Procedures for Deriving Wisconsin's Numeric Surface Water Quality Criteria

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Introduction

The purpose of this guidance document is to explain the procedures used to calculate the various numeric water quality criteria that apply to toxic substances. While the procedure for calculating water quality criteria are described in Chapter NR 105, Wis. Adm. Code, much can be gained by developing guidance on these processes, including:

- Documenting institutional knowledge on the intricacies involved in deriving water quality criteria
- Capturing the processes used to derive the different types of criteria (i.e., human health, wildlife, aquatic life) in one location
- Making the task of developing/revising criteria simpler and more efficient
- Facilitating communication with internal staff members and the public on issues related to water quality criteria

Water Quality Standards

Water quality criteria are one component of water quality standards, which the federal Clean Water Act (CWA) mandates that states/tribes adopt to enhance water quality. The other components of water quality standards are designated uses and an antidegradation policy. The objective of the federal CWA is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[1] Water quality standards help fulfill this objective by providing for "the protection and propagation of fish, shellfish, and wildlife" and "recreation in and on the water."[1]

Designated Uses

Designated uses establish the appropriate water quality goals for a given waterbody. The CWA requires each state/tribe to set designated uses that protect aquatic organisms (e.g., fish, shellfish) and humans and allows states/tribes to consider other uses (e.g., public water supply, agriculture, industry and navigation). Designated use

categories vary by state/tribe as each state/tribe is responsible for establishing its own categories.

Wisconsin has four general designated use categories as defined in s. NR 102.04, Wis. Adm. Code: fish and aquatic life, recreation, public health and welfare, and wildlife (Figure 1).[2]

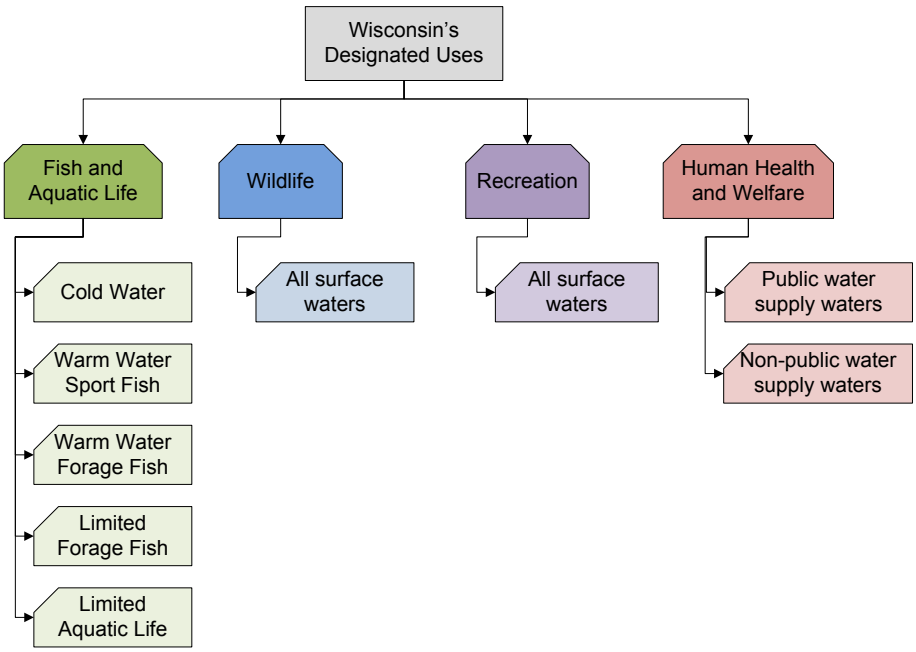

Figure 1. Wisconsin's designated use categories

Each of these uses apply to all surface waters. The fish and aquatic life use is further divided into the following classifications:

- **Cold water (CW):** surface waters capable of supporting a community of cold water fish and other aquatic life, or serving as a spawning area for cold water fish species.
- **Warm water sport fish (WWSF):** surface waters capable of supporting a community of warm water sport fish or serving as a spawning area for warm water sport fish.
- **Warm water forage fish (WWFF):** surface waters capable of supporting an abundant diverse community of forage fish and other aquatic life.

- **Limited forage fish (LFF):** surface waters of limited capacity and naturally poor water quality or habitat and are capable of supporting only a limited community of forage fish and other aquatic life.
- **Limited aquatic life (LAL):** surface waters of severely limited capacity and naturally poor water quality or habitat and are capable of supporting only a limited community of aquatic life.

Wisconsin derives separate human health criteria for each of the fish and aquatic life classifications because of differences in fish consumption and the fish species present in the different classifications. Additionally, the human health and welfare designated use distinguishes between waters considered public drinking water supply (as listed in Chapter NR 104, Wis. Adm. Code) and all other waters (i.e., non-public water supply).[3] These criteria and the procedures for deriving them are in Chapter NR 105, Wis. Adm. Code.[4]

Water Quality Criteria

Water quality criteria represent the quality of water that supports a particular use. Criteria can be expressed either narratively or numerically. Narrative criteria are used when pollutants cannot be precisely measured, and instead, a qualitative description is applied. Wisconsin has a number of narrative criteria. For example, s. NR 102.04(1), Wis. Adm. Code, states that, for all surface waters,

- Substances that will cause objectionable deposits on the shore or in the bed of a body of water, shall not be present in such amounts as to interfere with public rights in waters of the state.
- Floating or submerged debris, oil, scum or other material shall not be present in such amounts as to interfere with public rights in waters of the state.
- Materials producing color, odor, taste or unsightliness shall not be present in such amounts as to interfere with public rights in waters of the state.
- Substances in concentrations or combinations which are toxic or harmful to humans shall not be present in amounts found to be of public health significance,

nor shall substances be present in amounts which are acutely harmful to animal, plant or aquatic life.[2]

Numeric criteria are applied for pollutants that can be precisely measured. These criteria are quantitative and consist of three components:

- **Magnitude:** numeric expression of the maximum amount of the pollutant that may be present in a waterbody that supports the designated use
- **Duration:** the period of time over which the magnitude is calculated
- **Frequency:** the maximum number of times the pollutant may be present above the magnitude over the duration[5]

As criteria are designed to protect a particular use for a given waterbody, each designated use class has its own set of criteria. Table 1 shows Wisconsin's four designated use categories and the numeric criteria applicable to each use.[2]

Table 1. Wisconsin's designated use categories and applicable numeric criteria

Designated Use	Applicable Numeric Criteria
Fish and Aquatic Life	Dissolved oxygen pH Phosphorous Toxic substances Temperature
Recreational Use	Bacteria
Public Health and Welfare	Taste and odor Temperature Toxic substances
Wildlife	Toxic substances

Antidegradation Policy

The antidegradation policy is designed to maintain and protect high quality waters. The policy establishes how proposed new or increased discharges to high quality waters should be addressed. Section NR 102.05(1)(a), Wis. Adm. Code, states that "no waters of the state shall be lowered in quality unless it has been affirmatively demonstrated to the Department that such a change is justified as a result of necessary economic and

social development, provided that no new or increased effluent interferes with or becomes injurious to any assigned uses made of or presently possible in such waters."[2] Wisconsin's antidegradation policy can be found in Chapter NR 207, Wis. Adm. Code.[6] While the antidegradation policy is a crucial component to water quality standards, it does not relate directly to the development of water quality criteria. As such, detailed discussion of Wisconsin's antidegradation policy is beyond the scope of this document.

In the following sections of the document, the procedures and purposes for deriving fish and aquatic life, human health, and wildlife criteria are discussed. The appendices detail the requirements for data acceptability, include flowcharts for deriving fish and aquatic life criteria, and explain the methods for deriving the human health criteria components.

Fish and Aquatic Life Criteria

Fish and aquatic life (FAL) criteria are defined as "concentrations of pollutants in [surface] water that…are expected to protect fish, invertebrates, and other aquatic life from adverse effects associated with exposure."[5] To protect aquatic organisms from short- and long-term effects, both acute and chronic criteria are derived. Typically, acute criteria protect aquatic life from lethality caused by short-term exposure and chronic criteria protect aquatic life from sublethal effects (e.g., immobilization, stunted growth, impaired reproduction) caused by long-term exposure.

The Department uses the procedures established in the United States Environmental Protection Agency' (U.S. EPA) *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* and federal regulations on water quality standards as the basis for deriving Wisconsin's FAL water quality criteria.[7-8] Because Wisconsin's different surface waterbody types support a variety of habitats and associated aquatic communities, the Department derives separate criteria for each of the fish and aquatic life classifications (i.e., cold water, warm water, limited

forage fish, limited aquatic life). This ensures that each waterbody has criteria that provide reasonable protection without being over- or under-protective.

Toxicity Data Availability and Acceptability

The first step in deriving FAL water quality criteria is finding all available toxicity data and assessing this data for acceptability. Because toxicity data are not usually available for all of the organisms likely to be found in a given waterbody, data from representative species are used as an indication of the sensitivities of the untested species. There are a number of references for fish and aquatic life toxicity test results including the U.S. EPA's water quality criteria documents, Great Lakes Water Initiative Clearinghouse, and ECOTOX database.[9-11] Often times, not all of the available data are acceptable for use in calculating water quality criteria. Appendix A contains more detailed requirements for data acceptability including Table A-1 and Table A-2 which list the acceptable acute and chronic toxicity endpoints for the derivation of fish and aquatic life water quality criteria.

Once all acceptable toxicity data have been obtained, the data are evaluated to determine if water quality criteria can be derived. The exact procedure for deriving toxicity criteria or secondary values depends on whether toxicity is related to water quality parameters (e.g., hardness, pH, temperature). If toxicity is related to a water quality parameter, a linear regression is performed to establish the relationship between toxicity and the applicable water quality parameter. Figure 2 is a flowchart for selecting which method to use to calculate the criteria/secondary value.

Acute Toxicity

Acute Toxicity Criteria

Acute toxicity criteria can be derived if there is acceptable data from at least eight different families of organisms, as described in s. NR 105.05(1)-(3), Wis. Adm. Code.[4] These families are selected to represent the ecological, trophic, taxonomic and functional differences observed in the natural aquatic ecosystem and are referred to as the Minimum Dataset Requirements (MDRs).[7] They include at least one:

- Salmonid fish (e.g., trout, salmon)
- Non-salmonid fish (e.g., bluegill, largemouth bass)
- Planktonic crustacean (e.g., cladoceran, copepod)
- Benthic crustacean (e.g., amphipod, crayfish)
- Insect (e.g., mayfly, stonefly)
- Organism in a third family in the phylum Chordata (e.g., minnow, toad)
- Organism a family in a phylum not Arthropoda or Chordata (e.g., annelid, mollusc)
- One organism in a family in any order or any phylum not already represented.

If the MDRs are met, the acute toxicity criterion is derived using the species sensitivity distribution (SSD) method which is designed to protect 95% of taxa found in a given waterbody. Only 95% of the taxa are protected "because aquatic ecosystems can tolerate some stress and occasional adverse effects [thus] protection of all species at all times and places is not deemed necessary."[7] In this method, the average toxicity for each genus in the dataset is first calculated and each genus ranked by sensitivity. Then, a regression analysis is preformed to obtain the four most sensitive genus. Finally, the acute toxicity criterion is calculated by extrapolating the level that is protective of 95% of taxa. A flowchart depicting this procedure is available in Appendix B.

Secondary Acute Value

If the MDRs are not met, an acute toxicity criterion cannot be calculated. In cases where the MDRs are not met but there is acceptable data for at least one *Ceriodaphnia*, *Daphnia*, or *Simocephalus* species, a secondary acute value (SAV) can be calculated instead, as described in s. NR 105.05(4), Wis. Adm. Code.[4]

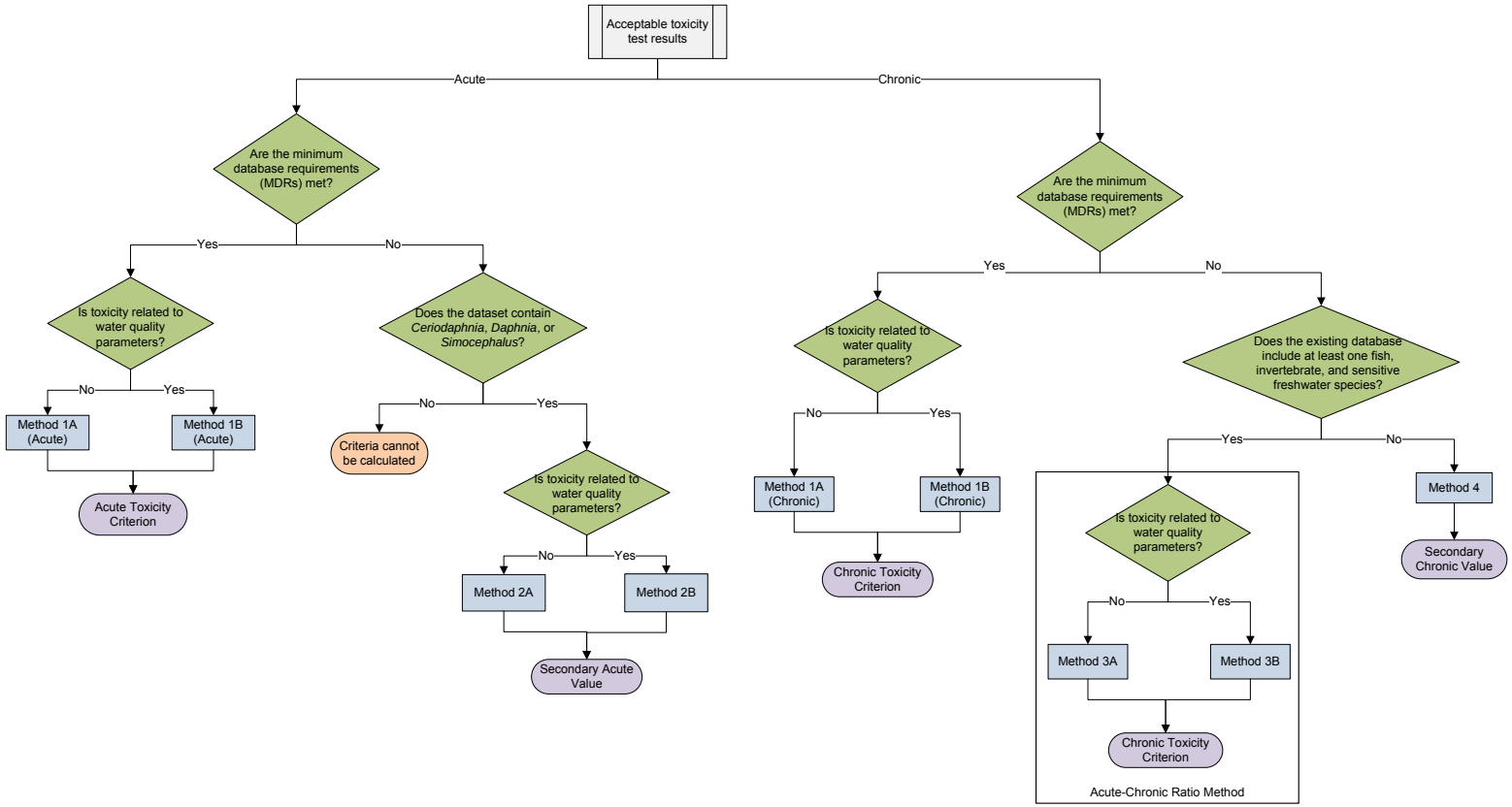

Figure 2. Methods used to derive fish and aquatic life water quality criteria

The secondary acute value is derived using an adjustment factor method. The goal of the method is to derive a secondary value that is comparable to what would be obtained if the data were available to calculate an acute toxicity criterion using the SSD method. In this method, the average toxicity for each genus in the dataset is first calculated and the most sensitive genus selected. Then, the secondary acute factor (SAF) is selected based on how many of the MDRs are met; the more MDRs that are met, the lower the SAF and vice versa. Finally, the secondary acute value is calculated by dividing the most sensitive toxicity value by the SAF. A flowchart depicting this procedure is available in Appendix B.

Chronic Toxicity

Chronic Toxicity Criteria

Due to the cost and time involved in conducting chronic toxicity tests, there is often less chronic toxicity data available for a given substance. Because of this, chronic toxicity criteria can be calculated using two different methods. The SSD method can be used to calculate a chronic toxicity criterion if data is available for each of the MDRs, as described in s. NR 105.06(1)-(4).[4] A flowchart depicting this procedure is available in Appendix B.

