
 - Consider as a target population if observed effects include development of the fetus, breastfed newborn baby, or female reproductive system

Children

- Consider as a target population if observed effects include postnatal developmental effects
- If a specific population or life stage is likely to be highly exposed versus general population

Subsistence fishers

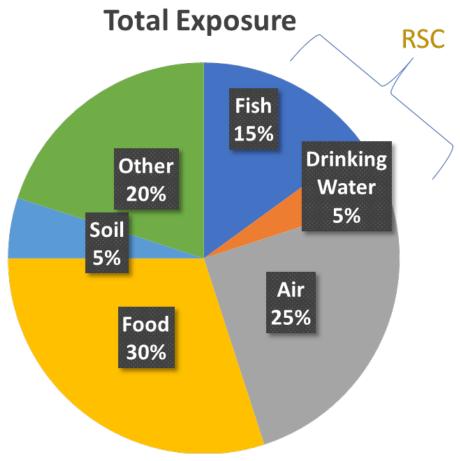
 Consider as a target population if there are subsistence fishers in the community, or if the toxicant bioaccumulates dramatically in fish, such that the majority of exposure occurs through fish consumption

Postnatal Childhood

 Consider as a target population due to incidental ingestion from recreational exposure in ambient waters

Relative Source Contribution (RSC)

- The RSC is the percentage of total exposure to a pollutant attributed to drinking water and eating fish and shellfish.
 - EPA follows the Exposure Decision Tree approach described in the 2000 methodology when making decisions about the RSC.
- Other sources of exposure could include:
 - Inhalation from ambient air
 - Consumption of food other than freshwater and estuarine fish/shellfish (especially locallygrown and prepared)
 - Consumption of soil or dust
 - Dermal exposure



Source: USEPA (2000a). Section 4.2 <u>Methodology for Deriving Ambient</u> Water Quality Criteria for the Protection of Human Health.

Identify population(s) of concern. Source: USEPA (2000a). Section 4.2 Methodology for Deriving Ambient Problem Water Quality Criteria for the Protection of Human Health. Formulation Is exposure from a single Describe exposures, uncertainties, source/pathway or multiple toxicity-related information, Yes sources/pathways potentially at control issues, and other Yes levels near (i.e., over 80%), or in information for management excess of, the RfD (or POD/UF)? decisions. Perform calculations associated with Boxes 12 and 13 as applicable. No Are there sufficient data, physical/chemical property 11. Is there more than one regulatory action (i.e., criteria, information, fate and transport information, and/or generalized standard, guidance) relevant for the chemical in information available to characterize the likelihood of exposure question? No 12. Yes Use subtraction of appropriate intake levels Yes from sources other than the source of concern, including 80% ceiling/20% floor. 6. Are there significant known or potential 13. Apportion the RfD (or uses/sources other than the source of POD/UF), including 80% concern? ceiling/20% floor, using the 8A. Yes percentage calculation. No Is there some information available Use 50% of the for each source/pathway to RfD (or characterize exposure? POD/UF). No Yes 8C. 8B Use 20% of the RfD (or Perform apportionment as described in Box 12 or 13, POD/UF). with a 50% ceiling/20% floor.

RSC Examples for AWQC

1,1 Dichloroethylene

- Air, drinking water, and non-fish food are potentially significant sources.
- Following the Exposure Decision Tree, significant potential sources other than fish and shellfish from inland and nearshore waters and water ingestion exist (Box 8A in the Decision Tree); however, information is not available to quantitatively characterize exposure from these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends an RSC of 20%.

Hexachlorobenzene

- For substances for which the toxicity endpoint is carcinogenicity based on a linear low-dose extrapolation, only the exposures from drinking water and fish ingestion are reflected in human health AWQC: non-water sources are not explicitly included and no RSC is applied.
- AWQC are derived with respect to the incremental lifetime cancer risk posed by the presence of a substance in water, rather than an individual's total risk from all sources of exposure.

A

May 2023

Source: USEPA (2015d) <u>Update of Human Health</u> Ambient Water Quality Criteria: Hexachlorobenzene

Source: USEPA (2015c) <u>Update of Human Health</u>
Ambient Water Quality Criteria: 1,1 <u>Dichloroethylene</u>

34

How Much Exposure Is Coming From Fish?

 Bioaccumulation Factors (BAFs) translate the kilograms of fish consumed into liters of contaminated water that results in the same amount of exposure.

