#### **Section 302.210 Other Toxic Substances**

Waters of the State must be free from any substances or combination of substances in concentrations toxic or harmful to human health or animal, plant, or aquatic life. Individual chemical substances or parameters for which numeric standards are specified in this Subpart are not subject to this Section.

- a) Any substance or combination of substances must be deemed to be toxic or harmful to aquatic life if present in concentrations that exceed the following:
  - 1) An Acute Aquatic Toxicity Criterion (AATC) validly derived and correctly applied under procedures in Sections 302.612 through 302.618 or in Section 302.621; or
  - 2) A Chronic Aquatic Toxicity Criterion (CATC) validly derived and correctly applied under procedures in Section 302.627 or 302.630.
- b) Any substance or combination of substances must be deemed to be toxic or harmful to wild or domestic animal life if present in concentrations that exceed any Wild and Domestic Animal Protection Criterion (WDAPC) validly derived and correctly applied under Section 302.633.
- c) Any substance or combination of substances must be deemed to be toxic or harmful to human health if present in concentrations that exceed criteria, validly derived and correctly applied, based on either of the following:
  - 1) Disease or functional impairment due to a physiological mechanism for which there is a threshold dose below which no damage occurs calculated under Sections 302.642 through 302.648302.640 through 302.643 (Human Health Threshold Criterion and Human Health Threshold Value); or
  - 2) Disease or functional impairment due to a physiological mechanism for which any dose may cause some risk of damage calculated under Sections 302.651 through 302.658302.640, 302.641, and 302.652 (Human Health Nonthreshold Criterion and Human Health Nonthreshold Value).
- d) The most stringent criterion of subsections (a), (b), and (c) applies at all points outside of any waters within which mixing is allowed under Section 302.102. In addition, the AATC derived under subsection (a)(1) applies in all waters except that it must not apply within a ZID that is prescribed in compliance with Section 302.102.
- e) The procedures of Subpart F set forth minimum data requirements, appropriate test protocols, and data assessment methods for establishing criteria under subsections (a), (b), and (c). No other procedures may be used to establish these criteria unless approved by the Board in a rulemaking or adjusted standard

proceeding under Title VII of the Act. The validity and applicability of the Subpart F procedures may not be challenged in any proceeding brought under Title VIII or X of the Act, although the validity and correctness of application of the numeric criteria derived under Subpart F may be challenged in proceedings under subsection (f).

## f) Challenges to Applying Criteria

- A permittee may challenge the validity and correctness of application of a criterion derived by the Agency under this Section only at the time the criterion is first applied in an NPDES permit under 35 Ill. Adm. Code 309.152 or in an action under Title VIII of the Act for violation of the toxicity water quality standard. Failure of a person to challenge the validity of a criterion at the time of its first application will constitute a waiver of the challenge in any subsequent proceeding involving the application of the criterion to that person.
- 2) Consistent with subsection (f)(1), if a criterion is included as, or is used to derive, a condition of an NPDES discharge permit, a permittee may challenge the criterion in a permit appeal under Section 40 of the Act and 35 Ill. Adm. Code 309.181.
- 3) Consistent with subsection (f)(1), in an action where the alleged violation of the toxicity water quality standard is based on an alleged excursion of a criterion, the person bringing the action will have the burdens of going forward with proof and of persuasion regarding the general validity and correctness of application of the criterion.
- g) Subsections (a) through (e) do not apply to USEPA-registered pesticides approved for aquatic application and applied under the following conditions:
  - 1) Application must be made in strict compliance with label directions;
  - 2) Applicator must be properly certified under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.);
  - 3) Applications of aquatic pesticides must comply with the laws, regulations, and guidelines of all state and federal agencies authorized by law to regulate, use, or supervise pesticide applications.
  - 4) Aquatic pesticides must not be applied to waters affecting public or food processing water supplies unless a permit to apply the pesticide has been obtained from the Agency. All permits must be issued so as not to cause a violation of the Act or any of the Board's rules. To aid applicators in determining their responsibilities under this subsection, a list of waters

affecting public water supplies will be published and maintained by the Agency's Division of Public Water Supplies.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

#### **Section 302.410 Other Toxic Substances**

Any substance or combination of substances toxic to aquatic life not listed in Section 302.407 must not exceed one-half of the 96-hour median tolerance limit (96-hour TL<sub>m</sub>) for native fish or essential fish food organisms in the South Fork of the South Branch of the Chicago River (Bubbly Creek). All other Chicago Area Waterway System and Lower Des Plaines River waters as designated in 35 Ill. Adm. Code 303 must be free from any substances or combination of substances in concentrations toxic or harmful to human health or animal, plant, or aquatic life. Individual chemical substances or parameters for which numeric standards are specified in this Subpart are not subject to this Section.