In cases where the MDRs are not met but there is acceptable acute and chronic toxicity data for at least one fish, one invertebrate, and one acutely sensitive freshwater species, the Acute-Chronic Ratio method can be used as described in s. NR 105.06(5).[4] In this method, the chronic toxicity value is extrapolated from the acute toxicity criterion using the relationship between the available acute and chronic data. To start, the acute toxicity criterion or secondary acute value is calculated as described above. Then, all acceptable acute and chronic test results from the same species are compiled. Next, the acute-chronic ratio is calculated for each species by dividing the acute value by the chronic value. Afterwards, the mean acute-chronic ratio is calculated for each organism category (fish, invertebrate, sensitive freshwater species) by averaging the ACRs for all species in each category. Then, a final acute-chronic ratio is calculated by averaging

the mean ACRs. Finally, the Chronic Toxicity Criterion is calculated by dividing the final acute value calculated by the final acute-chronic ratio. A flowchart depicting this procedure is available in Appendix B.

Secondary Chronic Value

There are several instances where a secondary chronic value may be appropriate, including:

- An acute criterion is available, but the chronic MDRs are not met and there is not chronic toxicity data for at least one fish, one invertebrate, and one sensitive freshwater species,
- A secondary acute value is available but the chronic MDRs are not met and there is not chronic toxicity data for at least one fish, one invertebrate, and one sensitive freshwater species, or
- A secondary acute value is available and the chronic MDRs are not met, but there is chronic toxicity data for at least one fish, one invertebrate, and one sensitive freshwater species.

In these cases, a secondary chronic value (SCV) can be derived using the Default Acute-Chronic Ratio method, as described in s. NR 105.06(6)-(7).[4] In this method, the chronic toxicity value is extrapolated from the acute toxicity criterion using default acute-chronic ratio values. This method is identical to the Acute-Chronic Ratio method for deriving Chronic Toxicity Criteria except that default mean ACR values are used for any organism category for which there is no enough data to calculate a mean ACR value. A flowchart depicting this procedure is available in Appendix B.

Selection of values for promulgation/implementation

Because of the rigorous data requirements, acute and chronic toxicity criteria are promulgated in rule but secondary values are not. However, both acute and chronic toxicity criteria and secondary values can be used to derive water quality based effluent

limits (WQBELs). To select the most appropriate value for promulgation/implementation, a two-step process is used.

First, the calculated value is compared to U.S. EPA's national ambient water quality criteria (NAWQC) to determine if the calculated value is more or less protective than the recommended criterion.[9] For this comparison, only the value derived for the cold water designated use subcategory is used because the dataset used for this classification is most similar to that used by the U.S. EPA.

Second, the calculated value for each of the fish and aquatic life designated use subcategories are compared to one another. Section NR 105.05(1)(a)9, Wis. Adm. Code, states:

> "In no case may the criterion for a lower quality fish and aquatic life subcategory…be less than the criterion for a higher quality fish and aquatic life subcategory."[4]

Because of this rule language, a "subset" approach has been used to select the appropriate values for promulgation/implementation. In this approach, the Cold Water fish and aquatic life designated use subcategory is considered the "dataset" and the

following fish and aquatic life subcategories are considered subsets of this dataset (

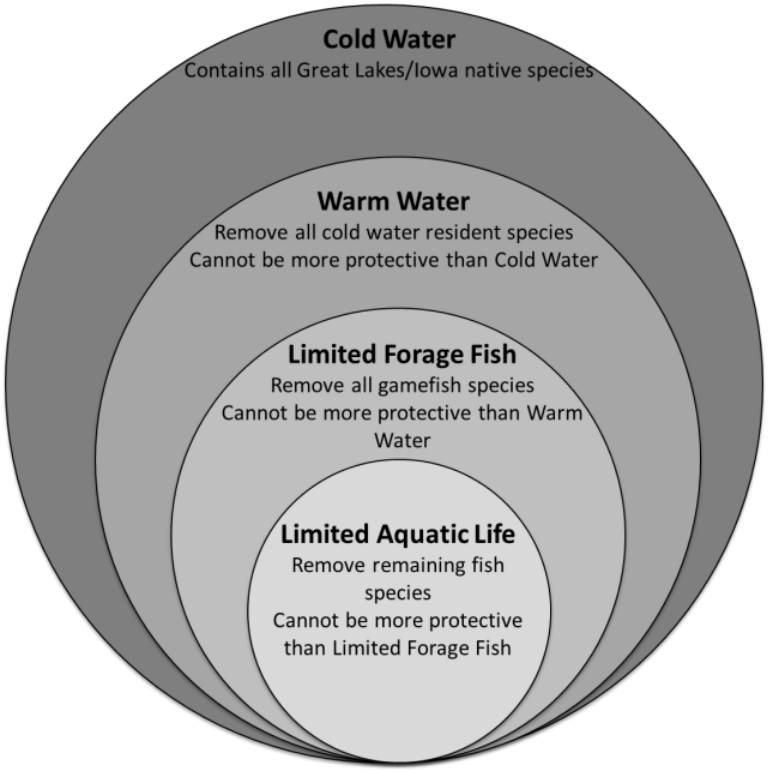

Figure 3).

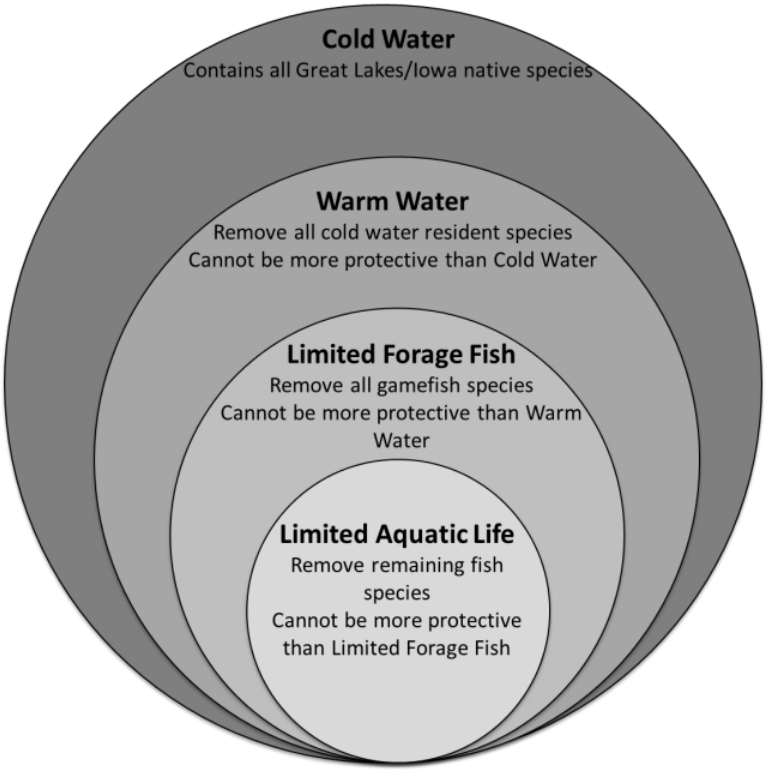

Figure 3. Diagram depicting the "subset" approach for selecting values for implementation

Human Health Criteria

A human health water quality criterion is defined as "the highest concentration of a pollutant in water that is not expected to pose a significant risk to human health."[4] Human health criteria are derived for substances that cause non-carcinogenic effects (i.e., human threshold criteria) and substances that cause carcinogenic effects (i.e., human cancer criteria). For substances that cause both non-carcinogenic and carcinogenic effects, both types of criteria can be derived.

To derive a human health criterion, an exposure equation is used to model human exposure to the substance through the drinking of surface waters or incidental consumption of water during recreation and consumption of aquatic organisms. The exposure equations and parameters used to derive Wisconsin's human health criteria were established in the U.S. EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*.[12] Table 2 details the general parameters used to derive a human health criterion.

Table 2. Human health criteria (HHC) exposure equation and parameters

Human Health Criteria

Exposure Equation	
$HHC = \frac{TV \times BW}{W_H + (F_H \times BAF)}$	
Equation Parameters	
Toxicity	
Toxicity Value (TV)	Maximum amount of a substance that would not cause harm to humans if consumed via drinking water and fish consumption daily for a lifetime
Exposure	
Body Weight (BW)	Average weight of an adult male (70 kg)
Water Consumption Rate (W_H)	Average per capita daily consumption of water for surface waters classified as - Public water supply waters: 2 L/d - All other waters: 0.01 L/d
Fish Consumption Rate (F_H)	Average per capita daily consumption of sport-caught fish by WI anglers (0.02 kg/d)
Bioaccumulation	
Bioaccumulation Factor (BAF)	The ratio of a substance's concentration in the tissue of an aquatic organism to its concentration in the ambient water (L/kg)

When deriving a human health criterion, the following assumptions are made:

- Individuals are exposed to the substance every day for 70 years.
- Treatment of a surface water prior to its use as a public water supply does not remove the substance.
- If the calculated human health criterion for a substance exceeds the maximum contaminant level (MCL) for that substance as specified in Chapter NR 809, Wis. Adm. Code, the MCL is used as the human health criterion.[13]
- The concentration of the substance in fish is not affected by preparation or cooking.

Because human health criteria include a factor related to fish consumption and different fish species are present in the different FAL classifications, Wisconsin derives separate human health criteria for each of the fish and aquatic life classifications (i.e., cold water, warm water, limited forage fish, limited aquatic life). Figure 4 shows the types of human health criteria that are derived for non-carcinogenic and carcinogenic substance.

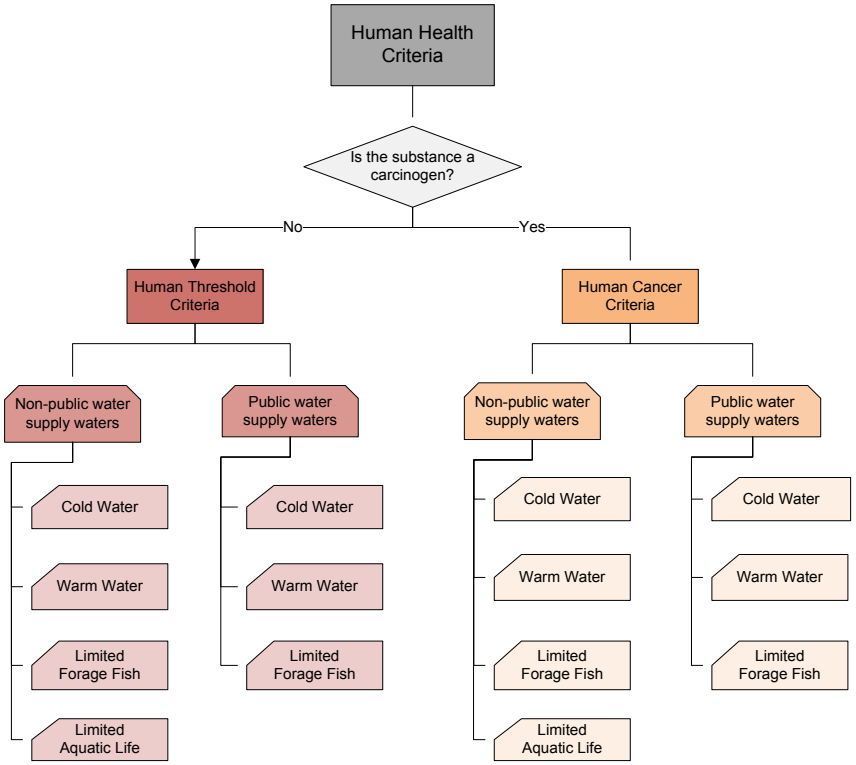

Figure 4. Wisconsin's human health criteria for non-carcinogenic and carcinogenic substances

Additionally, separate criteria are derived for waterbodies designated as public water supply because of differences in the water consumption rate. Table 3 lists the exposure routes considered for each designated use classification for both public and non-public water supply waters.

Table 3. Exposure Routes for Public and Non-Public Water Supply Waters

Exposure Route	Public Water Supply			Non-public Water Supply			
	Cold	Warm	LFF	Cold	Warm	LFF	LAL*
Drinking	X	X	X				
Incidental Ingestion				X	X	X	X
Fish Consumption	X	X	X	X	X	X	

* For LAL waters, drinking and fish consumption are not likely exposure routes
X indicates that exposure route is considered

In this section, the general exposure parameters considered when deriving a human health criterion and the specifics for deriving a human threshold criterion and a human cancer criterion will be discussed in further detail.

Exposure Parameters

There are a number of exposure parameters that are considered when deriving a human health criterion. These include:

- Body weight
- Water consumption rate
- Fish consumption rate
- Bioaccumulation

These parameters are used to derive both the human threshold criteria and human cancer criteria.

Body Weight

The Department currently uses 70 kg (~ 150 lbs) as the average body weight of an adult male for the derivation of Wisconsin's human health criteria. This value is from the U.S. EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* and was chosen based data from the 1988-1994 National Health and Nutrition Examination Survey (NHANES III).[12]

In 2015, U.S. EPA released updates to several of the human health criteria parameters including the average body weight.[14] In these revisions, the average body weight of an adult male was increased to 80 kg (~175 lbs). The revised body weight is based on data from the most recent survey conducted from 1999 to 2006 (NHANES III).

Everyt\ three years, the Department reviews Wisconsin's water quality standards or related guidance for development or revision during the following three years.[15] This process is referred to as the Triennial Standards Review. Changes to the average body weight used to develop Wisconsin's human health criteria will be evaluated as part of the 2018–2020 Triennial Standards Review. If necessary, revisions to Chapter NR 105 and this guidance document will be made.

Water Consumption Rate

The Department currently uses two water consumption rates to derive Wisconsin's human health criteria: one for waters that are designated as public water supply and another for all other waterbodies. Drinking water is included as an exposure route for public water supply waters in Wisconsin and is recommended by the U.S. EPA for several reasons:

- Under the CWA, criteria are needed to assure that all designated uses, including drinking water, are protected and maintained.
- For some substances, existing treatment may not be effective in reducing levels in drinking water supply to those necessary for protection of human health.
- To protect water quality in accordance with the CWA, criteria for public water supply waters are necessary to ensure that waters are not contaminated to a level where the burden of achieving human health standards is placed on downstream users.

For more information regarding ambient water quality criteria for drinking water designated uses, see the U.S. EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*.[12]

For public water supply waters, the Department uses 2 liters per day (L/d) as the average per capita daily water consumption. This value is from the U.S. EPA's *Methodology* guidance and was chosen based on data from the 1994-96 Continuing Survey of Food Intake by Individuals (CSFII) conducted by the U.S. Department of Agriculture (USDA). It represents the 86th percentile for adults.[12]

The U.S. EPA's 2015 updates to the human health criteria also include revisions to the average water consumption rate.[14] In these revisions, the average water consumption rate of an adult was increased to 2.4 L/d based on data from the recent NHANES survey (NHANES III). This valued represents the 90th percentile for adults. Changes to the average water consumption rate used to develop Wisconsin's human health criteria

will be evaluated as part of the 2018–2020 Triennial Standards Review. If necessary, revisions to Chapter NR 105 and this guidance document will be made.

For all other waters in Wisconsin, the Department uses 0.01 L/d as the average per capita daily water consumption. While the U.S. EPA does not have a recommendation for incidental water consumption, the Department felt it was necessary to provide protection for incidental water consumption that can occur during recreation in and on Wisconsin waters.[16] The value of 0.01 L/d was developed by the State of Michigan to represent exposure (i.e., ingestion, absorption) that can happen during recreational activities such as swimming, fishing, and boating.[17]

Fish Consumption Rate

The Department currently uses 0.02 kilograms per day (kg/d) as the fish consumption rate to derive Wisconsin's human health criteria. This represents the average per capita daily consumption of sport-caught fish by Wisconsin anglers and differs from U.S. EPA's recommended fish consumption rates recommended by the U.S. EPA in their 1980 *Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Quality Criteria Documents* regulation (6.5 g/d) and 2000 *Methodology* guidance (17.5 g/d).[12, 18]

When the Department revised their human health criteria values and procedures in the late 1980s, the U.S. EPA recommended 0.0065 kg/d as the national fish consumption rate. The Department determined that the recommended fish consumption rate was inappropriate and inadequate for use in deriving Wisconsin's human health criteria because it:

- Incorporated both freshwater and estuarine fish and shellfish consumption,
- Underestimated the amount of freshwater fish consumed by freshwater fish consumers,
- Represented a national average and underestimated freshwater fish consumption in regions more representative of Wisconsin, and

- Would not adequately protect recreational anglers, who are the highest exposed population in Wisconsin.[16]

Given these reasons, the Department derived a specific fish consumption rate that would protect anglers from excessive health risk associated with the consumption of locally for Wisconsin. To do this, the Department evaluated the existing studies that provided freshwater fish consumption rates which were representative of Wisconsin's average recreational anglers. A description of these studies including the region evaluated, the study design, the benefits/drawbacks of the study, and the resultant consumption rate is provided in Table 4. From these studies and through public and legislative hearings, the Department selected the value of 20 g/d (0.02 kg/d) as the average fish consumption rate.