Total Exposure
$$\left(\frac{L}{day}\right) = DI \left(\frac{L}{day}\right) + FI \left(\frac{kg}{day}\right) * BAF \left(\frac{L}{kg}\right)$$

Source: USEPA (2000a). Section 5 Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.

Goals of the National BAF/BCF

- To represent the long-term, average bioaccumulation potential of a chemical in edible tissues of aquatic organisms that are commonly consumed by humans throughout the United States.
- Derive separate BAFs/BCFs for each trophic level to account for potential biomagnification of some chemicals in aquatic food webs and broad physiological differences among organisms that may influence bioaccumulation.

Helpful Guidance: EPA (2000c). <u>Technical Support Document Volume 2: Development of National BAFs</u>; EPA (2016) <u>Development of BAFs</u>; Supplemental Information for EPA's 2015 Human Health Criteria Update

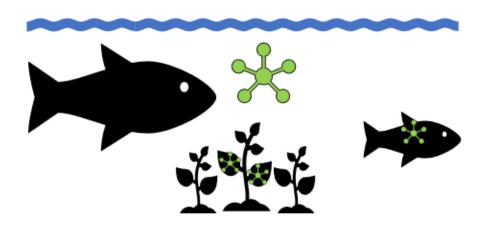
Source: USEPA (2000a). Section 5.1 Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health

Ways to Determine the Bioaccumulation

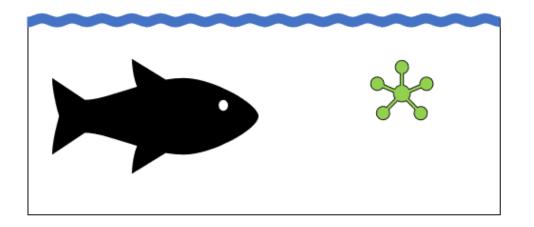
$$Bioaccumulation = \frac{Concentration in fish tissue}{Concentration in water}$$

Bioaccumulation Factor (BAF):

measurements in natural conditions



Bioconcentration Factor (BCF): measurement in lab with only direct water exposure



While BAFs are preferred, BCFs can be used in the absence of BAF values.

EPA Methods for Deriving Bioaccumulation Factors (BAFs)

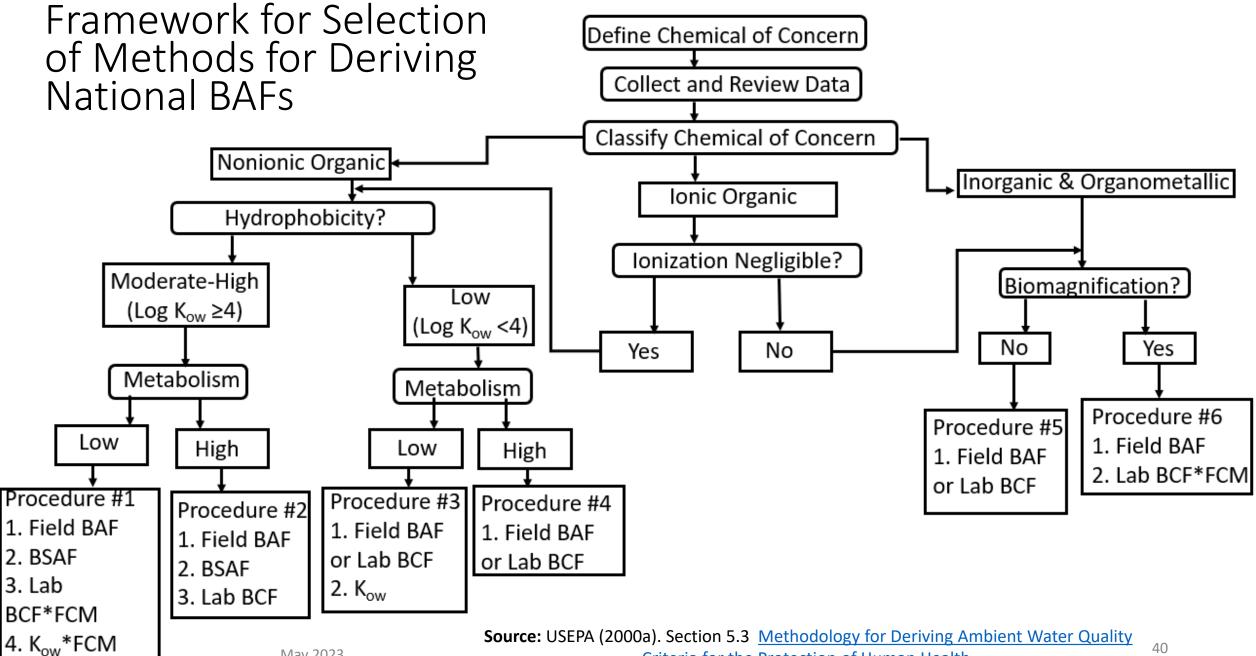
- The degree of bioaccumulation depends on the bioavailable concentration of the compound in water
 - **Dissolved organic carbon (DOC)** and **particulate organic carbon (POC)** concentrations correlate to the bioavailable fraction of the compound.
 - When compiling field BAF data from the literature 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 <u>EPA's published</u> <u>baseline BAFs</u> 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.