- a) Any substance or combination of substances will be deemed to be toxic or harmful to aquatic life if present in concentrations that exceed the following:
  - 1) An Acute Aquatic Toxicity Criterion (AATC) validly derived and correctly applied under procedures in Sections 302.612 through 302.618 or in Section 302.621; or
  - 2) A Chronic Aquatic Toxicity Criterion (CATC) validly derived and correctly applied under procedures in Section 302.627 or 302.630.
- b) Any substance or combination of substances will be deemed to be toxic or harmful to wild or domestic animal life if present in concentrations that exceed any Wild and Domestic Animal Protection Criterion (WDAPC) validly derived and correctly applied under Section 302.633.
- c) Any substance or combination of substances will be deemed to be toxic or harmful to human health if present in concentrations that exceed criteria, validly derived and correctly applied, based on either of the following:
  - 1) Disease or functional impairment due to a physiological mechanism for which there is a threshold dose below which no damage occurs calculated under Sections 302.642 through 302.648302.640 through 302.643 (Human Health Threshold Criterion and Human Health Threshold Value); or
  - Disease or functional impairment due to a physiological mechanism for which any dose may cause some risk of damage calculated under Sections 302.651 through 302.658302.640, 302.641, and 302.652 (Human Health Nonthreshold Criterion and Human Health Nonthreshold Value).
- d) The most stringent criterion of subsections (a), (b), and (c) applies at all points outside of any waters within which mixing is allowed under Section 302.102. In

- addition, the AATC derived under subsection (a)(1) applies in all waters except that it must not apply within a ZID that is prescribed in compliance with Section 302.102.
- e) The procedures of Subpart F set forth minimum data requirements, appropriate test protocols, and data assessment methods for establishing criteria under subsections (a), (b), and (c). No other procedures may be used to establish these criteria unless approved by the Board in a rulemaking or adjusted standard proceeding under Title VII of the Act. The validity and applicability of the Subpart F procedures may not be challenged in any proceeding brought under Title VIII or X of the Act, although the validity and correctness of application of the numeric criteria derived under Subpart F may be challenged in the proceedings under subsection (f).
- f) Agency derived criteria may be challenged as follows:
  - 1) A permittee may challenge the validity and correctness of application of a criterion derived by the Agency under this Section only at the time the criterion is first applied in an NPDES permit under 35 Ill. Adm. Code 309.152 or in an action under Title VIII of the Act for violation of the toxicity water quality standard. Failure of a person to challenge the validity of a criterion at the time of its first application constitutes a waiver of the challenge in any subsequent proceeding involving the application of the criterion to that person.
  - Consistent with subsection (f)(1), if a criterion is included as, or is used to derive, a condition of an NPDES discharge permit, a permittee may challenge the criterion in a permit appeal under Section 40 of the Act and 35 Ill. Adm. Code 309.181. In any such action, the Agency must include in the record all information upon which it has relied in developing and applying the criterion, whether that information was developed by the Agency or submitted by the petitioner. The burden of proof is on the petitioner to demonstrate that the criterion-based condition is not necessary to accomplish the purposes of subsection (f)(1) (see Section 40(a)(1) of the Act), but there is no presumption in favor of the general validity and correctness of the application of the criterion as reflected in the challenged condition.
  - 3) Consistent with subsection (f)(1), in an action in which the alleged violation of the toxicity water quality standard is based on an alleged excursion of a criterion, the person bringing the action has the burdens of going forward with proof and of persuasion regarding the general validity and correctness of application of the criterion.
- g) Subsections (a) through (e) do not apply to USEPA registered pesticides approved for aquatic application and applied under the following conditions:

- 1) Application must be made in strict compliance with label directions;
- 2) Applicator must be properly certified under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq); and
- 3) Applications of aquatic pesticides must comply with the laws, regulations, and guidelines of all state and federal agencies authorized by law to regulate, use, or supervise pesticide applications.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

### SUBPART F: PROCEDURES FOR DETERMINING WATER QUALITY CRITERIA

### Section 302.601 Scope and Applicability

This Subpart contains the procedures for determining the water quality criteria in Sections 302.210(a), (b), and (c) and 302.410(a), (b), and (c).