Table 4. Summary of the studies used to derive Wisconsin's fish consumption rate

Study	Region	Study Design	Benefits/Drawbacks	Consumption Rate
Rupp et al. (1980)[19]	East North Central Region (OH, IN, IL, MI, WI)	One-year survey of individuals asked to record their fish consumption	• Represented average consumption of freshwater fish by freshwater fish consumers in a region that included WI • Did not differentiate between commercially and recreationally caught freshwater fish • Did not identify fish consumption by anglers • Did not reflect most up-to-date state of the fisheries	11.2 g/d (freshwater fish consumed by the average freshwater fish consumer)
Cox (1985)[20]	Ontario	Questionnaire sent to Ontario sport anglers by the Ontario Ministry of the Environment in 1983	• Represented average consumption rate of locally caught freshwater fish by recreational anglers • The sport fishery encompassed by the study was similar to that found in WI	21.8 g/d (local freshwater fish recreationally caught)
Olson (1988)[21]	Inland waters of Wisconsin, Lake Michigan, Green Bay, and Lake Superior	Questionnaire sent to Wisconsin residents with fishing licenses in 1984	• Represented average consumption rate of locally caught freshwater fish by WI recreational anglers • Survey as not specifically designed to quantify the fish intake of WI anglers	12.3 g/d (sport-caught fish by Wisconsin anglers)

The U.S. EPA's 2015 updates to the human health criteria also include revisions to the average fish consumption rate.[14] In these revisions, the average fish consumption rate of an adult was increased to 0.022 kg/d based on data from the recent NHANES survey (NHANES 2003-2010). This valued represents the 90th percentile for adults. The data used to derive Wisconsin's fish consumption rate will be evaluated to ensure that the current rate provides adequate protection changes as part of the 2018–2020 Triennial Standards Review. As part of this Review, the Department will also evaluate whether changes to the fish consumption rate are needed to protect subsistence fishing. If necessary, revisions to Chapter NR 105 and this guidance document will be made.

Bioaccumulation

Bioaccumulation is the process that describes the uptake of a substance by aquatic organisms. The Bioaccumulation Factor (BAF) measures the likelihood a substance will accumulate in an aquatic organism from exposure via all possible routes (i.e., ambient water, diet, sediment). The BAF is defined as the "ratio of a substance's concentration in the tissue of an organism to its concentration in the ambient water, in situations where both the organism and its food are exposed to the substance and where the ratio does not change substantially over time."[4] The BAF is an important component of human health criteria because certain substances are able to accumulate within aquatic organisms from the water, their diet, and/or other sources. The BAF is important because the substance could still be present in fish at levels that are unsafe for human consumption even when it is not present in the water at a level that would cause human health effects from drinking.

To derive the specific BAF for a human health criterion, a baseline BAF is first determined. The baseline BAF allows extrapolation of the BAF from one waterbody to another. For organic chemicals, the baseline BAF is defined as "a bioaccumulation factor normalized to 100% lipid that is based on the concentration of a freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical

within the organism."[4] For inorganic chemicals, the baseline BAF defined as "a bioaccumulation factor based on the wet weight of the tissue."[4]

Data for deriving baseline BAFs can be found from a number of references including U.S. EPA's water quality criteria documents, published scientific literature, U.S. EPA and other similar reports, and unpublished data. More details on the data requirements for each of these methods are available in Appendix A and more detailed discussion on the methods used to derive a baseline BAF is available in Appendix C (*Note: if the baseline BAF is greater than 1000, a human health criterion cannot be calculated. Instead, a secondary human threshold value is derived*).

Once the baseline BAF is determined, the human health BAF is then calculated. For organic substances, the fraction of the substance that is freely dissolved in water is first calculated using the following equation:

Equation 1:

$$f_{fd} = \frac{1}{\left(\frac{DOC \times K_{OW}}{10}\right) \times (POC \times K_{OW})}$$

Where:
- POC is the concentration of particulate organic carbon (4×10^{-8} kg/L)
- DOC is the concentration of dissolved organic carbon (2×10^{-6} kg/L)
- K_{OW} is the octanol-water coefficient and is a measure of how soluble a substance is in hydrophobic solutions (i.e., oil, fat) versus hydrophilic solutions (i.e., water). The higher the K_{OW}, the more soluble the substance is in hydrophobic solutions and more likely it is to bioaccumulate in organisms.

This fraction is then used to calculate the human health BAF is calculated with the following equation:

Equation 2: Human Health BAF = [(baseline BAF)(lipid fraction) +1] x (f_{fd})

When the Department revised their human health criteria values and procedures in the late 1980s, it also calculated the lipid content of locally caught and consumed freshwater fish such that the BAFs used to derive Wisconsin's human health criteria are

based on data specific to Wisconsin.[16] For this analysis, the Department used data from the fish contaminant monitoring database and a survey of WI anglers conducted by the Department of Health and Social Services. From the contaminant database, the Department obtained the lipid content of over 70 species of Wisconsin fishes. From the survey, the Department was able to obtain information on the amount and type of fish caught and consumed by Wisconsin anglers. Lipid content values were then sorted by fish species and location and the average lipid content for each species/location combination was calculated. The weighted-average lipid content value was calculated by dividing the averages for each species/location combination for a given FAL use category by the weight of the fish species/location caught and kept for consumption for that category. The Department derived a lipid fraction of 0.044 for Wisconsin's cold waters and a lipid fraction of 0.013 for Wisconsin's warm waters.

For inorganic substances, the human health BAF is set equal to baseline BAF.

Equation 3: $$\text{Human Health BAF} = \text{Baseline BAF}$$

Human Threshold Criteria

For a non-carcinogenic substance, a human threshold criterion (HTC) is derived which is defined as "the maximum concentration of a substance established to protect humans from adverse effects resulting from contact with or ingestion of surface waters of the state and from ingestion of aquatic organisms taken from surface waters of the state."[4] Human threshold criteria are based on a threshold level because these substances typically have a concentration below which no adverse effects are likely to occur.

To derive a human threshold criterion, the exposure equation shown in

Table 5 is used and the following assumptions made:

- When two or more non-carcinogenic substances are present in the same waterbody, their effects are independent and noncumulative.
- For a non-carcinogenic substance, exposure from all possible routes (e.g., non-fish diet, inhalation) is additive.
- The HTC specific exposure parameters will be discussed in further detail in this section.

The standard exposure parameters (i.e., body weight, water consumption rate, fish consumption rate) and bioaccumulation factor described above are used. The acceptable daily exposure (ADE) is used as the toxicity parameter and the relative source contribution (RSC) is used as an additional exposure parameter.

Table 5. Human threshold criteria (HTC) exposure equation and parameters

Human Threshold Criteria	
Exposure Equation	
$HTC = \frac{ADE \times BW \times RSC}{W_H + (F_H \times BAF)}$	
Equation Parameters	
Toxicity	
Acceptable Daily Exposure (ADE)	Maximum amount of a substance which if ingested daily for a lifetime results in no adverse effects to humans (mg/kg-d)
Exposure	
Body Weight (BW)	Average weight of an adult male (70 kg)
Water Consumption Rate (W_H)	Average per capita daily consumption of water for surface waters classified as - Public water supply waters: 2 L/d - All other waters: 0.01 L/d
Fish Consumption Rate (F_H)	Average per capita daily consumption of sport-caught fish by WI anglers (0.02 kg/d)
Relative Source Contribution (RSC)	Factor used to account for routes of exposure other than consumption of contaminated water and aquatic organisms (default = 0.8)
Bioaccumulation	
Bioaccumulation Factor (BAF)	The ratio of a substance's concentration in the tissue of an aquatic organism to its concentration in the ambient water (L/kg)

The acceptable daily exposure (ADE) level is the "maximum amount of a substance which if ingested daily for a lifetime results in no adverse effects to humans" and is used to derive a human threshold criterion for a given substance.4 There are a number of references for obtaining ADEs including U.S. EPA's water quality criteria documents, public health advisories, and Wisconsin groundwater standards. Most of this information is available on the U.S. EPA's Integrated Risk Information System (IRIS) website.[22]

In many cases, the U.S. EPA's oral reference dose (RfD) is used as the ADE. If a U.S. EPA approved reference dose (RfD) is not available, the ADE is derived using the following steps:

- Identify the most sensitive toxicity endpoint

- Select the most appropriate no observable adverse effect level (NOAEL) for this endpoint. Note: if a NOAEL is not available, select the most appropriate lowest observable adverse effect level (LOAEL) for the same endpoint.
- Divide the NOAEL/LOAEL by the appropriate uncertainty factors

Figure 5 illustrates how the ADE can be derived from a NOAEL. More detailed discussion of these steps is available in Appendix C.

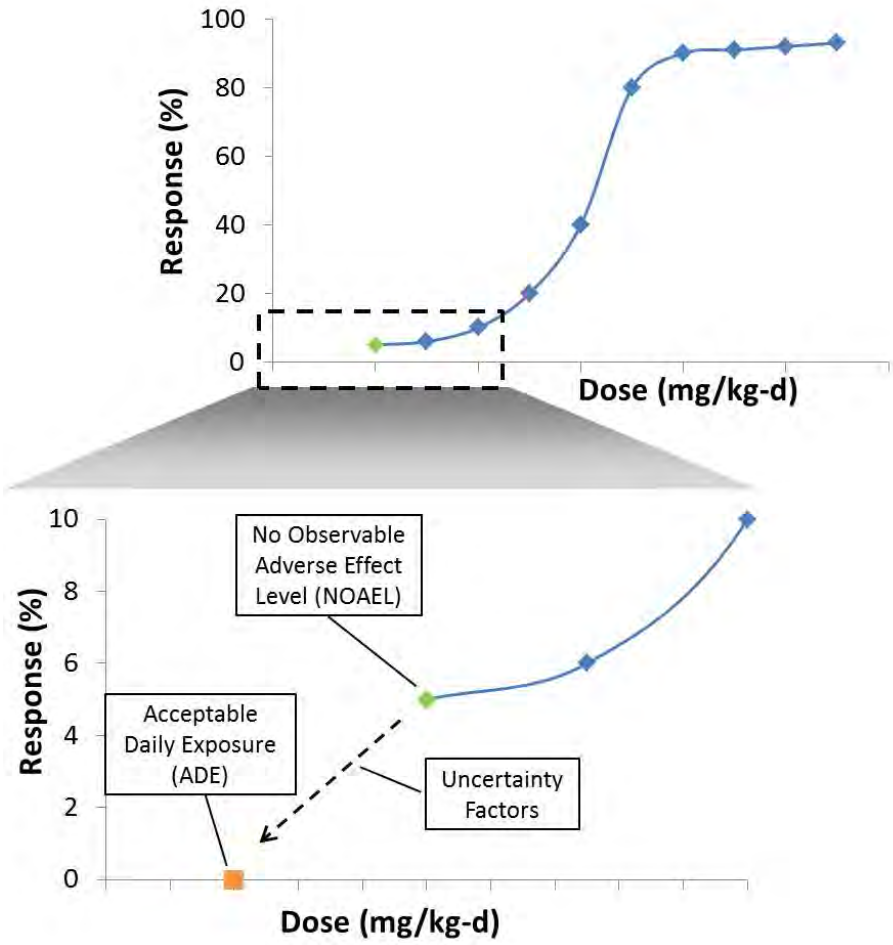

Figure 5. Representative dose-response curve for a non-carcinogenic substance illustrating how the ADE is determined from the NOAEL

The relative source contribution (RSC) is a "factor used to account for routes of exposure other than consumption of contaminated water and aquatic organisms."[4] The factor ensures that an individual's total exposure from all sources of the substance does not exceed the threshold level. A RSC can be calculated for a substance by determining

how much of the total exposure to a substance occurs from drinking contaminated water and eating contaminated aquatic organisms. Often, there is not enough data on alternative sources of exposure for the substance for a RSC to be calculated. In these instances, a default value of 0.8 is used.

Human Cancer Criteria

Human cancer criteria (HCC) are derived for carcinogenic substances and are defined as "the maximum concentration of a substance or mixture of substances established to protect humans from an unreasonable incremental risk of cancer resulting from contact with or ingestion of surface waters of the state and from ingestion of aquatic organisms taken from surface waters of the state."[4] A carcinogenic substance is defined as "a substance for which the induction of benign or malignant neoplasms has been demonstrated in humans; or two mammalian species; or one mammalian species, independently reproduced; or one mammalian species, to an unusual degree with respect to increased incidence, shortened latency period, variety of site, tumor type, or decreased age at onset; or one mammalian species, supported by reproducible positive results in at least 3 different types of short−term tests which are indicative of potential oncogenic activity."[4]

To derive a human cancer criterion, the exposure equation shown in

Table 6 is used and the following assumptions are made:

- The incremental cancer risk from exposure to a single carcinogenic substance or a mixture of carcinogenic substances from consumption of surface water and aquatic organisms is 1 in 100,000.
- The combined cancer risk of individual carcinogenic substances is additive.
- A linear, non-threshold dose-response relationship exists between the dose of the substance and the increased risk of cancer.

Table 6. Human cancer criteria (HCC) exposure equation and parameters

Human Cancer Criteria

Exposure Equation	
$HCC = \frac{RAD \times BW}{W_H + (F_H \times BAF)}$	
Equation Parameters	
Toxicity	
Risk Associated Dose (RAD)	Maximum amount of a substance which if ingested daily for a lifetime has an incremental cancer risk equal to 1 case of human cancer in a population of 100,000 (mg/kg-d) $RAD = \frac{1 \times 10^{-6}}{q_1^*}$ Where: - 1×10^{-6} is the incremental cancer risk - q_1^* is the upper 95% confidence limit of the carcinogenic potency factor (d-kg/mg)
Exposure	
Body Weight (BW)	Average weight of an adult male (70 kg)
Water Consumption Rate (W_H)	Average per capita daily consumption of water for surface waters classified as - Public water supply waters: 2 L/d - All other waters: 0.01 L/d
Fish Consumption Rate (F_H)	Average per capita daily consumption of sport-caught fish by WI anglers (0.02 kg/d)
Bioaccumulation	
Bioaccumulation Factor (BAF)	The ratio of a substance's concentration in the tissue of an aquatic organism to its concentration in the ambient water (L/kg)

The standard exposure factors (i.e., body weight, water consumption rate, fish consumption rate) and bioaccumulation factor described above are used. The risk associated dose (RAD) is used as the toxicity parameter.

The RAD is defined as the "maximum amount of a substance which if ingested daily for a lifetime has an incremental cancer risk equal to 1 case of human cancer in a population of 100,000."[4] The RAD can be derived from the carcinogenic potency factor, q_1^*, of the substance using the following equation:

Equation 4: $$\mathrm{RAD} = \frac{1}{q_1^*} \text{ x } 0.00001$$

Where:
- 0.00001 is the incremental cancer risk
- q_1^* is the upper 95% confidence limit of the carcinogenic potency factor (d-kg/mg)

There are a number of references for obtaining the RAD including U.S. EPA's water quality criteria documents, public health advisories, and Wisconsin groundwater standards. Most of this information is available on the U.S. EPA's Integrated Risk Information System (IRIS) website.[22] The U.S. EPA uses different terms for the values used in the derivation of a human cancer criterion; Table 7 lists U.S. EPA's and Wisconsin's terminology.

Table 7. Human cancer criteria toxicity value terminology used by Wisconsin and the U.S. EPA

Wisconsin	U.S. EPA
RAD Risk-associated dose (mg/kg/day)	RSD Risk-specific dose (mg/kg-d)
Incremental cancer risk (10^{-6})†	Target incremental cancer risk (10^{-4} to 10^{-6})†
q_1^* carcinogenic potency factor (mg/kg-d)	m cancer potency factor (mg/kg-d)

† U.S. EPA guidance recommends a target incremental cancer risk range of 10^{-4} to 10^{-6}. However, federal regulations states that "the risk associated dose shall be set at a level corresponding to an incremental cancer risk of one in 100,000" (10^{-6}) for all waters of the Great Lakes system.[8] As such, Department uses an incremental cancer risk of 10^{-6} for the derivation of all human cancer criteria.