38

EPA Methods for Deriving BAFs

| Field-measured BAF | Applicable to all chemical types High-quality data currently limited to a few sites and chemicals | |
|---|---|--|
| BAF predicted from field-measured BSAF | Limited to nonionic organic chemicals Useful for chemicals that are difficult to analyze in water | |
| BAF predicted from lab- measured BCF x FCM | Applicable to all chemicals types Chemical metabolism, when present in food web, generally not accounted for | |
| BAF predicted from a K _{ow} x FCM | Limited to nonionic organic chemicals Readily applied with minimal input data | |



Criteria for the Protection of Human Health

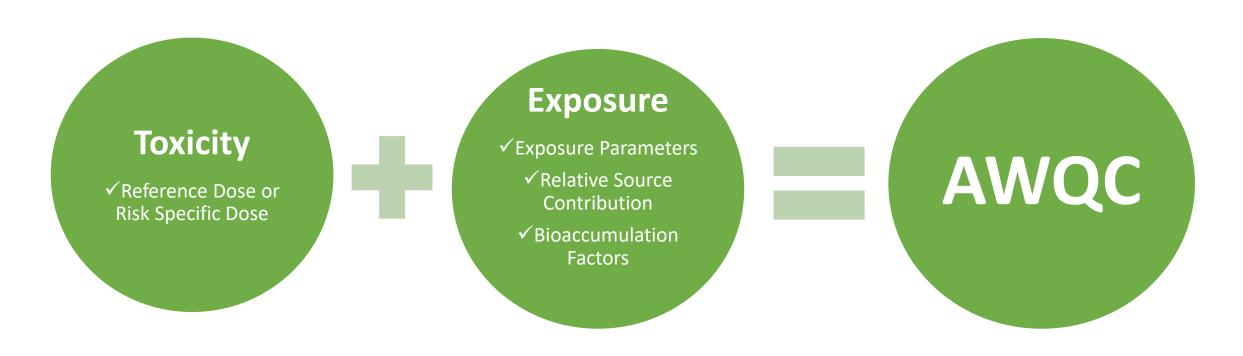
BAF Examples for AWQCs

| Trophic Level (TL) | 1,1 Dichloroethylene BAF (L/kg) | Hexachlorobenzene BAFs (L/kg) |
|--------------------|--|-------------------------------------|
| Primary producer | | |
| TL 2 | 2.0 | 18,000 |
| TL 3 | 2.4 | 46,000 |
| TL 4 | 2.6 | 90,000 |
| Method | Procedure 3: K _{ow} Method | Procedure 1: Field-measured BAFs |

Source: USEPA (2015c) <u>Update of</u>
<u>Human Health Ambient Water</u>
<u>Quality Criteria: 1,1 Dichloroethylene</u>

Source: USEPA (2015d) <u>Update of</u>
<u>Human Health Ambient Water</u>
Quality Criteria: Hexachlorobenzene

Required Input Values for Criteria Development



Calculating Criteria for a Threshold Contaminant

Ambient Water Quality Criteria (AWQC) definition: At this concentration, the majority of the population is exposed to a total dose of pollutant from water and fish consumption that is equal to or less than the dose that is unlikely to cause adverse health effects.