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

#### **Section 302.603 Definitions**

As used in this Subpart, the following terms have the meanings specified.

"Acceptable daily exposure" or "ADE" means an estimate of the maximum daily dose of a substance that is not expected to result in adverse noncancerous effects to the general human population, including sensitive subgroups.

"Acute toxicity" means adverse effects that result from an exposure period that is a small portion of the life span of the organism.

"Adverse effect" means any deleterious effect to organisms due to exposure to a substance. This includes effects that are or may become debilitating, harmful, or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

"Baseline BAF" for organic chemicals, means a bioaccumulation factor (BAF) 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 BAF is based on the wet weight of the tissue.

"Baseline BCF" for organic chemicals, means a bioconcentration factor (BCF) 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 BCF is based on the wet weight of the tissue.

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

"Bioaccumulation factor" or "BAF" is 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 and the ratio does not change substantially over time.

"Bioconcentration" means an increase in the concentration of a chemical and its metabolites in an organism (or its specified tissues) relative to the concentration of the chemical in the ambient water acquired through contact with the water alone.

"Bioconcentration Factor" or "BCF" is 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 the ratio does not change substantially over time.

"Biota-sediment accumulation factor" or "BSAF" means 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 the surface sediment is representative of average surface sediment in the vicinity of the organism.

"Carcinogen" means a chemical that causes an increased incidence of benign or malignant neoplasms, or a statistically significant decrease in the latency period between exposure and onset of neoplasms, in at least one mammalian species or man through epidemiological or clinical studies.

"Chronic toxicity" means adverse effects that result from an exposure period that is a large portion of the life span of the organism.

"Dissolved organic carbon" or "DOC" means concentration of dissolved organic carbon, presented in units of kg of dissolved organic carbon/L of water.

"EC-50" means the concentration of a substance or effluent that causes a given effect to 50% of the exposed organisms in a given time period.

"LC-50" means the concentration of a toxic substance or effluent that is lethal to 50% of the exposed organisms in a given time period.

"Food chain" means the energy stored by plants is passed along through

the ecosystem through trophic levels in a series of steps of eating and being eaten, also known as a food web.

"Food chain multiplier" or "FCM" means the ratio of a BAF to an appropriate BCF.

"Linearized multi-stage model" means a mathematical model for cancer risk assessment. This model fits linear dose-response curves to low doses. It is consistent with a no-threshold model of carcinogenesis.

"LOAEL" or "Lowest Observable Adverse Effect Level" means the lowest tested concentration of a chemical or substance that produces a statistically significant increase in frequency or severity of non-overt adverse effects between the exposed population and its appropriate control.

"MATC" or "Maximum Acceptable Toxicant Concentration" means the value obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test. A lower chronic limit is the highest tested concentration that did not cause a specified adverse effect. An upper chronic limit is the lowest tested concentration that did cause a specified adverse effect and above which all tested concentrations caused a specified adverse effect.

"NOAEL" or "No Observable Adverse Effect Level" means the highest tested concentration of a chemical or substance which does not produce a statistically significant increase in frequency or severity of non-overt adverse effects between the exposed population and its appropriate control.

"Octanol-water partition coefficient" or "Kow" is the ratio of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system. For log Kow, the log of the octanol-water partition coefficient is a base 10 logarithm.

"Particulate organic carbon" or "POC" means concentration of particulate organic carbon, presented in units of kg of particulate organic carbon/L of water.

"Relative source contribution" or "RSC" means the percentage of total exposure that can be attributed to surface water through water intake and fish consumption.

"Resident or Indigenous Species" means species that currently live a substantial portion of their lifecycle or reproduce in a given body of water or that are native species whose historical range includes a given body of water.

"Risk associated dose" or "RAD" means a dose of a known or presumed carcinogenic substance in mg/kg/day that, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental

cancer risk equal to one in 100,000.

"Slope factor" or "q<sub>1</sub>\*" is the incremental rate of cancer development calculated by a linearized multistage model or another appropriate model. It is expressed in mg/kg/day of exposure to the chemical in question.

"Subchronic effect" means an adverse effect, measured by assessing an acceptable endpoint, resulting from continual exposure for a period of time less than that deemed necessary for a chronic test.

"Standard Methods" means "Standard Method for the Examination of Water and Wastewater", available from the American Public Health Association.

"Test species" is a species that has test data available to derive a criterion.