If the carcinogenic potency factor (q_1^*) is not available, it can be estimated using the U.S. EPA's benchmark dose modeling program. This program fits various mathematical models to the observed toxicity data and estimates the benchmark dose (BMD), which is an estimate of the dose or concentration that produces a predetermined change in the response rate of an adverse effect.[23] The BMD is then used to derive the cancer slope factor. Figure 6 illustrates how the RAD can be derived from a benchmark dose

(BMD). Additional information on benchmark dose modeling can be found on U.S. EPA's website.[24]

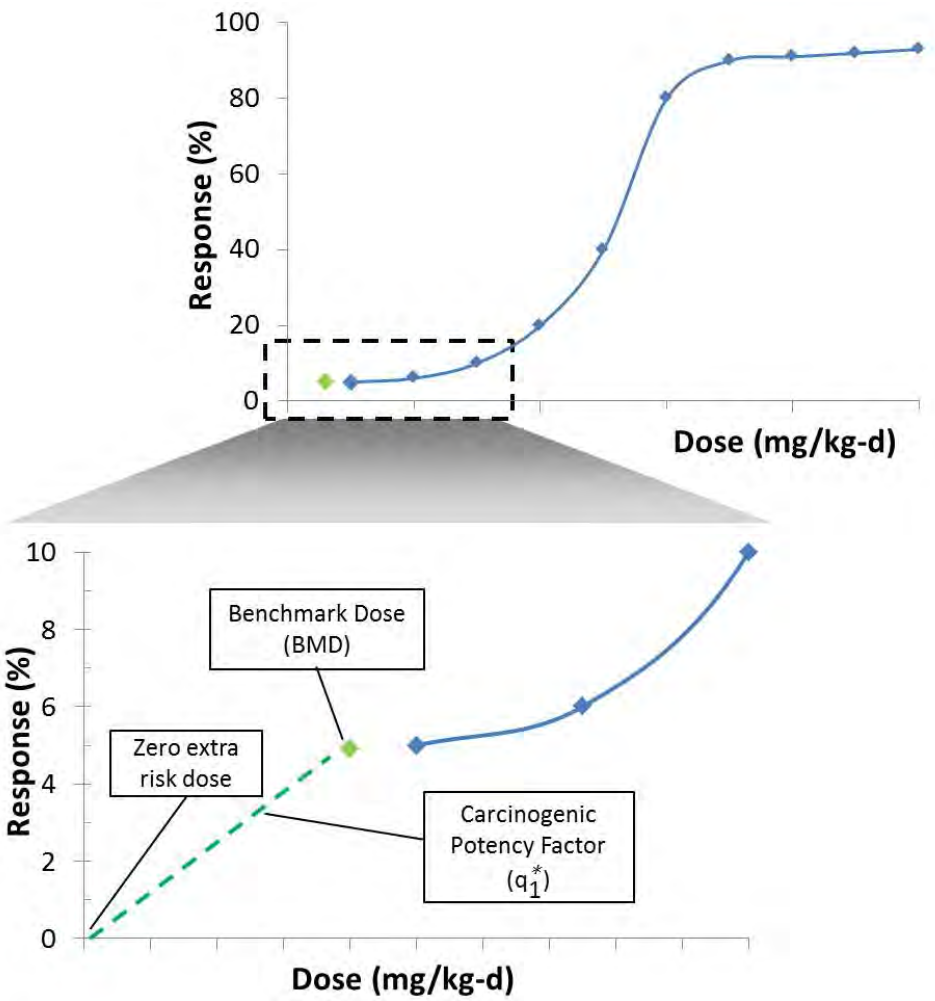

Figure 6. Representative dose-response curve for a carcinogenic substance illustrating how the q_1* is determined from the BMD

Using the procedures described in this section and the applicable appendices, criteria can be derived that protect humans from the adverse effects associated with long-term exposure to both non-carcinogenic and carcinogenic substances.

Wildlife Criteria

A wildlife criterion is defined as "the concentration of a substance which if not exceeded protects Wisconsin's wildlife from adverse effects resulting from ingestion of surface waters of the state and from ingestion of aquatic organisms taken from the surface waters of the state."[4] The wildlife criteria do not apply to domestic animals because domestic animals do not regularly consume aquatic organisms. Separate criteria can be derived on an as-needed basis for the protection of domestic animals using an exposure model that accounts for drinking water exposure.

Wildlife criteria are derived for any substance that may cause long-term effects in wildlife species that consume aquatic organisms. The methods used to derive Wisconsin's wildlife criteria are similar to those used to derive the human threshold criteria and were developed by the U.S. EPA.[8]

The following steps are used to derive a wildlife criterion:

1. The wildlife value is calculated for each of the required species
2. The mean wildlife value is calculated for mammals and birds
3. The wildlife criterion is set equal to lower of mean wildlife values

Step 1. Calculate the wildlife values for each species

The wildlife value is calculated using an exposure equation that models exposure to the substance through the drinking of surface waters and consumption of aquatic organisms (Table 8).

To derive a wildlife criterion, wildlife values must be calculated for 5 species (mammals: mink, river otter; and birds: bald eagle, kingfisher, herring gull). These species serve as representatives of those likely to experience the highest exposures to toxic substances through the aquatic food chain. Although less common, a wildlife value can be calculated for reptiles, if acceptable data is available.

Toxicity Parameters

The toxicity value used to derive wildlife criteria is the NOAEL or LOAEL related to reproduction, development, survival, growth, and any other parameters that directly influence population dynamics. The studies must provide enough data to generate a subchronic or chronic dose-response curve (see Appendix A for more data requirements).

Table 8. Wildlife value (WV) exposure equation and parameters

Wildlife Criteria	
Exposure Equation	
$$WV = \frac{TV \times Wt \times SSF}{W + \sum (F_{TL_i} \times BAF_{TL_i})}$$	
Equation Parameters	
Toxicity	
Toxicity Value (TV)	$$TV = \frac{\text{Toxicity Dose}}{UF_S \times UF_L}$$ Where: - The toxicity dose is the NOAEL or LOAEL from a subchronic or chronic mammalian or avian study (mg/kg-d) - UF_S and UF_L are uncertainity factors that account for extrapolation between subchronic and chronic endpoints and between LOAELs and NOAELs
Species Sensitivity Factor (SSF)	Factor that accounts for the interspecies difference in sensitivity (0.01-1)
Exposure	
Weight (Wt)	Average weight of the representative species (kg)
Water Consumption Rate (W)	Average daily volume of water consumed by the representative species (L/d)
Fish Consumption Rate (F_{TLi})	Average daily amount of food consumed from trophic level I by the representative species (kg/d)
Bioaccumulation	
Bioaccumulation Factor (BAF_{TLi})	The ratio of a substance's concentration in the tissue of an aquatic organism in trophic level i to its concentration in the ambient water (L/kg)

In some cases, uncertainty factors are necessary to account for the uncertainty in how well the available data estimates the potential for adverse effects. For wildlife criteria, the following uncertainity factors may be applied:

- Species sensitivity factor (SSF)

- Subchronic extrapolation uncertainity factor (UF_S)
- LOAEL extrapolation uncertainity factor (UF_L)

The species sensitivity factor (SSF) accounts for the variability in sensitivity between different species and ranges from 0.01 to 1. The SSF is selected by considering the available toxicological data, the physicochemical, toxicological properties of the substance, and the quality of the available data. A SSF is applied to each of the five species, but the value applied may differ for each species based on existing data and best professional judgment. The SSF is equal to the inverse of the U.S. EPA's interspecies uncertainity factor (UF_A).[8]

The subchronic extrapolation uncertainity factor (UF_S) is used when acceptable results from a chronic study are not available but acceptable results from a subchronic study are available. The UF_S accounts for the possibility that the subchronic study underestimates the potential for adverse effects and ranges from 1 to 10. The UF_S is selected by considering the length of the exposure, sensitivity and life stages of the species tested, and the toxicological properties of the substance.

The LOAEL extrapolation uncertainity factor (UF_L) is used when a NOAEL from an acceptable study is not available but a LOAEL is available. The UF_L accounts for the possibility that the LOAEL underestimates the potential for adverse effects and ranges from 1 to 10. The UF_L is selected by considering the magnitude of the measured LOAEL, the steepness of the dose-response curve, and the severity of the effects observed. For more information regarding the selection of the appropriate uncertainity factors for wildlife criteria derivation, see the U.S. EPA's *Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria*.[25]

Exposure Parameters

Typically, the relevant exposure parameters (weight, water consumption rate, fish consumption rate) are obtained from the study from which the toxicity value was

derived. However, if these parameters are not provided, average exposure parameters for the five required species can be used (Table 9).[25]

Table 9. Average exposure parameters for the species required for deriving a wildlife criterion[17]

Representative Species	Adult Body Weight (kg)	Water Ingestion Rate (L/d)	Aquatic Food Ingestion Rate (kg/d)
Mink	0.78	0.081	Trophic Level 3 = 0.159
River Otter	7.4	0.60	Trophic Level 3 = 0.976 Trophic Level 4= 0.244
Belted Kingfisher	0.15	0.017	Trophic Level 3 = 0.0672
Bald Eagle	4.6	0.16	Trophic Level 3 = 0.371 Trophic Level 4 = 0.0928 Fish eating birds = 0.0283
Herring Gull	1.1	0.063	Trophic Level 3 = 0.192 Trophic Level 4 = 0.048

Bioaccumulation

While bioaccumulation was previously described in relation to human health criteria, it is also an important consideration in deriving wildlife criteria because exposure for wildlife is most likely to be through consumption of aquatic organisms that have accumulated the substance over time.

To derive the specific BAF for a wildlife criterion, the baseline BAF is first determined using the procedures described in Appendix C. Once the baseline BAF is determined, the wildlife BAF is then calculated.

For organic substances, the fraction of the substance that is freely dissolved in water is first calculated using Equation 1. The wildlife BAF is then calculated using the following equation:

Equation 5: $$\text{Wildlife BAF} = [(\text{baseline BAF})(\text{lipid fraction}) + 1] \times (f_{fd})$$

Where: - The standardized lipid fraction values are used to derive wildlife BAF. These values depend on the trophic level and are referenced in the Great Lakes Water Quality Initiative.[1]

Trophic Level	Lipid Content
3	0.0646
4	0.1031

For inorganic substances, the wildlife BAF is set equal to baseline BAF.

Equation 6: Wildlife BAF = Baseline BAF

Step 2. Calculate the mean wildlife values

The mean wildlife value (WV) is then calculated for the mammalian and avian species. The mean mammalian wildlife value equals the geometric mean of the mink and river otter values.

Equation 7: $$WV_{Mammals} = \text{Geometric mean } (WV_{mink}, WV_{otter})$$

The mean avian wildlife value equals the geometric mean of the bald eagle, kingfisher, and herring gull wildlife values.

Equation 8: $$WV_{Birds} = \text{Geometric mean } (WV_{kingfisher}, WV_{eagle}, WV_{gull})$$

Step 3. Set the wildlife criterion

The wildlife criterion (WC) is equal to the lower two mean wildlife values.

Equation 9: $$WC = \text{Minimum } (WV_{mammals}, WV_{birds})$$

Using the procedures described in this section and the applicable appendices, criteria can be derived that protect wildlife from the adverse effects associated with long-term exposure to toxic substances.

Conclusion

Water quality criteria are one component of water quality standards and are designed to protect the designated use. Wisconsin has water quality criteria to protect fish and aquatic life, human health, and wildlife. To protect fish and aquatic life, both acute and

chronic criteria are derived for a given substance. The acute toxicity criteria protect aquatic life from lethality caused by short-term exposure and chronic toxicity criteria protect aquatic life from sublethal effects caused by long-term exposure. To protect humans, human health criteria are derived for substances that cause non-carcinogenic effects and substances that cause carcinogenic effects. A human health criterion is derived using an exposure equation that models exposure to the substance through the drinking of surface waters or incidental consumption of water during recreation and consumption of aquatic organisms. To protect wildlife, criteria are derived for any substance that may cause long-term effects in wildlife species that consume aquatic organisms using a method that is similar to one used to derive the human threshold criteria.

Glossary

Acute toxicity: the ability of a substance to cause mortality or an adverse effect in an organism which results from a single or short−term exposure to the substance.

Acute toxicity criterion (ATC): maximum daily concentration of a substance which ensures adequate protection of sensitive species of aquatic life from the acute toxicity of that substance and will adequately protect the designated fish and aquatic life use of the surface water if not exceeded more than once every 3 years; also referred to as Tier I aquatic life criteria by the U.S. EPA.

Acute toxicity equation (ATE): the equation used to calculate the acute toxicity criterion at a given water quality parameter value when toxicity depends on that water quality parameter.

Acute-chronic ratio (ACR): method used to estimate the chronic toxicity of a substance to fish or other aquatic species when the minimum database requirements (MDRs) are not met; equals the acute concentration divided by the chronic concentration.

Adequate protection: level of protection which ensures survival of a sufficient number of healthy individuals in a population of aquatic species to provide for the continuation of an unreduced population of these species.

Adverse effect: any effect resulting in a functional impairment or a pathological lesion, or both, which may affect the performance of the whole organism, or which contributes to a reduced ability to respond to an additional challenge.

Baseline bioaccumulation factor (baseline BAF): for organic chemicals, a bioaccumulation factor normalized to 100% lipid that is based on the concentration of a freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism. For inorganic chemicals, a bioaccumulation factor is based on the wet weight of the tissue.

Baseline bioconcentration factor (baseline BCF): for organic chemicals, a bioconcentration factor normalized to 100% lipid that is based on the concentration of freely dissolved chemical in the ambient water and takes into

account the partitioning of the chemical within the organism. For inorganic chemicals, a bioconcentration factor is based on the wet weight of the tissue.

Bioaccumulation: the net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF): the ratio (in L/kg) of a substance's concentration in the tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed to the substance and where the ratio does not change substantially over time.

Bioconcentration: the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through its gill membranes or other external body surfaces.

Bioconcentration factor (BCF): the ratio (in L/kg) of a substance's concentration in the tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and where the ratio does not change substantially over time.

Biota−sediment accumulation factor (BSAF): the ratio (in kg of organic carbon/kg of lipid) of a substance's lipid−normalized concentration in the tissue of an aquatic organism to its organic carbon−normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and where the surface sediment is representative of the average surface sediment in the vicinity of the organism.

Carcinogen: any substance for which the induction of benign or malignant neoplasms has been demonstrated in humans; or two mammalian species; or one mammalian species, independently reproduced; or one mammalian species, to an unusual degree with respect to increased incidence, shortened latency period, variety of site, tumor type, or decreased age at onset; or one mammalian species, supported by reproducible positive results in at least 3 different types of short−term tests which are indicative of potential oncogenic activity.

Chronic toxicity: the ability of a substance to cause an adverse effect in an organism which results from exposure to the substance for a time period representing that substantial portion of the natural life expectancy of that organism.

Chronic toxicity criterion (CTC): the maximum 4−day concentration of a substance which ensures adequate protection of sensitive species of aquatic life from the chronic toxicity of that substance and will adequately protect the designated fish and aquatic use of the surface water if not exceeded more than once every 3 years; also referred to as Tier I aquatic life criteria by the U.S. EPA.

Cumulative probability (P): probability that the value of a random variable falls within a specified range.

Dissolved Concentration: the portion of the substance which will pass through a 0.45 µm filter.

EC50: concentration of a toxic substance which causes an adverse effect including mortality in 50% of the exposed organisms in a given time period.

Final acute value (FAV): an estimate of the concentration of the material corresponding to a cumulative probability of 0.05 in the acute toxicity values for the genus with which acceptable acute tests have been conducted on the material.

Final acute-chronic ratio (FACR): Ratio of the available chronic data to the acute toxicity criterion; used to calculate a chronic toxicity criterion when chronic data from all of the minimum data requirements (MDRs) are not available.

Final chronic value (FCV): an estimate of the concentration of the material corresponding to a cumulative probability of 0.05 in the chronic toxicity values for the genus with which acceptable acute tests have been conducted on the material.

Final plant value (FPV): the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test substance were measured and the adverse effect was biologically important; used to compare the relative sensitivities of aquatic plants and animals.

Final toxicity equation (FTE): the equation used to calculate the chronic toxicity criterion at a given water quality parameter value when toxicity depends on that water quality parameter.

Food−chain multiplier (FCM): the ratio of a bioaccumulation factor (BAF) to an appropriate bioconcentration factor (BCF).

Genus mean acute intercept (GMAI): the geometric mean of the all species mean acute intercepts (SMAIs) for a given genus.

Genus mean acute value (GMAV): the geometric mean of the all species mean acute values (SMAVs) for a given genus.

Genus mean chronic intercept (GMCI): the geometric mean of the all species mean chronic intercepts (SMCIs) for a given genus.

Genus mean chronic value (GMCV): the geometric mean of the all species mean chronic values (SMCVs) for a given genus.