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

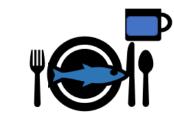
Source: USEPA (2000a) Section 1.6 Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health

AWQC Example: 1,1, Dichloroethylene

Input Values: Toxicity RfD = 0.05 mg/kg-dayRSC = 0.20BW = 80 kgDI = 2.4 L/dayFCR = Exposure • TL 2 = 7.6 g/day• TL 3 = 8.6 g/day• TL 4 = 5.1 g/dayBAFs =• TL 2 = 2.0 (L/kg)• TL 3 = 2.4 (L/kg)• TL 4 = 2.6 (L/kg)

For consumption of water and organisms:

AWQC (μ g/L) = toxicity value (RfD [mg/kg-d] × RSC) × BW (kg) × 1,000 (μ g/mg) DI (L/d) + $\sum_{i=2}^{4}$ (FCR_i (kg/d) × BAF_i (L/kg))



= $0.05 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1,000 \text{ µg/mg}$ 2.4 L/d + ((0.0076 kg/d × 2.0 L/kg) + (0.0086 kg/d × 2.4 L/kg) + (0.0051 kg/d × 2.6 L/kg))

 $= 327 \mu g/L$

= 300 μ g/L (rounded)

For consumption of organisms only:

AWQC (μ g/L) = toxicity value (RfD [mg/kg-d] × RSC) × BW (kg) × 1,000 (μ g/mg) $\sum_{i=2}^{4} (FCR_i (kg/d) \times BAF_i (L/kg))$



= $\frac{0.05 \text{ mg/kg-d} \times 0.20 \times 80.0 \text{ kg} \times 1,000 \mu\text{g/mg}}{(0.0076 \text{ kg/d} \times 2.0 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 2.4 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 2.6 \text{ L/kg})}$

 $= 16,293 \mu g/L$

= 20,000 μ g/L (rounded)

EPA recommends rounding the number of significant figures at the end of the criterion calculation to the same number of significant figures in the least precise parameter.

Source: USEPA (2015c) <u>Update of Human Health Ambient Water Quality Criteria</u>: 1,1 <u>Dichloroethylene</u>

AWQC: Calculating Criteria for a Linear Carcinogen

Ambient Water Quality Criteria (AWQC) for a linear carcinogen definition: At this concentration, the majority of the population is exposed to a dose of pollutant from water and fish consumption that results in the population achieving the target cancer risk level (e.g., 1 in a million or 10⁻⁶ excess cases of cancer from exposure).

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

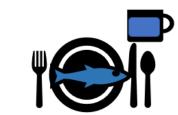
Source: USEPA (2000a) Section 1.6 Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health

AWQC Example: Hexachlorobenzene

Input Values: Toxicity $RSD = 9.8 \times 10^{-7} \, \text{mg/kg-day}$ RSC = N/ABW = 80 kgDI = 2.4 L/dayFCR = Exposure • TL 2 = 7.6 g/day• TL 3 = 8.6 g/day• TL 4 = 5.1 g/dayBAFs = TL 2 = 18,000 (L/kg) • TL 3 = 46,000 (L/kg)TL 4 = 90,000 (L/kg)

For consumption of water and organisms:

AWQC (μ g/L) = toxicity value (10⁻⁶ / CSF) [mg/kg-d] × BW (kg) × 1,000 (μ g/mg) DI (L/d) + $\sum_{i=2}^{4}$ (FCR_i (kg/d) × BAF_i (L/kg))



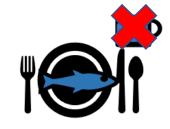
= $\frac{(10^{-6} / 1.02) \text{ mg/kg-d} \times 80.0 \text{ kg} \times 1,000 \text{ µg/mg}}{2.4 \text{ L/d} + ((0.0076 \text{ kg/d} \times 18,000 \text{ L/kg}) + (0.0086 \text{ kg/d} \times 46,000 \text{ L/kg}) + (0.0051 \text{ kg/d} \times 90,000 \text{ L/kg}))}$

 $= 0.00007892 \mu g/L$

 $= 0.000079 \,\mu g/L \,(rounded)$

For consumption of organisms only:

AWQC (μ g/L) = toxicity value (10⁻⁶ / CSF) [mg/kg-d] × BW (kg) × 1,000 (μ g/mg) $\sum_{i=2}^{4} (FCR_i (kg/d) \times BAF_i (L/kg))$



- = $(10^{-6} / 1.02)$ mg/kg-d × 80.0 kg × 1,000 µg/mg (0.0076 kg/d × 18,000 L/kg) + (0.0086 kg/d × 46,000 L/kg) + (0.0051 kg/d × 90,000 L/kg)
- $= 0.00007911 \,\mu g/L$

 $= 0.000079 \,\mu g/L \,(rounded)$

EPA recommends rounding the number of significant figures at the end of the criterion calculation to the same number of significant figures in the least precise parameter.