"Tier I criteria" are numeric values derived by use of the Tier I methodologies that either have been adopted as numeric criteria into a water quality standard or are used to implement narrative water quality criteria.

"Tier II values" are numeric values derived by use of the Tier II methodologies that are used to implement narrative water quality criteria. They are applied as criteria, have the same effect, and are subject to the same appeal rights as criteria.

"Trophic level" means a functional classification of taxa within a community that is based on feeding relationships. For example, aquatic green plants and herbivores comprise the first and second trophic levels in a food chain.

"Uncertainty factor" or "UF" is one of several numeric factors used in deriving criteria from experimental data to account for the quality or quantity of the available data.

"USEPA" means the United States Environmental Protection Agency.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

#### Section 302.604 Mathematical Abbreviations

This Subpart uses the following mathematical abbreviations:

exp x base of the natural logarithm, e, raised to x-power ln x natural logarithm of x log x logarithm to the base 10 of x A\*\*B A raised to the B-power SUM(x) summation of the values of x

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

### **Section 302.606 Data Requirements**

The Agency must review, for validity, applicability, and completeness, data used in calculating criteria. To the extent available and not otherwise specified, testing procedures, selection of test species and other aspects of data acquisition must be according to methods published by USEPA or nationally recognized standards organizations, including methods found in "Standard Methods", incorporated by reference in 35 Ill. Adm. Code 301.106.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

# Section 302.612 Determining the Acute Aquatic Toxicity Criterion for an Individual Substance - General Procedures

- a) A chemical-specific Acute Aquatic Toxicity Criterion (AATC) is calculated using procedures specified in Sections 302.615 and 302.618 if acute toxicity data are available for at least five resident or indigenous species from five different North American genera of freshwater organisms, including representatives of the following taxa:
  - 1) Representatives of two families in the Class Osteichthyes (Bony Fish).
  - 2) The family Daphnidae.
  - 3) A benthic aquatic macroinvertebrate.
  - 4) A vascular aquatic plant or a third family in the Phylum Chordata that may be from the Class Osteichthyes.
- b) If data are not available for resident or indigenous species, data for non-resident species may be used if the non-resident species is of the same family or genus and has a similar habitat and environmental tolerance. The procedures of Section 302.615 must be used to obtain an AATC for individual substances whose toxicity is unaffected by ambient water quality characteristics. The procedures of Section 302.618 must be used if the toxicity of a substance is dependent upon some other water quality characteristic.
- c) If data are not available that meet the requirements of subsection (a), an AATC is calculated by obtaining at least one EC-50 or LC-50 value from both a daphnid species and either fathead minnow or bluegill. If there are data available for any other North American freshwater species, they must also be included. An AATC is calculated by dividing the lowest Species Mean Acute Value (SMAV), as determined according to Section 302.615, by 10.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

# Section 302.615 Determining the Acute Aquatic Toxicity Criterion - Toxicity Independent of Water Chemistry

If the acute toxicity of the chemical has not been shown to be related to a water quality characteristic, including hardness, pH, or temperature, the AATC is calculated by using the procedures below.

- a) For each species for which more than one acute value is available, the Species Mean Acute Value (SMAV) is calculated as the geometric mean of the acute values from all tests.
- b) For each genus for which one or more SMAVs are available, the Genus Mean Acute Value (GMAV) is calculated as the geometric mean of the SMAVs available for the genus.
- c) The GMAVs are ordered from high to low.
- d) Ranks (R) are assigned to the GMAVs from "1" for the lowest to "N" for the highest. If two or more GMAVs are identical, successive ranks are arbitrarily assigned.
- e) The cumulative probability, P, is calculated for each GMAV as R/(N + 1).
- f) The GMAVs to be used in the calculations of subsection (g) must be those with cumulative probabilities closest to 0.05. If there are less than 59 GMAVs in the total data set, the values utilized must be the lowest obtained through the ranking procedures of subsections (c) and (d). "T" is the number of GMAVs that are to be used in the calculations of subsection (g). T is equal to 4 when the data set includes at least one representative from each of the five taxa in Section 302.612 and a representative from each of the three taxa listed below. T is equal to 3 when the data includes at least one representative from each of the five taxa in Section 302.612 and one or two of the taxa listed below. T is equal to 2 when the data set meets the minimum requirements of Section 302.612 but does not include representatives from any of the three taxa listed below. When toxicity data on any of the three taxa listed below are available, they must be used along with the minimum data required pursuant to Section 302.612.
  - 1) A benthic crustacean, unless one was used under Section 302.612(a)(3), in which case an insect must be used.
  - 2) A member of a phylum not used in subsection (a), (b), or (f)(1).
  - 3) An insect from an order not already represented.