Geometric mean: for N values, the Nth root of the product of the N value; it can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. Used instead of arithmetic means because the distributions of individual organisms sensitivities and the distributions of species sensitivities within a genus are more likely to be lognormal than normal.

LC50: the concentration of a toxic substance which is lethal to 50% of the exposed organisms in a given time period.

LD50: the internal dose of a toxic substance which is lethal to 50% of the exposed organisms in a given time period.

Lipid−soluble substance: a substance which is soluble in nonpolar organic (hydrophobic) solvents and which tends to accumulate in the fatty tissues of an organism exposed to the substance.

Log K_{OW}: base 10 logarithm of the octanol-water coefficient.

Lowest observable adverse effect level (LOAEL): the lowest tested concentration that caused an adverse effect in comparison with a control when all higher test concentrations caused the same effect.

Mean water quality parameter value (X): Geometric mean of all water quality parameter values for a given species.

Mean toxicity value (W): Geometric mean of all acceptable toxicity tests for a given species.

No observable adverse effect level (NOAEL): highest tested concentration that did not cause an adverse effect in comparison with a control when no lower test concentration caused an adverse effect.

Octanol-water coefficient (KOW): the ratio of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated 2-phase octanol-water system.

Secondary acute equation (SAE): the equation used to calculate the secondary acute value at a given water quality parameter value when toxicity depends on that water quality parameter.

Secondary acute factor (SAF): an adjustment factor that corresponds to the number of minimum data requirements (MDRs) that are met; used to calculate a secondary acute value.

Secondary acute intercept (SAI): the intercept of the equation relating the water quality parameter value to the toxicity value for each species for the derivation of a secondary acute value.

Secondary acute-chronic ratio (SACR): Ratio used when a final acute-chronic ratio (FACR) cannot be calculated because data for one of the three required taxa is not available; equals the geometric mean of three acute-chronic ratios (ACRs); use of this value will result in a secondary chronic value.

Secondary value: temporary value that represents the concentration of a substance which ensures adequate protection of sensitive species of aquatic life, wildlife or human health from the toxicity of that substance and will adequately protect the designated use of the surface water until database requirements are fulfilled to calculate a water quality criterion; also referred to as Tier II aquatic life value by the U.S. EPA.

Species mean acute intercept (SMAI): the intercept of the equation relating the water quality parameter value to the toxicity value for each species for the derivation of an acute toxicity criterion.

Species mean acute value (SMAV): the geometric mean of all acceptable acute toxicity values for a given species.

Species mean acute-chronic ratio (SMACR): the geometric mean acute-chronic ratio that is calculated for each species using the available ratios for that species.

Species mean chronic intercept (SMCI): the intercept of the equation relating the water quality parameter value to the toxicity value for each species for the derivation of a chronic toxicity criterion.

Species mean chronic value (SMCV): the geometric mean of all acceptable chronic toxicity values for a given species.

Taxa: category of organisms

Toxic substance: a substance or mixture of substances which through sufficient exposure, or ingestion, inhalation or assimilation by an organism, either directly from the environment or indirectly by ingestion through the food chain, will cause death, disease, behavioral or immunological abnormalities, cancer, genetic mutations, or developmental or physiological malfunctions, including malfunctions in reproduction or physical deformations, in such organisms or their offspring.

Trophic level: a functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic plants comprise the first trophic level, herbivores comprise the second, small fish comprise the third, predatory fish the fourth, etc.).

Water quality parameter: one of the indicators available for describing the distinctive quality of water including, but not limited to, hardness, pH, or temperature.

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Appendix A: Data Acceptability Requirements

Fish and Aquatic Life

Table A-1. Acceptable acute toxicity endpoints for the derivation of fish and aquatic life water quality criteria[9]

Test Organism	Age at Start of Test	Result	Test Duration	Endpoint
Cladoceran	< 24 hr	Percentage of organisms immobilized plus percentage of organisms killed OR Percentage of organisms killed	48 hr	EC50
Midge	< 24 hr	Percentage of organisms immobilized plus percentage of organisms killed OR Percentage of organisms killed	48 hr	EC50
Barnacles, bivalve molluscs, sea urchins, lobsters, crabs, shrimp, and abalones	Embryo/Larvae	Percentage of organisms with incompletely developed shells plus the percentage of organisms killed OR Percentage of organisms killed	96-hr	EC50
	older life stages	Percentage of organisms exhibiting loss of equilibrium plus the percentage of organisms immobilized plus the percentage of organisms killed OR Percentage of organisms killed	96-hr	LC50
All other freshwater species	Any	Percentage of organisms exhibiting loss of equilibrium plus the percentage of organisms immobilized plus the percentage of organisms killed OR Percentage of organisms killed	96-hr	LC50

Table A-2. Acceptable chronic toxicity endpoints for the derivation of fish and aquatic life water quality criteria[9]

Test Organism	Type of Test	Age at Start of Test	Result	Test Duration	Endpoint
Fish	Life-cycle[a]	< 48 hr old	Survival Growth of adults and young Maturation of males and females Eggs spawned per female Embryo viability (salmonids) Hatchability	Until after hatching of next generation	LOAEL[d] NOAEL[e]
	Partial Life-cycle[b]	juvenile	Survival Growth of adults and young Maturation of males and females Eggs spawned per female Embryo viability (salmonids) Hatchability	Until after hatching of next generation	LOAEL NOAEL
	Early life stage[c]	Fertilization	Survival Growth	Until after juvenile development	LOAEL NOAEL
Daphnia	Life-cycle	< 24 hr old	Survival Young per female	≥ 21 days	LOAEL NOAEL
Mysids	Life-cycle	< 24 hr old	Survival Growth Young per female	Until 7 days after first brood release	LOAEL NOAEL

a. Exposures of each of two or more groups of individuals of a species to a different concentration of the test material throughout a life cycle
b. Exposures of each of two or more groups of individuals of a species of fish to a different concentration of the test material through most portions of a life cycle; allowed with fish species that require more than a year to reach sexual maturity, so that all major life stages can be exposed to the test material in less than 15 months .
c. Early life-stage tests are used as predictors of life-cycle and partial life-cycle tests with the same species. Therefore, when results of a life-cycle or partial life-cycle test are available, results of an early life-stage test with the same species should not be used.
d. LOAEL = lowest observable adverse effect level
e. NOAEL = no observable adverse effect level

General Requirements

Data format

- The study should be available in a typed, dated, and signed hard copy (e.g., report, publication, manuscript, letter, memorandum) with enough supporting information to indicate that acceptable test procedures were used and that the results are probably reliable.
- The study should not contain questionable data. The agreement of the data within and between species should be considered. Values that appear to be questionable in comparison with other data for the same species and for other species in the same genus should not be used.
- The study should be in English.

Test organisms

- The test organism should be an aquatic organism.
- The test organism should be a native freshwater resident (i.e., a species that has reproducing wild populations in North America).
- The study should use whole organisms and not tissue/cell cultures.
- Details on the test organisms (e.g., age, source, acclimation) should be provided.
- The test organisms should not have been previously exposed to the test material or other contaminants.
- The test organisms should not be from more than one source.

Test materials

- The test material should not be a formulated mixture or emulsifiable concentrate of the material of concern.
- If the test substance was a highly volatile, hydrolyzable, or degradable material, the test should have been conducted under flow-through conditions in which the concentrations of test material in the test solutions were measured often using acceptable analytical methods.

- Exposure to the test material should have been continuous.
- The test material should be an individual element and not a mixture or a component of another material.
- The purity of the test material should be >80%.
- The test material should not contain an organic solvent that was not miscible with water.
- The test material should not have a very short half-life in water (e.g., highly volatile, hydrolysable, degradable).
- If the dilution water was distilled or deionized water, appropriate salts should have been added prior to exposure.
- If the dilution water was chlorinated, adequate dechlorination should have been performed before exposure.

Experimental Design

- Details of the test chambers (e.g., size, material) should be provided.
- Details on the preparation of the test solutions and dilution water should be provided.
- If toxicity is related to a water quality parameters (i.e., hardness, pH), the parameter should be provided.
- An acceptable level of dissolved organic carbon (i.e., TOC < 5 mg/L) should be used.
- An appropriate temperature (i.e. normal range for that spp.) should be used.
- An appropriate pH (6.5 - 9.0) should be used.
- The correct number of organisms (10 per treatment) should be used.
- The correct number of treatments (> 4 not including control) should be used.
- A control treatment should be included and the effect level in the control treatment should be acceptable.

Test Results

- Details on how the result was calculated should be provided.
- Test results reported as "greater than" values can be used if the tests were conducted properly.

Specific Requirements

Acute Toxicity

- If one or more life stages are at least a factor of two more resistant than one or more other life stages of the same species, the data for the most sensitive life stage(s) should be used.
- Acute values should be based on endpoints which reflect the total severe acute adverse impact of the test material on the organisms used in the test (see Table A-2 – pg. A-3).
- For each species for which at least one acute value is available, the results of all flow-through tests in which the concentrations of test material were measured should be used. For a species for which no such results are available, all available acute values can be used.
- The test organisms should not have been fed during the test.

Chronic toxicity

- Chronic values should be based on results of flow-through (except renewal is acceptable for daphnids) tests in which the concentrations of test material were properly measured at appropriate times during the test

Acute-Chronic Ratio Method

- The same dilution water for both acute and chronic tests should be used.
- Tests should use flow-through conditions (except static conditions are acceptable for tests with *Daphnia*).
- Tests with fish should be conducted with juveniles.

Aquatic Plants

- Acceptable toxicity values:
  - Acute (96−hour) test conducted with an algae
  - Chronic test conducted with an aquatic vascular plant.
- A test of the toxicity of a metal to a plant may not be used if the medium contained an excessive amount of a complexing agent (e.g., EDTA) that might affect the toxicity of the metal.

Human Health

Table A-3. Data Requirements for Baseline BAF Determination

Requirements	Applicable Method			
	1	2	3	4
Field studies are conducted in representative waters (i.e., Great Lakes, U.S. EPA Region 5) with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).	X	X		
The trophic level of the fish species is determined.	X	X		
The site of the field study is not so unique that the BAF cannot be extrapolated to other locations.	X	X		
For organic chemicals, the percent lipid is measured or reliably estimated.	X	X	X	
The concentration of the chemical in the water is measured and should be relatively constant during the steady-state time period.	X		X	
For organic chemicals with log K_{OW} >4, the concentrations of POC and DOC in the ambient water (test solution) are measured or reliably estimated.	X		X	
BAF/BCFs are expressed on a wet weight basis	X		X	
Samples of surface sediments are from locations in which there is net deposition of fine sediment and are representative of average surface sediment in the vicinity of the organism.		X		
The test organisms are not diseased, unhealthy, or adversely affected by the concentration of the chemical.			X	
The test organisms are exposed to the chemical using a flow-through or renewal procedure.			X	
A fish species is used to determine laboratory-measured BCFs.			X	
If laboratory-measured BCFs change as the concentration of the chemical increases, the BCF measured at the lowest test concentration that is above control values is used.			X	

For inorganic chemicals, the chemical concentrations in a bioconcentration test should be - Greater than normal background levels, and - Greater than levels required for normal nutrition (if the chemical is a micronutrient), and - Below levels that adversely affect the species.		X	
For organic substances, BCFs can be based on measurement or radioactivity if the BCF includes metabolites or if there is no interference due to the metabolites.		X	
The calculation of the BCF addresses growth dilution.		X	
If more than one acceptable K_{OW} values are available, the mean of the values is used			X

Wildlife

General Requirements

- Exposure routes other than oral can only be considered if the equivalent oral daily dose can be estimated
- All data not part of the selected subset can be used to assess the reasonableness of the toxicity value and the appropriateness of the uncertainity factors

Data preference

- Endpoints
    - Development and reproduction are most preferred endpoints
- Study type
    - Peer-reviewed field studies of wildlife species of adequate quality (1st)
    - Peer-reviewed laboratory study with wildlife species (2nd)
    - Peer-reviewed laboratory study with traditional species (3rd)

Acceptable field study

- Subchronic or chronic duration
- Chemical-specific dose-response curve
- cause and effect are clearly established

Acceptable lab study

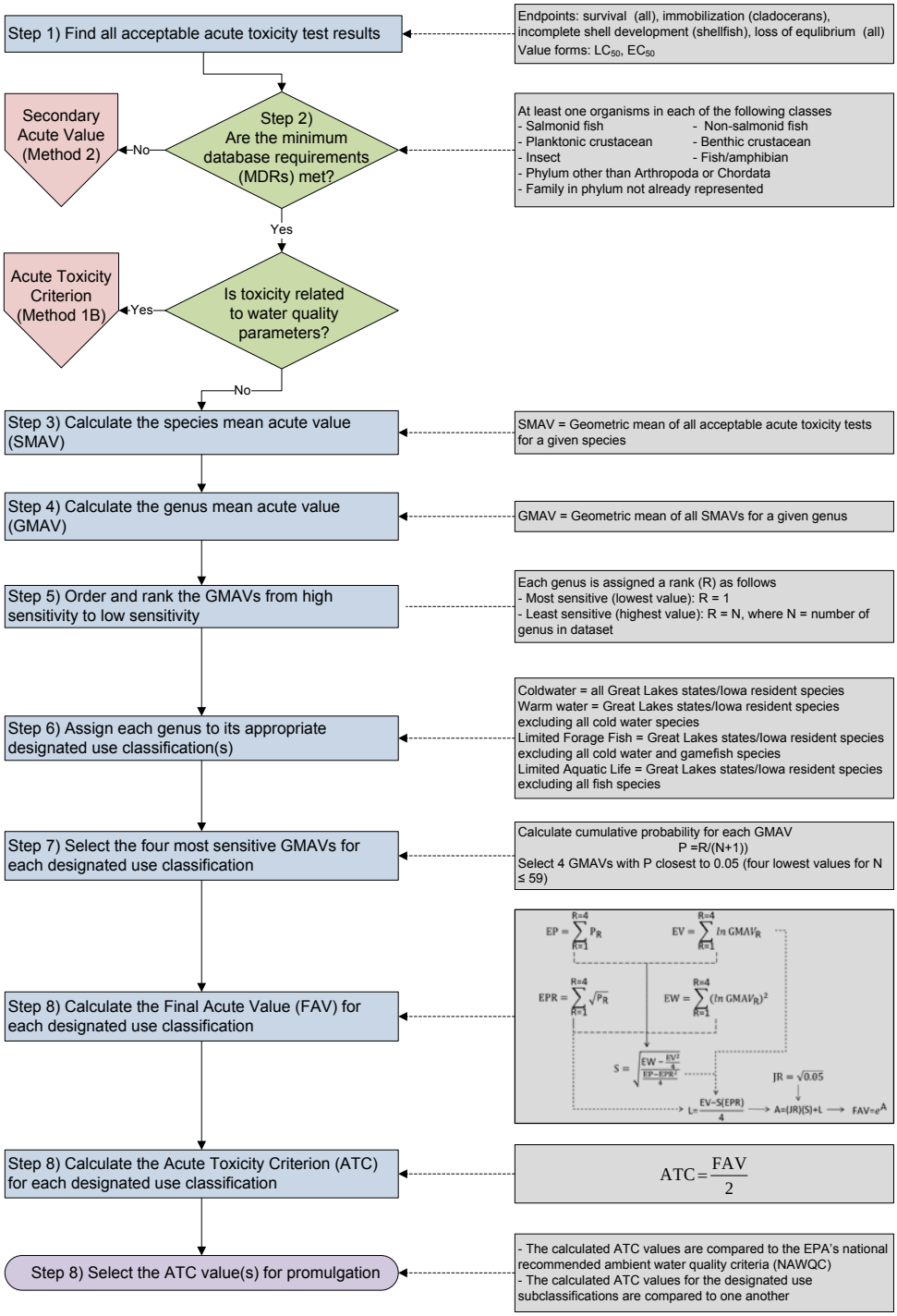
- Mammalian data must come from a least one study of ≥90 d designed to observe subchronic or chronic effects
- Avian data must come from a least one study of ≥70 d designed to observe subchronic or chronic effects