Helpful Resources

Methodology Resources

- Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health
- Technical Support Documents:
 - Volume 1: Risk Assessment
 - Volume 2: Development of National Bioaccumulation Factors
 - Volume 3: Development of Site-Specific Bioaccumulation Factors
- Human Health Ambient Water Quality Criteria Fish Consumption Rates FAQ
- Guidelines for Carcinogen Risk Assessment
- Benchmark Dose Tools
- Update for Chapter 3 of the Exposure Factors Handbook

2015 Update Resources

- <u>Fact Sheet: Human Health Ambient Water Quality Criteria: 2015</u>
 Update
- <u>Table Comparing EPA's Updated 2015 Final Updated Human</u> Health Criteria
- <u>Table Summarizing Updated Input Values for EPA's 2015 Final</u>
 Updated Human Health Criteria
- <u>Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)</u>
- 2015 National Bioaccumulation Factors- Supplemental Information Document

For a full list of available resources, visit EPA's Human Health Water Quality Criteria and Methods for Toxics homepage.

References

- USEPA. 2000a. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. http://water.epa.gov/scitech/swguidance/standards/upload/2005 05 06 criteria humanhea lth method complete.pdf.
- USEPA. 2000b. Technical Support Document Volume 1: Risk Assessment. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2018-12/documents/methodology-wqc-protection-hh-2000-volume1.pdf
- USEPA. 2000c. Technical Support Document Volume 2: Development of National BAFs. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000-volume2.pdf
- USEPA. 2002. Toxicological Review of 1,1-Dichloroethylene. U.S. Environmental Protection Agency, Office of Research and Development, Integrated Risk Information System, Washington, DC. Accessed April 2023. https://iris.epa.gov/static/pdfs/0039tr.pdf
- USEPA. 2005. Guidelines for Carcinogen Risk Assessment. U.S. Environmental Protection Agency, Washington, DC. Accessed April 2023. http://www2.epa.gov/sites/production/files/2013 09/documents/cancer_guidelines_final_3-25-05.pdf.
- USEPA. 2012. Benchmark Dose Technical Guidance. U.S. Environmental Protection Agency, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2015-01/documents/benchmark_dose_guidance.pdf
- USEPA. 2014. Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010). U.S. Environmental Protection Agency, Washington, DC, Accessed April 2023. https://www.epa.gov/sites/default/files/2015-01/documents/fish-consumption-rates-2014.pdf
- USEPA. 2015a. Human Health Ambient Water Quality Criteria: 2015 Update Factsheet. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2015-10/documents/human-health-2015-update-factsheet.pdf

- USEPA. 2015b. Update of Human Health Ambient Water Quality Criteria: Chlorobenzene. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.regulations.gov/document/EPA-HQ-OW-2014-0135-0214
- USEPA. 2015c. Update of Human Health Ambient Water Quality Criteria: 1,1 Dichloroethylene. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.regulations.gov/document/EPA-HQ-OW-2014-0135-0204
- USEPA. 2015d. Update of Human Health Ambient Water Quality Criteria: Hexachlorobenzene. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.regulations.gov/document/EPA-HQ-OW-2014-0135-0198
- USEPA. 2015e. Update of Human Health Ambient Water Quality Criteria: 2,4, -Dinitrophenol. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2015-10/documents/final-2-4-dinitrophenol.pdf
- USEPA. 2015f. Update of Human Health Ambient Water Quality Criteria: 1,1,1-Trichloroethane. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2015-10/documents/final-1-1-trichloroethane.pdf
- USEPA. 2015g. Update of Human Health Ambient Water Quality Criteria: 1,2 Dichloroethane. U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Washington, DC. Accessed April 2023. https://www.regulations.gov/document/EPA-HQ-OW-2014-0135-0190

- USEPA. 2016. Development of BAFs; Supplemental Information for EPA's 2015 Human Health Criteria Update. U.S. Environmental Protection Agency, Office of Water, Office and Technology, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2016-01/documents/national-bioaccumulation-factors-supplemental-information.pdf
- USEPA. 2019. Update for Chapter 3 of the Exposure Factors Handbook. U.S. Environmental Protection Agency, Office of Research and Development, Integrated Risk Information System, Washington, DC. Accessed April 2023. https://www.epa.gov/sites/default/files/2019-02/documents/efh chapter 3 update.pdf
- USEPA. 2022. IRIS Glossary. U.S. U.S. Environmental Protection Agency, Office of Research and Development, Integrated Risk Information System, Washington, DC. Accessed April 2023. https://www.epa.gov/iris/iris-glossary#r
- USEPA. 2023. Benchmark Dose Tools. U.S. Environmental Protection Agency, Washington, DC. Accessed April 2023. https://www.epa.gov/bmds