g) Using the GMAVs and T-value identified under subsection (f) and the Ps calculated under subsection (e), the Final Acute Value (FAV) and the AATC are calculated as:

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FAV = \exp(A) \text{ and } \\ AATC = FAV/2 \\ Where: \\ A = L + 0.2236 \text{ S}; \\ L = [SUM(1n \text{ GMAV}) - S(SUM(P^{**}0.5))]/T; \text{ and } \\ S = [[SUM((1n \text{ GMAV})^{**}2) - ((SUM(1n \text{ GMAV}))^{**}2)/T]/[SUM(P) - ((SUM(P^{**}0.5))^{**}2)/T]]^{**}0.5.
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h) If a resident or indigenous species, whose presence is necessary to sustain commercial or recreational activities, or prevent disruptions of the waterbody's ecosystem, including loss of species diversity or a shift to a biotic community dominated by pollution-tolerant species, will not be protected by the calculated FAV, then the EC-50 or LC-50 for that species is used as the FAV.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

# Section 302.618 Determining the Acute Aquatic Toxicity Criterion - Toxicity Dependent on Water Chemistry

If data are available to show that a relationship exists between a water quality characteristic (WQC) and acute toxicity to two or more species, an Acute Aquatic Toxicity Criterion (AATC) may be calculated. The best-documented relationship is between the water quality characteristic, hardness, and acute toxicity of metals. Although this relationship between hardness and acute toxicity is typically non-linear, it can be linearized by a logarithmic transformation (i.e., for any variable, K, f(K) = logarithm of K) of the variables and plotting the logarithm of hardness against the logarithm of acute toxicity. Similarly, relationships between acute toxicity and other water quality characteristics, such as pH or temperature, may require a transformation, including no transformation (i.e., for any variable, K, f(K) = K), for one or both variables to obtain a least squares linear regression of the transformed acute toxicity values on the transformed values of the water quality characteristic. An AATC is calculated using the following procedures:

a) For each species for which acute toxicity values are available at two or more different values of the water quality characteristic, a least squares linear regression of the transformed acute toxicity (TAT) values on the transformed water quality characteristic (TWQC) values is performed to obtain the slope of the line describing the relationship.

- b) Each of the slopes determined pursuant to subsection (a) is evaluated as to whether or not it is statistically valid, taking into account the range and number of tested values of the water quality characteristic and the degree of agreement within and between species. If slopes are not available for at least one fish and one invertebrate species, if the available slopes are too dissimilar, or if too few data are available to define the relationship between acute toxicity and the water quality characteristic, then the AATC must be calculated using the procedures in Section 302.615.
- c) Normalize the TAT values for each species, by subtracting W, the arithmetic mean of the TAT values of a species from each of the TAT values used in the determination of the mean, such that the arithmetic mean of the normalized TAT values for each species individually or for any combination of species is zero (0.0).
- d) Normalize the TWQC values for each species using X, the arithmetic mean of the TWQC values of a species, in the same manner as in subsection (c).
- e) Group all the normalized data by treating them as if they were from a single species and perform at least squares linear regression of all the normalized TAT values on the corresponding normalized TWQC values to obtain the pooled acute slope, V.
- f) For each species, the graphical intercept representing the species TAT intercept, f(Y), at a specific selected value, Z, of the WQC is calculated using the equation:

$$f(Y)=W - V(X - g(Z))$$

f ( ) is the transformation used to convert acute toxicity values to TAT values;

Y is the species acute toxicity intercept or species acute intercept;

W is the arithmetic mean of the TAT values as specified in subsection (c);

V is the pooled acute slope as specified in subsection (e);

X is the arithmetic mean of the TWQC values as specified in subsection (d);

g ( ) is the transformation used to convert the WQC values to TWQC values; and  $\,$ 

Z is a selected value of the WQC.