Addressing multiple toxicity values

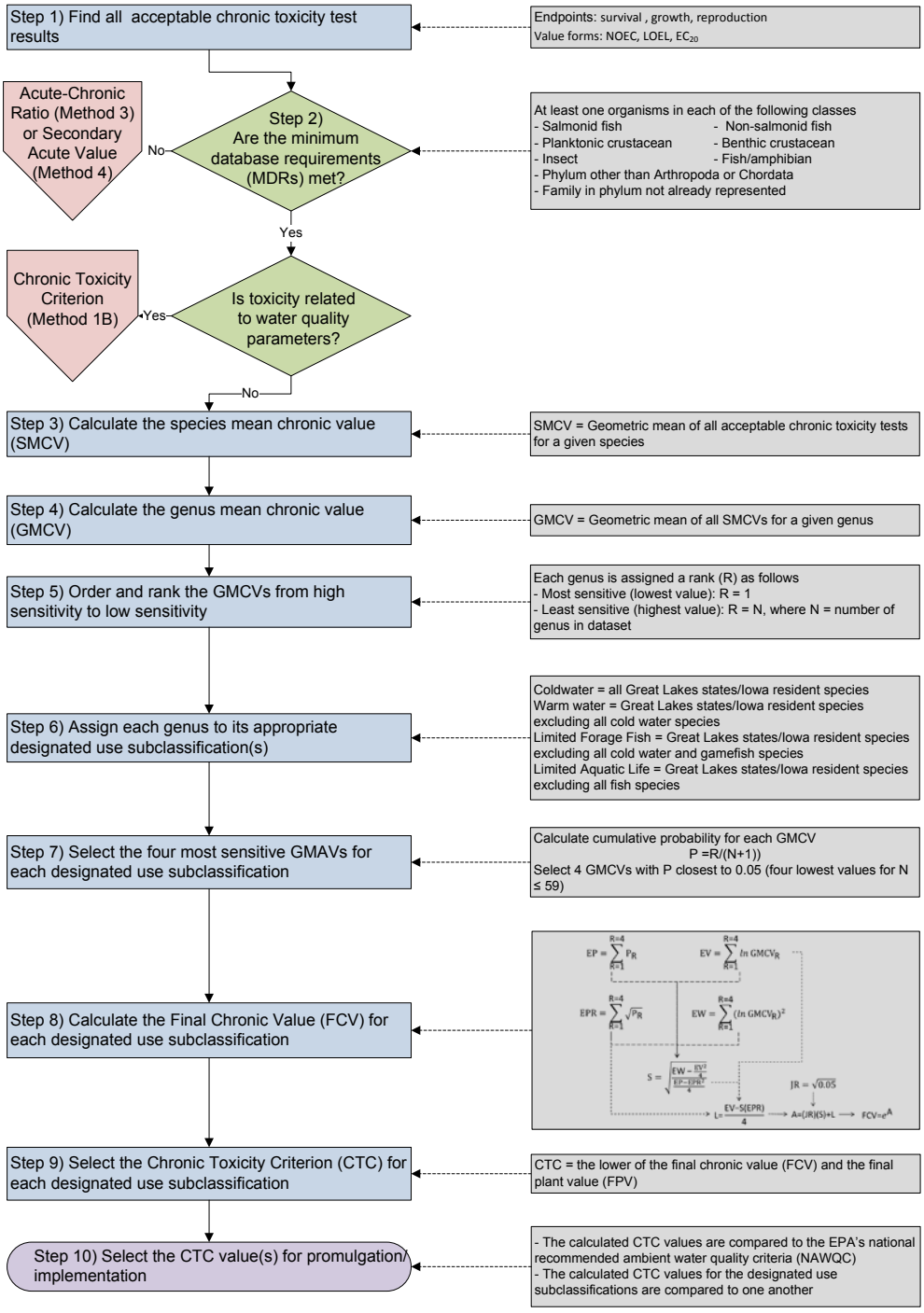
- If more than one TV is available within a class (mammals, avian) based on different endpoints, the WV that is likely to best reflect potential impacts to wildlife populations through changes in mortality or fecundity rates is used to calculate the WVs
- If more than one TV is available for a species based on the same endpoint, the WV for that species is the is the geometric mean of the TVs

Appendix B: Procedures for Calculating Fish and Aquatic Life Criteria

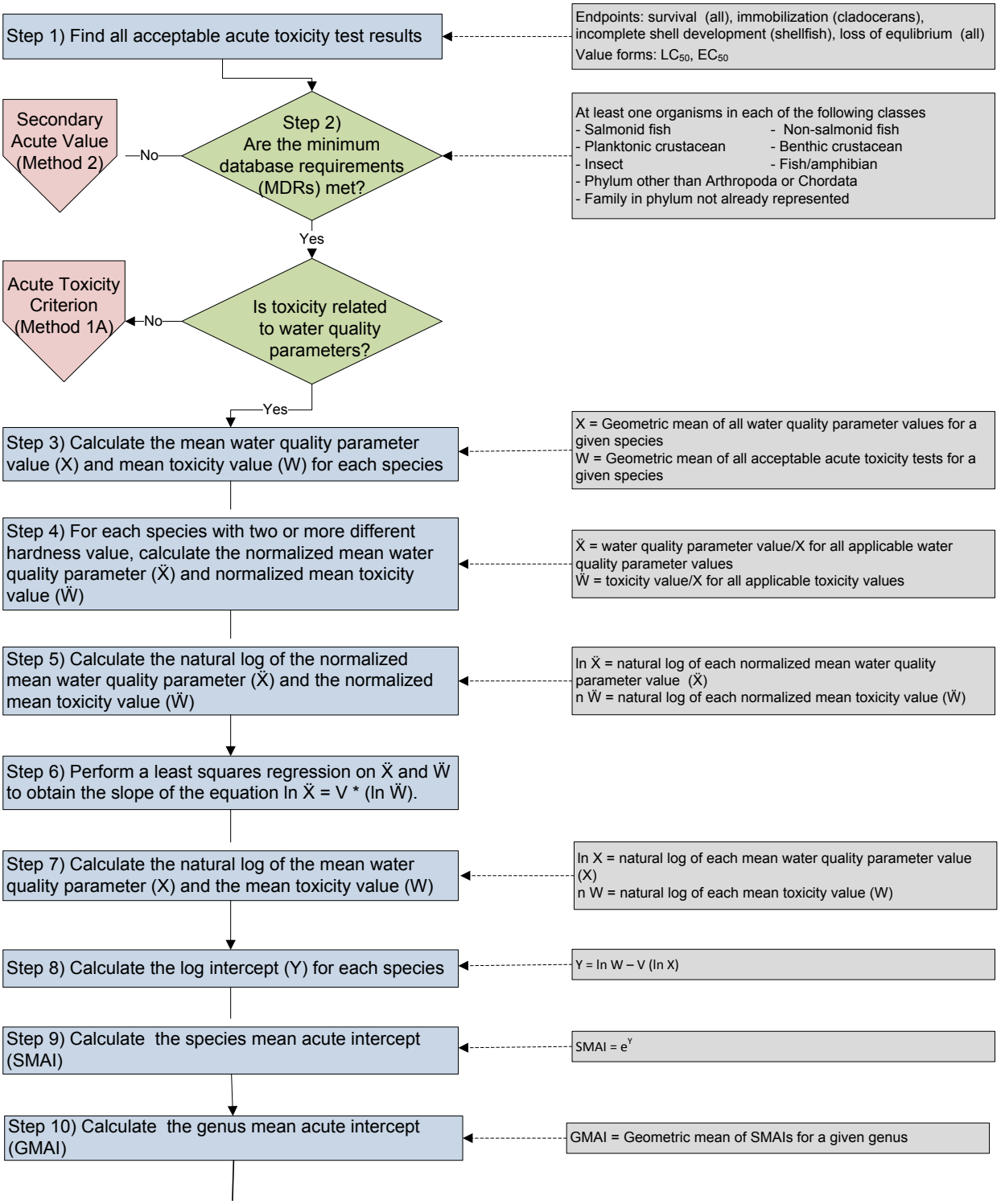
Acute Toxicity Criterion Flowchart (Method 1A)



Chronic Toxicity Criterion Flowchart (Method 1A)



Acute Toxicity Criterion Flowchart (Method 1B)



Step 11) Order and rank the GMAIs from high sensitivity to low sensitivity

Each genus is assigned a rank (R) as follows
- Most sensitive (lowest value): R = 1
- Least sensitive (highest value): R = N, where N = number of genus in dataset

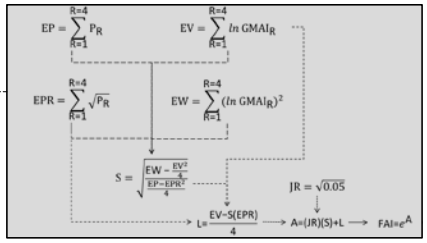
Step 12) Assign each genus to its appropriate designated use subclassification(s)

Coldwater = all Great Lakes states/Iowa resident species
Warm water = Great Lakes states/Iowa resident species excluding all cold water species
Limited Forage Fish = Great Lakes states/Iowa resident species excluding all cold water and gamefish species
Limited Aquatic Life = Great Lakes states/Iowa resident species excluding all fish species

Step 13) Select the four most sensitive GMAIs for each designated use subclassification

Calculate cumulative probability for each GMAI
P =R/(N+1))
Select 4 GMAIs with P closest to 0.05 (four lowest values for N ≤ 59)

Step 14) Calculate the Final Acute Intercept (FAI) for each designated use subclassification



Step 15) Calculate the Acute Criterion Intercept (ACI) for each designated use subclassification

$$ACI = \frac{FAI}{2}$$

Step 16) Select the equation parameters for promulgation/implementation

- The calculated parameters are compared to those for the EPA's national recommended ambient water quality criteria (NAWQC)
- The calculated parameters for the designated use subclassifications are compared to one another

Step 17) Use the Acute Toxicity Equation (ATE) to calculate the Acute Toxicity Criterion (ATC)

$$ATC = e^{[V * \ln(\text{water quality parameter}) + \ln ACI]}$$

Chronic Toxicity Criterion Flowchart (Method 1B)

Step 11) Order and rank the GMCIs from high sensitivity to low sensitivity

Step 12) Assign each genus to its appropriate designated use subclassification(s)

Coldwater = all Great Lakes states/Iowa resident species
Warm water = Great Lakes states/Iowa resident species excluding all cold water species
Limited Forage Fish = Great Lakes states/Iowa resident species excluding all cold water and gamefish species
Limited Aquatic Life = Great Lakes states/Iowa resident species excluding all fish species

Step 13) Select the four most sensitive GMCIs for each designated use subclassification

Calculate cumulative probability for each GMCI
P =R/(N+1))
Select 4 GMAIs with P closest to 0.05 (four lowest values for N ≤ 59)

Step 14) Calculate the Final Chronic Intercept (FCI) for each designated use subclassification

$$EP = \sum_{R=1}^{R=4} P_R \qquad EV = \sum_{R=1}^{R=4} ln\,GMCI_R$$

$$EPR = \sum_{R=1}^{R=4} \sqrt{P_R} \qquad EW = \sum_{R=1}^{R=4} (ln\,GMCI_R)^2$$

$$S = \sqrt{\frac{EW - \frac{EV^2}{4}}{\frac{EP - EPR^2}{4}}} \qquad JR = \sqrt{0.05}$$

$$L = \frac{EV - S(EPR)}{4} \longrightarrow A = (JR)(S) + L \longrightarrow FCI = e^A$$

Step 15) Select the equation parameters for promulgation/implementation

- The calculated parameters are compared to those for the EPA's national recommended ambient water quality criteria (NAWQC)
- The calculated parameters for the designated use subclassifications are compared to one another

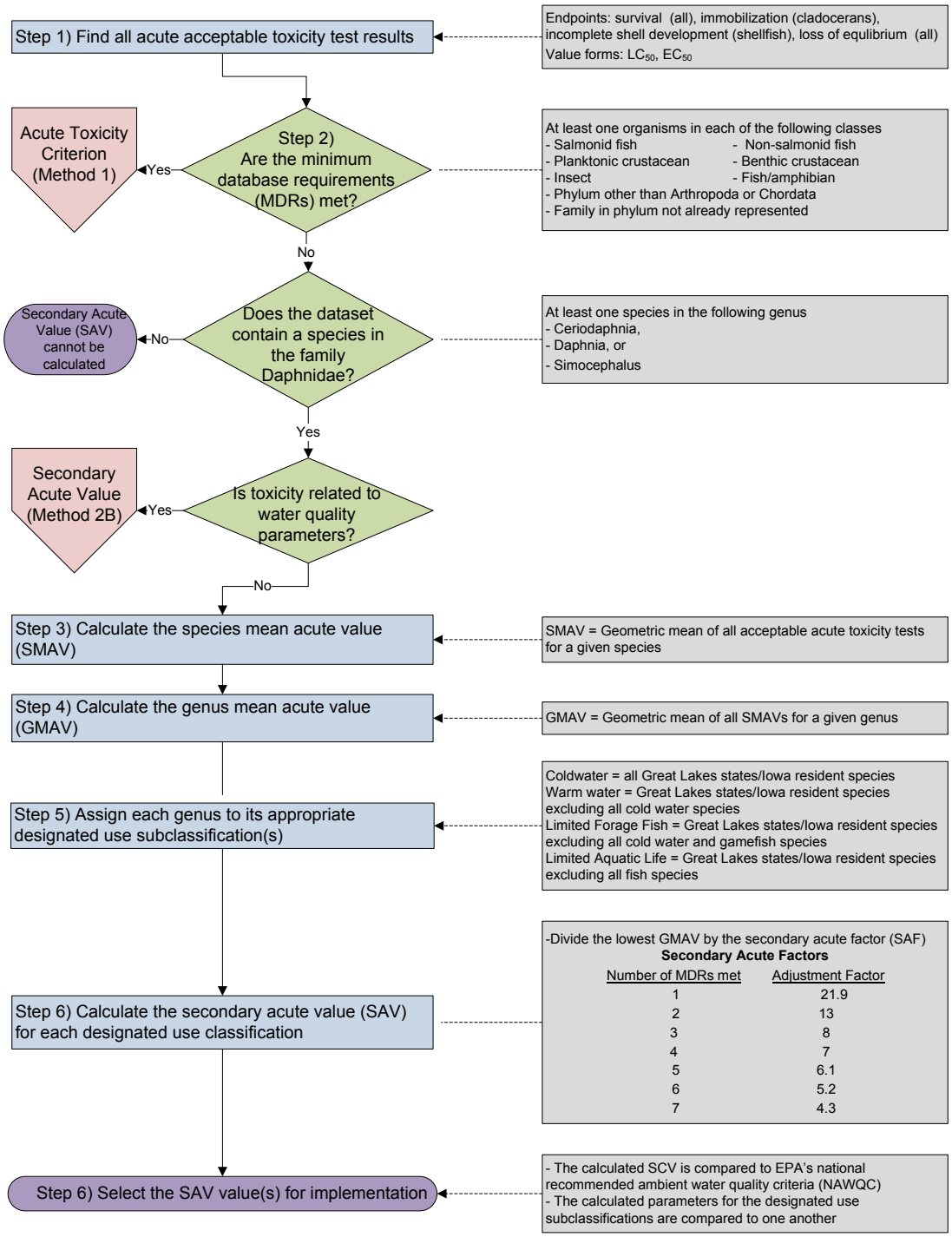
Step 16) Use the Chronic Toxicity Equation (CTE) to calculate the Chronic Toxicity Criterion (CTC) for each designated use subclassification

$$CTC = e^{[V * \ln(\text{water quality parameter}) + \ln FCI]}$$

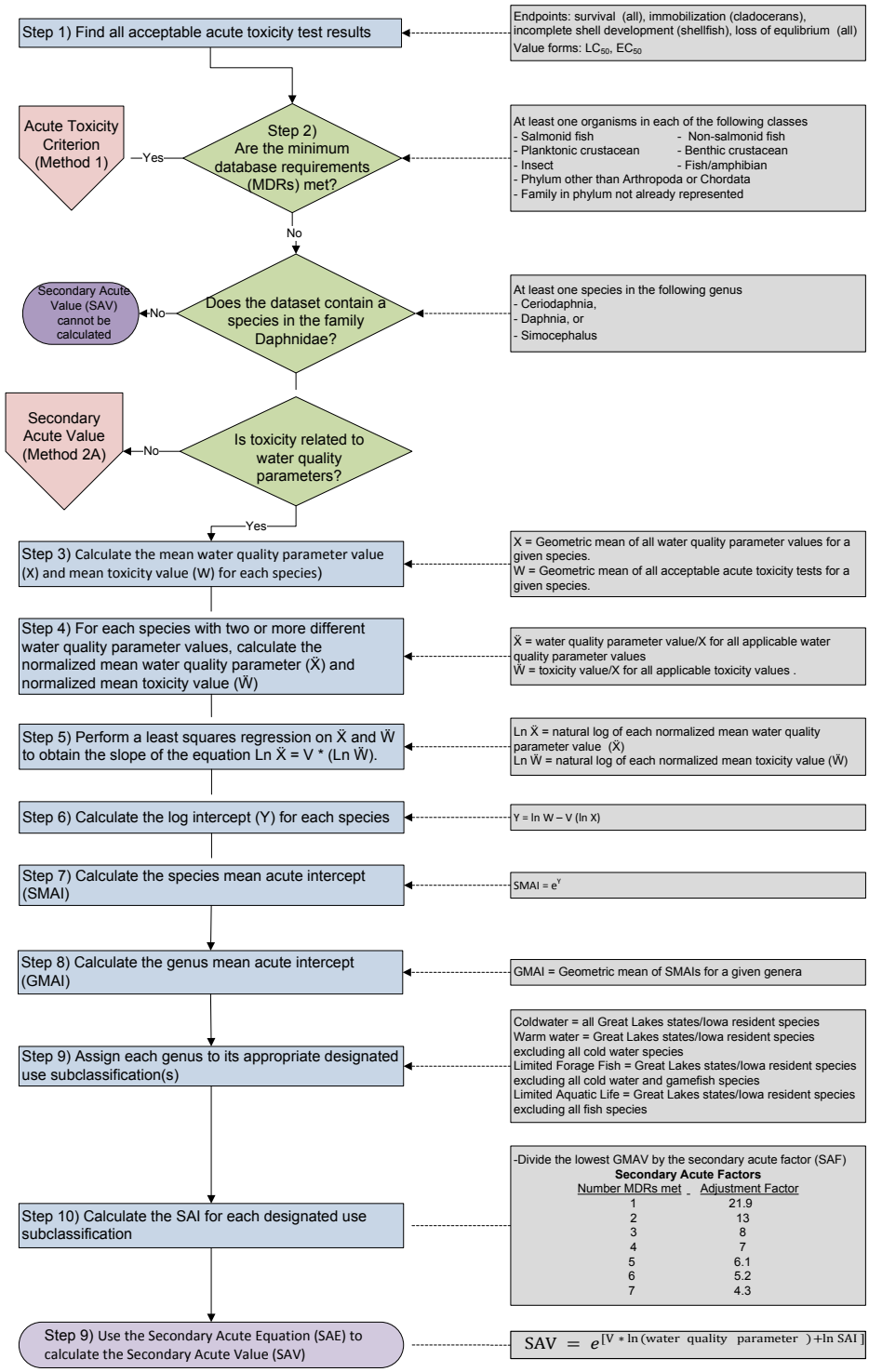
Step 17) Select the chronic toxicity criterion (CTC) for each designated use class

CTC = the lower of the final chronic value (FCV) and the final plant value (FPV) at a given water quality parameter value

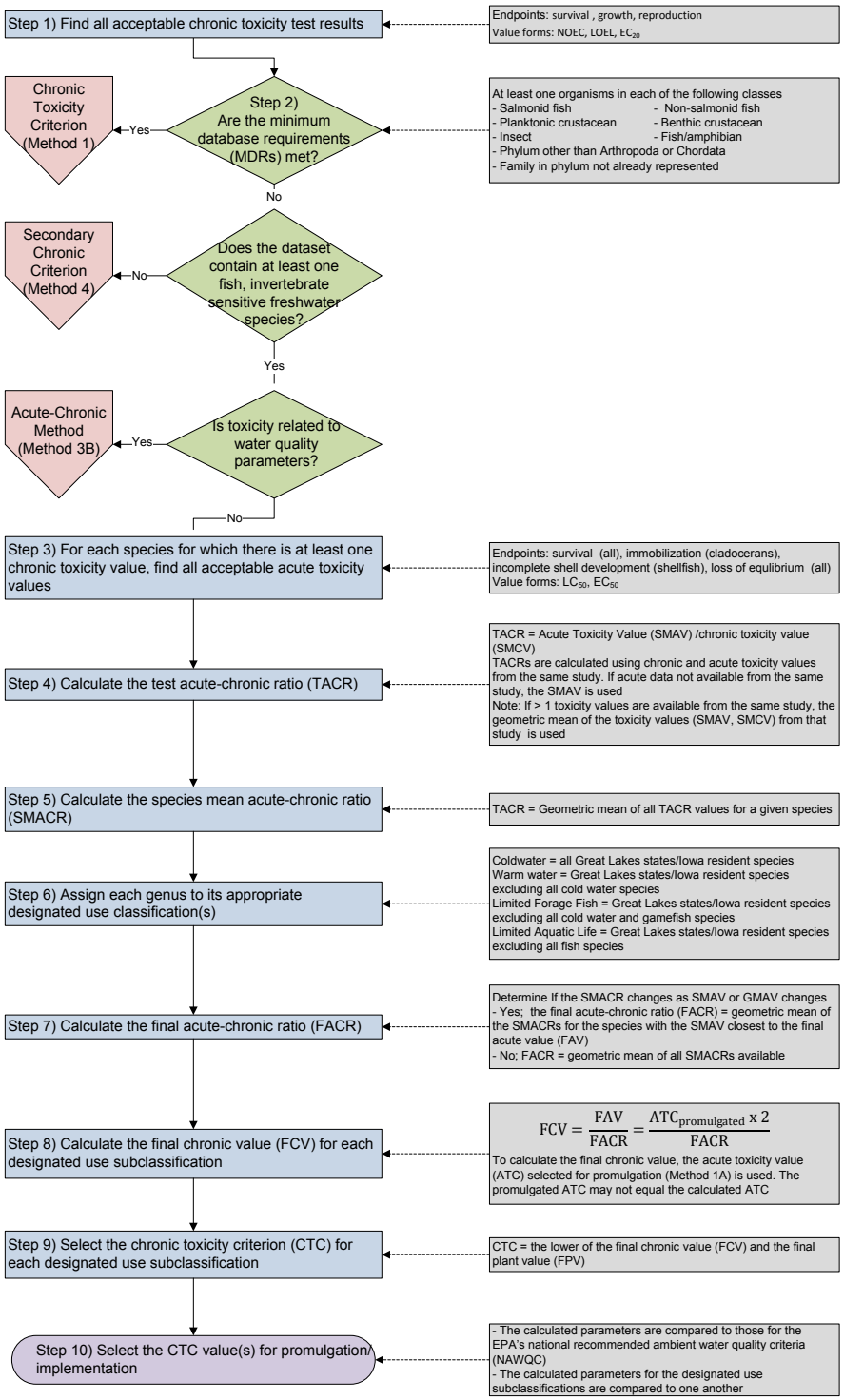
Secondary Acute Value Flowchart (Method 2A)



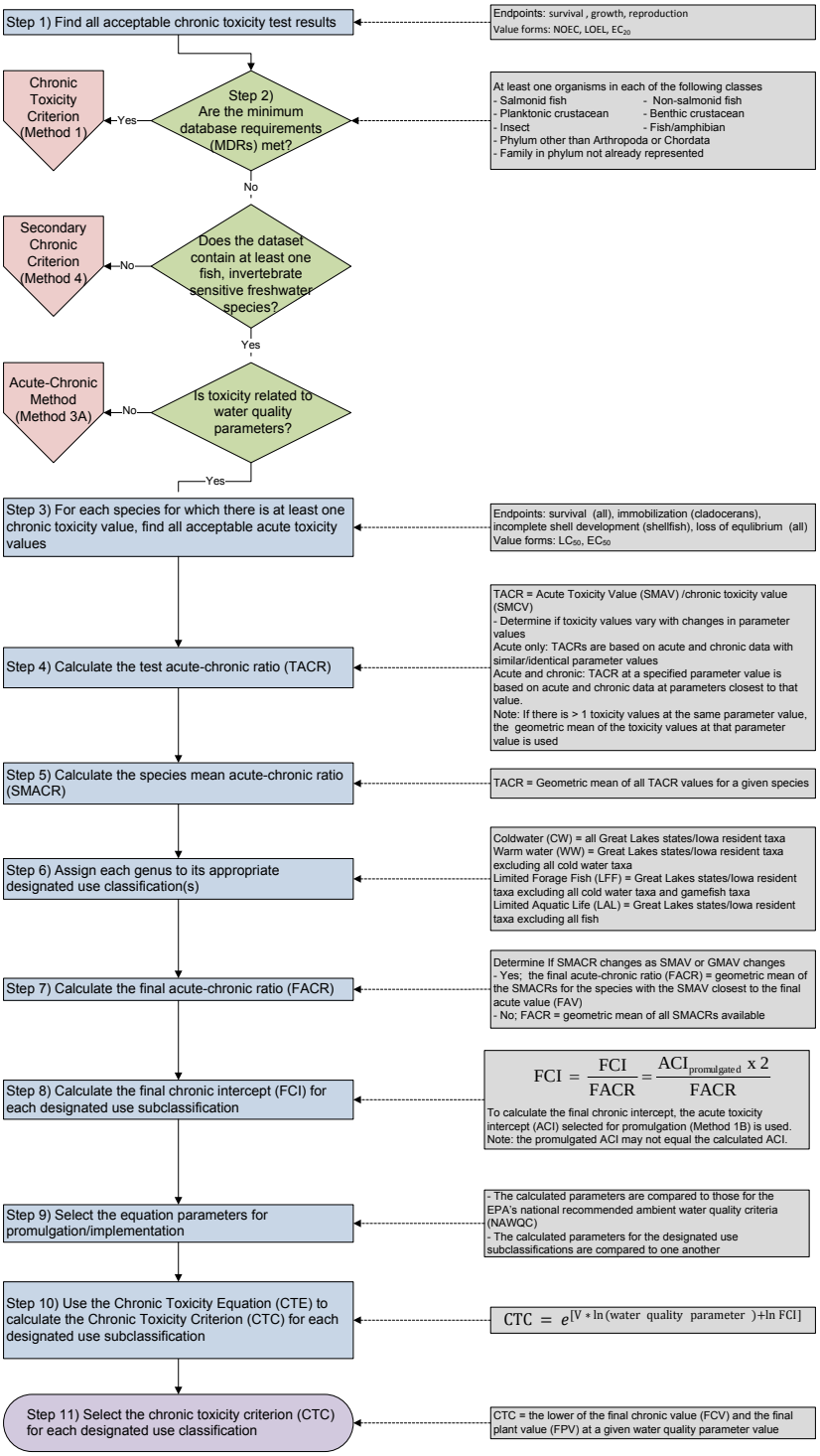
Secondary Acute Value Flowchart (Method 2B)



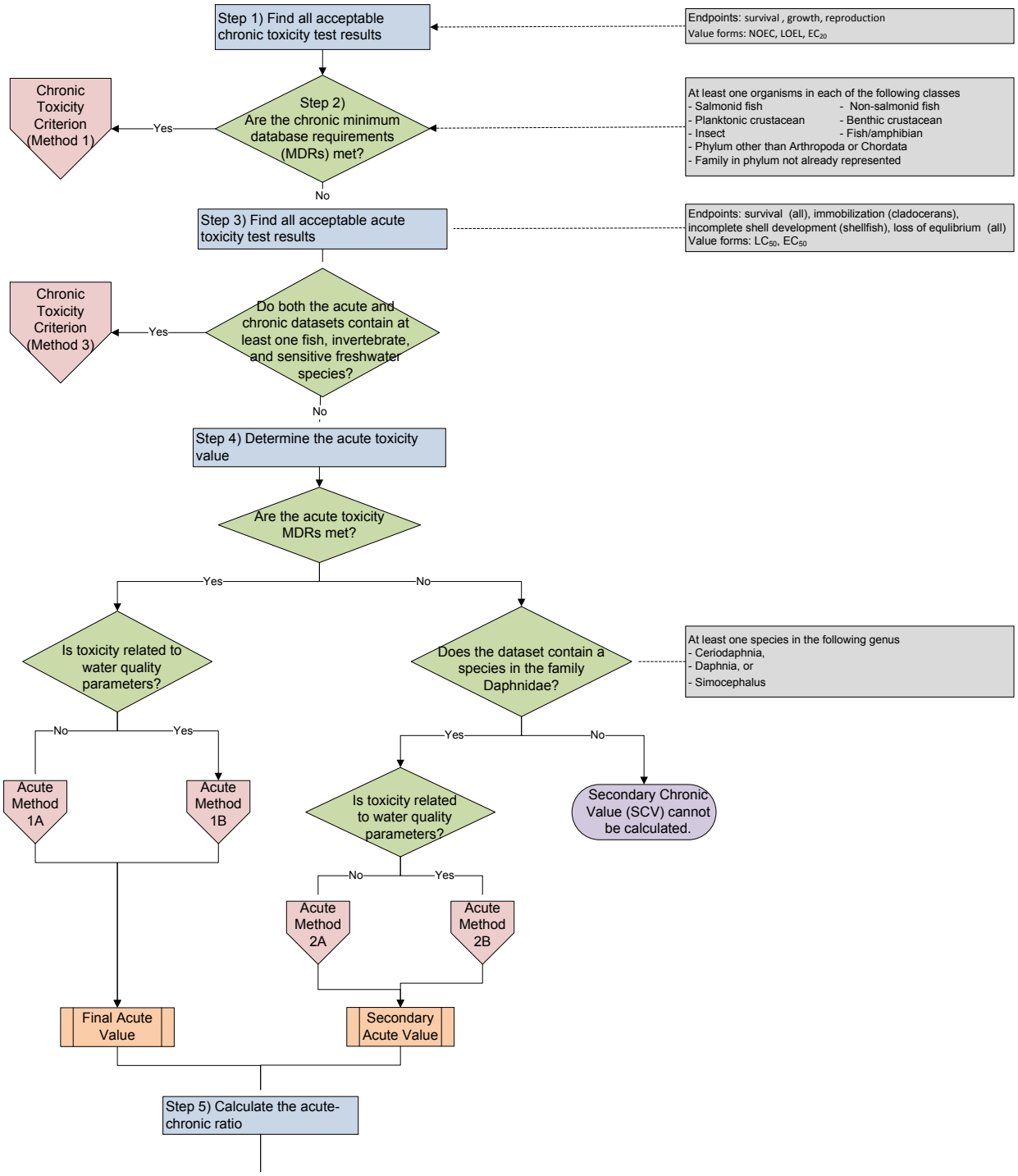
Chronic Toxicity Criterion Flowchart (Method 3A)

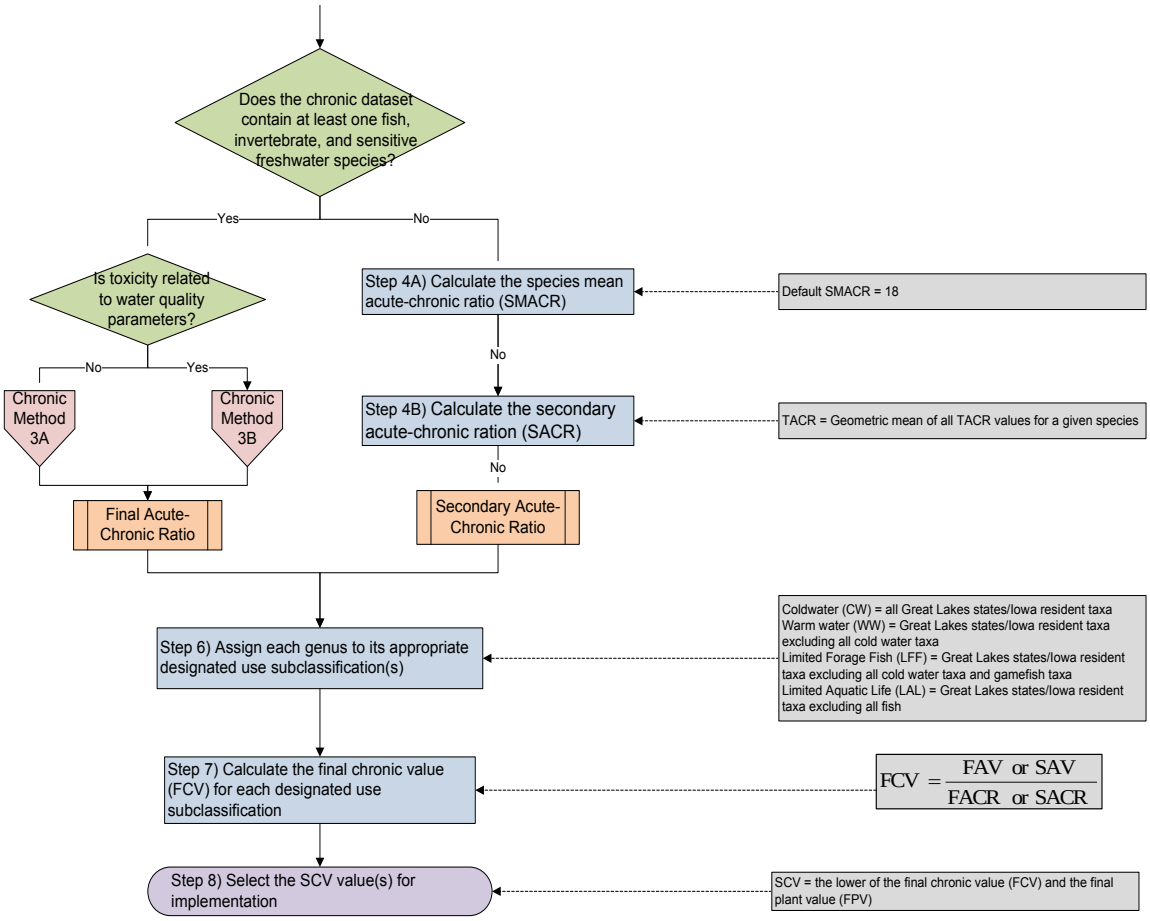


Chronic Toxicity Criterion Flowchart (Method 3B)



Secondary Chronic Value Flowchart (Method 4)




Does the chronic dataset contain at least one fish, invertebrate, and sensitive freshwater species?
Yes
No
Is toxicity related to water quality parameters?
No
Yes
Chronic Method 3A
Chronic Method 3B
Final Acute-Chronic Ratio
Step 4A) Calculate the species mean acute-chronic ratio (SMACR)
Default SMACR = 18
No
Step 4B) Calculate the secondary acute-chronic ration (SACR)
TACR = Geometric mean of all TACR values for a given species
No
Secondary Acute-Chronic Ratio
Step 6) Assign each genus to its appropriate designated use subclassification(s)
Coldwater (CW) = all Great Lakes states/Iowa resident taxa
Warm water (WW) = Great Lakes states/Iowa resident taxa excluding all cold water taxa
Limited Forage Fish (LFF) = Great Lakes states/Iowa resident taxa excluding all cold water taxa and gamefish taxa
Limited Aquatic Life (LAL) = Great Lakes states/Iowa resident taxa excluding all fish
Step 7) Calculate the final chronic value (FCV) for each designated use subclassification
$FCV = \frac{FAV \text{ or } SAV}{FACR \text{ or } SACR}$
Step 8) Select the SCV value(s) for implementation
SCV = the lower of the final chronic value (FCV) and the final plant value (FPV)

Appendix C: Supporting Information for the Derivation of Human Health Criteria

Derivation of a Baseline Bioaccumulation Factor

To derive the specific BAF for a human health criterion, a baseline BAF is first determined. The baseline BAF allows extrapolation of the BAF from one waterbody to other. Several methods can be used to derive baseline BAFs from field studies, laboratory studies, or estimated from the physicochemical properties of the substance (Figure C-1).[C-1, C-2]

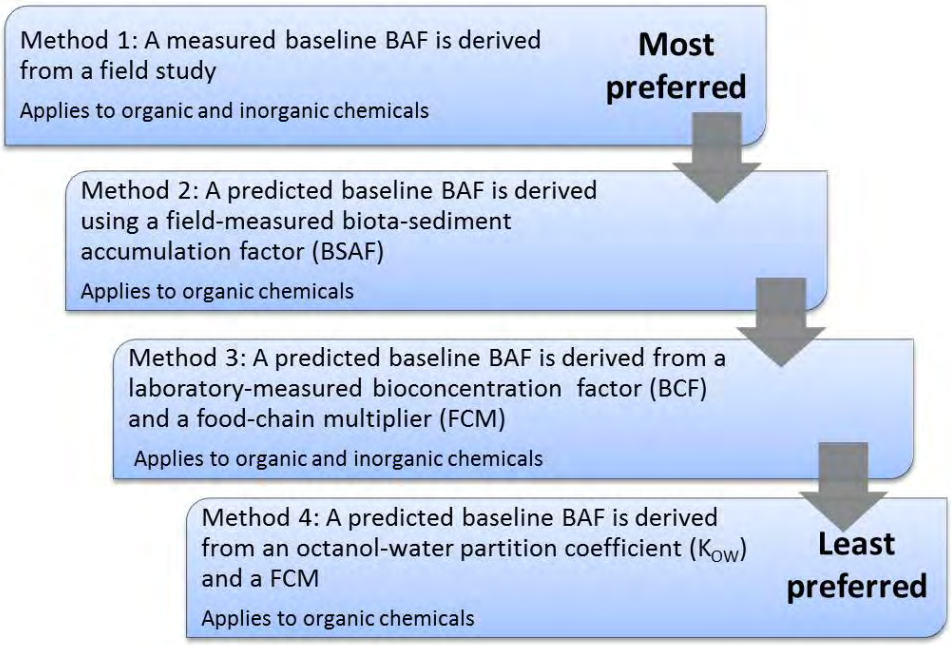


Figure C-1. Methods for deriving baseline bioaccumulation factors (BAFs)

Method 1

In Method 1, the BAF is calculated from measured concentrations of the substance in the aquatic organism and the water column of a field site.

Equation C-1:

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

This method can be used for both organic and inorganic substances and the most preferred for deriving a baseline BAF because the studies are conducted in the natural ecosystem and reflects the organism's exposure to the substance via all relevant pathways.

For <u>organic substances</u>, baseline BAF values are calculated using the following equation:

Equation C-1: $$\text{Baseline BAF}_{\text{Organic}} = \left[\frac{\text{Measured BAF}}{f_{fd}} - 1\right]\left[\frac{1}{f_1}\right]$$

Where:
- f_{fd} is the fraction of the substance that is freely dissolved in the water column and is calculated using Equation 1
- f_1 is the fraction of the tissue in the sample that is lipid

If more than one baseline BAF values are available, the geometric mean is calculated.

Equation C-2: $$\text{Baseline BAF}_{\text{Organic}} = \text{Geometric Mean (Baseline BAFs)}$$

For <u>inorganic substances</u>, measured BAFs are used as the baseline BAF without adjustment. If more than one measured BAF values are available, the baseline BAF equals the geometric mean of the measured BAFs *(Note: when using a measured BAF, data from aquatic plants and invertebrates should not be used and measured BAFs should be based on edible tissue (e.g., muscle) of freshwater fish*).

Equation C-3: $$\text{Baseline BAF}_{\text{Inorganic}} = \text{Geometric Mean (Measured BAFs)}$$

Method 2

In Method 2, the BAF is estimated from the biota-sediment accumulation factor (BSAF). The BSAF is calculated from measured concentrations of the substance in the aquatic organism and the sediment of a field site.

Equation C-4: $$\text{BSAF} = \frac{\text{Concentration in Tissue}}{\text{Concentration in Sediment}}$$

This method is the second preferred method because the studies are conducted in the natural ecosystem and reflect the organism's exposure to the substance via all relevant exposure pathways. However, since only hydrophobic substances typically accumulate in sediment, this method is only used for <u>organic substances</u>.

Baseline BAF values are calculated using the following equation:

Equation C-5: $$\text{Baseline BAF}_i = (\text{Baseline BAF})_r \times \frac{(\text{Normalized BSAF})_i \times (K_{OW})_i}{(\text{Normalized BSAF})_r \times (K_{OW})_r}$$

Where:
- "i" denotes the substance
- "r" denotes a reference substance for which the baseline BAF, K_{OW}, and BSAF are known
- K_{OW} is the octanol-water coefficient

If more than one baseline BAF values are available, the geometric mean of the baseline BAFs is calculated using Equation C-3 (*Note: when using a measured BSAF, data from aquatic plants and invertebrates should not be used and measured BSAFs should be based on edible tissue (e.g., muscle) of freshwater fish*).

Method 3

In Method 3, the BAF is predicted from a laboratory-measured bioconcentration factor (BCF) and the food chain multiplier (FCM). The bioconcentration factor (BCF) is defined as "the ratio of a substance's concentration in the tissue of an aquatic organism to its concentration in the ambient water."[6] The BCF is a measure of how likely a substance is to accumulate in an aquatic organism from exposure via the ambient water and does not account for accumulation that may occur via other exposure routes such as diet and sediment. The food chain (FCM) is a factor that accounts for accumulation that may occur via other exposure routes (i.e., diet, sediment).

In this method, the concentration in the water column and the organism are measured.

Equation C-6: $$\text{BCF} = \frac{\text{Concentration in Tissue}}{\text{Exposure Concentration}}$$

This method is less preferred and is only when an acceptable measured baseline BAF is not available but a BCF is. This method can be used for both organic and inorganic substances.

For organic substances, baseline BCF values are calculated from measured BCF values using the following equation:

Equation C-7: $$\text{Baseline BAF}_{\text{Organic}} = (\text{FCM})\left[\frac{\text{Measured BCF}}{f_{fd}} - 1\right]\left[\frac{1}{f_1}\right]$$

Where:
- FCM is the food-chain multiplier. The log K_{OW} is used to derive the FCM from the values in Table B-1 of 40 CFR 132. If the log K_{OW} is not available, a default value of 1.0 is used.
- f_{fd} is the fraction of the substance that is freely dissolved in the water column and is calculated using Equation 1
- f_1 is the fraction of the tissue in the sample that is lipid

If more than one baseline BAF values are available, the geometric mean is calculated using Equation C-2.

For inorganic substances, baseline BCF values are calculated from measured BCF values using the following equation:

Equation C-8: Baseline BAF = Measured BCF x FCM

Where:
- BCF is the bioconcentration factor and is the
- FCM is the food-chain multiplier – a default value of 1 is used unless substance-specific data is available.

Note: when using a measured BCF, data from aquatic plants and invertebrates should not be used and measured BCFs should be based on edible tissue (e.g., muscle) of freshwater fish.

Method 4

In Method 4, baseline BAF is predicted from the substance's octanol-water coefficient (K_{OW}). This method is the least preferred method because it based on a relationship between K_{OW} and BCF and does not consider the various biological and environmental factors that can impact bioaccumulation. This method can only be used for organic substances.

The baseline BAF value is predicted using the following equation:

Equation C-8: $$\text{Baseline BAF} = K_{OW} \text{ x FCM}$$

Where:
- BCF is the bioconcentration factor and is the
- K_{OW} is the octanol-water coefficient

Derivation of an Acceptable Daily Exposure (ADE) Value

The acceptable daily exposure (ADE) level is the "maximum amount of a substance which if ingested daily for a lifetime results in no adverse effects to humans" and is used to derive a human threshold criterion for a given substance. The ADE level can be derived using the following steps:

- Identify the most sensitive toxicity endpoint
- Select the most appropriate no observable adverse effect level (NOAEL) for this endpoint.

  Note: if a NOAEL is not available, select the most appropriate lowest observable adverse effect level (LOAEL) for the same endpoint.
- Divide the NOAEL/LOAEL by the appropriate uncertainty factors

Each of these steps will be discussed in further detail in this section

Step 1. Sensitive Toxicity Endpoint Selection

Available toxicological and epidemiological studies are evaluated to select the principle studies. These studies "contribute the most significantly to the assessment of whether or not the chemical is potentially a systemic toxicant to humans".[10] From these studies, the effect that exhibits the lowest NOAEL is selected as the sensitive toxicity endpoint. This endpoint represents the "highest level tested in which 'no adverse effect' was demonstrated."[10] Because the most sensitive toxicity endpoint is used to derive the ADE, the resulting water quality criteria are assumed protective of all non-carcinogenic effects from that substance.

Step 2. NOAEL Selection

Once the sensitive endpoint has been identified, the most appropriate NOAEL is selected. When selecting the NOAEL, factors such as the study protocol, experimental animals, exposure routes, and exposure duration are evaluated. In general, preference is given NOAEL values based on human studies followed by NOAEL values based on studies with experimental animals. Figure C-2 shows the guidelines for selecting the appropriate study to use in determining the ADE (Note: *when 2 or more acceptable daily*

exposure values are available and have been derived from studies having equal preference, the lowest acceptable daily exposure is generally selected).

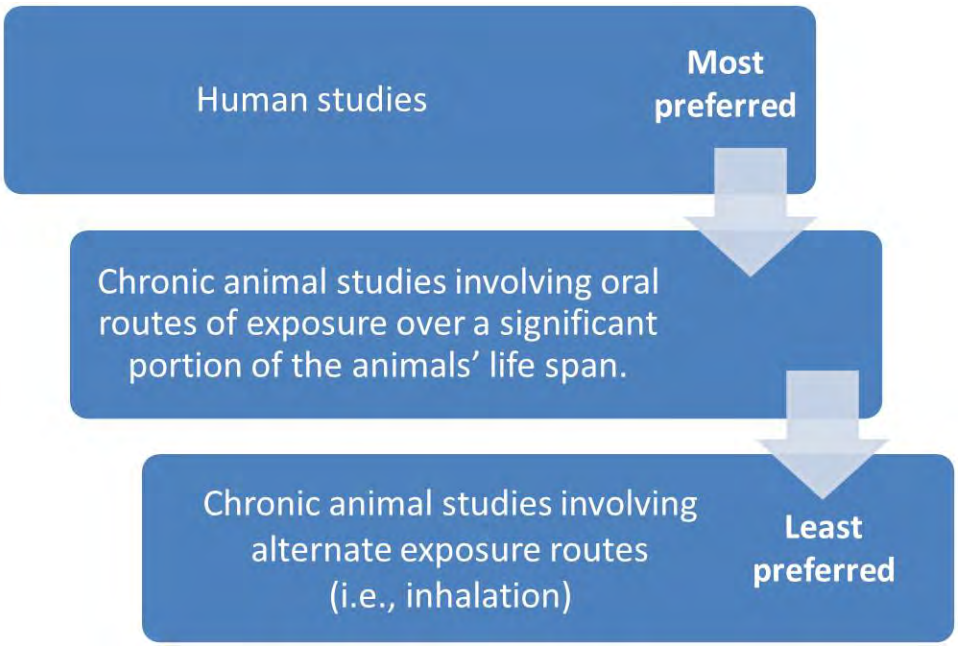


Figure C-2. Guidelines for selecting the appropriate study to use in determining the acceptable daily exposure

<u>Step 3. Incorporation of Uncertainty Factors</u>

Uncertainty factors are chosen to account for the uncertainty in predicting acceptable exposure levels for the general human population based upon experimental animal data or limited human data. Factors are often selected to account for uncertainty inherent in the available data. Factors are applied to account for uncertainty in the toxicological test design, endpoint format (i.e., NOAEL vs. LOAEL), and substance's potential for carcinogenicity. Table C-1 details the process to be used for selecting the appropriate uncertainty factors.

Table C-1. Process used to select uncertainty factors

Uncertainty Factor Requirements and Rationale	Uncertainty Factor Value
The appropriate UF value is selected for each category. The Uncertainty Factor Total is then calculated using the selected UF values and the equation below.	
Test Design (UF_1)	
Data is from a prolonged study on ingestion of the substance in humans. Purpose of UF: - Protect sensitive members of the human population (human variability).	10
Data is from a chronic study with experimental animals. Purpose of UF: - Protect sensitive members of the human population (human variability). - Account for the uncertainty in extrapolating between animals and humans (interspecies variability).	100
Data is from a sub-chronic study with experimental animals. Purpose of UF: - Protect sensitive members of the human population (human variability). - Account for the uncertainty in extrapolating between animals and humans (interspecies variability). - Account for uncertainty in extrapolating from sub-chronic to chronic exposure	1000
	UF_1 =
Test Endpoint (UF_2)	
Endpoint is a No Observable Adverse Effect LEVEL (NOAEL) - No additional factor needed	1
Endpoint is a Lowest Observable Adverse Effect LEVEL (LOAEL) Purpose of UF: - Reduces the LOAEL into the range of a NOAEL * A value between 1 and 10 is selected based on severity of the adverse impact observed	1 to 10*
	UF_2 =
Carcinogenicity (UF_3)	
The substance is not classified as a known, probable, or possible carcinogen by the U.S. EPA and does not met the definition of carcinogen in NR 105.03(13) - No additional factor needed	1
The substance has been classified as a "probable human carcinogen" by the U.S. EPA but does not meet the definition of carcinogen in NR 105.03(13) Purpose of UF: - Account for potential for substance to cause cancer	10
	UF_3 =
Additional Uncertainity (UF_4)	
Additional uncertainty factors may be included based on recommendations from the U.S. EPA and other regulatory agencies	
	UF_4 =
Uncertainity Factor Total (UF_T)	
$UF_T = UF_1 \times UF_2 \times UF_3 \times UF_4$	**UF_T =**

References

C-1. Federal Water Pollution Control Act. *U.S. Code,* Sections 131-132, Title 33, 2002.

C-2. U.S. EPA. (2000). Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health; EPA-882-B-00-004; Office of Science and Technology: Washington, DC (2000).