- g) For each species, determine the species acute intercept, Y, by carrying out an inverse transformation of the species TAT value, f(Y). For example, in the case of a logarithmic transformation, Y = antilogarithm of (f(Y)); or in the case where no transformation is used, Y = f(Y).
- h) The Final Acute Intercept (FAI) is derived by using the species acute intercepts, obtained from subsection (g), in compliance with the procedures described in Section 302.615(b) through (g), with the word "value" replaced by the word "intercept". Note that in this procedure, geometric means and natural logarithms are always used.
- i) The Aquatic Acute Intercept (AAI) is obtained by dividing the FAI by two.
- j) The AATC at any value of the WQC, denoted by WQCx, is calculated using the terms defined in subsection (f) and the equation:

$$AATC = \exp[V(g(WQCx) - g(Z)) + f(AAI)].$$

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

# Section 302.621 Determining the Acute Aquatic Toxicity Criterion - Procedure for Combinations of Substances

An AATC for any combination of substances (including effluent mixtures) must be determined by the following toxicity testing procedures:

- a) Not more than 50% of test organisms from the most sensitive species tested may exhibit mortality or immobility after a 48-hour test for invertebrates or a 96-hour test for fish.
- b) Three resident or indigenous species of ecologically diverse taxa must be tested initially. If resident or indigenous species are not available for testing, non-resident species may be used if the non-resident species is of the same family or genus and has a similar habitat and environmental tolerance.

(Source: Amended at 47 III. Reg. 4437, effective March 23, 2023)

# Section 302.627 Determining the Chronic Aquatic Toxicity Criterion for an Individual Substance - General Procedures

- a) A chemical-specific Chronic Aquatic Toxicity Criterion (CATC) is calculated using procedures specified in subsection (b) when chronic toxicity data are available for at least five species from five different North American genera of freshwater organisms, including representatives from the following taxa:
  - 1) Representatives of two families in the Class Osteichthyes (Bony Fish).

- 2) The family Daphnidae.
- 3) A benthic aquatic macroinvertebrate.
- 4) An alga (96-hour test) or a vascular aquatic plant.
- b) A CATC is derived in the same manner as the FAV in Section 302.615 or 302.618 by substituting CATC for FAV or FAI, chronic for acute, MATC for LC-50, SMCV (Species Mean Chronic Value) for SMAV, and GMCV (Genus Mean Chronic Value) for GMAV.
- c) If data are not available to meet the requirements of subsection (a), a CATC is calculated by dividing the FAV by the highest acute-chronic ratio obtained from at least one fish and one invertebrate species. The acute-chronic ratio for a species equals the acute toxicity concentration from data considered under Sections 302.612 through 302.618, divided by the chronic toxicity concentration from data calculated under subsections (a) and (b) subject to the following conditions:
  - 1) If the toxicity of a substance is related to any water quality characteristic (WQC), the acute-chronic ratio must be based on acute and chronic toxicity data obtained from organisms exposed to test water with WQC values that are representative of the WQC values of the waterbody under consideration. Preference under this subsection must be given to data from acute and chronic tests done by the same author or in the same reference to increase the likelihood of comparable test conditions.
  - 2) If the toxicity of a substance is unrelated to water quality parameters, the acute-chronic ratio may be derived from any acute and chronic test on a species regardless of the similarity in values of those water quality parameters. Preference under this subsection must be given to data from acute and chronic tests done on the same organisms or their descendants.
  - 3) If there is more than one acute-chronic ratio for a species, a geometric mean of the ratio is calculated, corrected for the relationship of toxicity to water quality parameters.
  - 4) If the acute and chronic toxicity data indicate that the acute-chronic ratio varies with changes in water quality parameters, the acute-chronic ratio used over specified values of the water quality parameters must be based on the ratios at water quality parameter values closest to those specified.
  - 5) If acute and chronic toxicity data are unavailable to determine an acutechronic ratio for at least two North American freshwater species, a ratio of 25 must be used.

d) If a resident or indigenous species whose presence is necessary to sustain commercial or recreational activities, or prevent disruptions of the waterbody's ecosystem, including loss of species diversity or a shift to a biotic community dominated by pollution-tolerant species, will not be protected by the calculated CATC, then the MATC for that species is used as the CATC.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

# Section 302.630 Determining the Chronic Aquatic Toxicity Criterion - Procedure for Combinations of Substances

A CATC for any combination of substances (including effluent mixtures) may be determined by toxicity testing procedures pursuant to the following:

- a) A combination of substances must not exceed concentrations greater than a NOAEL as determined for the most sensitive of the species tested.
- b) Three resident or indigenous species of ecologically diverse taxa must be tested initially. If resident or indigenous species are not available for testing, non-resident species may be used if the non-resident species is of the same family or genus and has a similar habitat and environmental tolerance.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

#### Section 302.633 The Wild and Domestic Animal Protection Criterion

The Wild and Domestic Animal Protection Criterion (WDAPC) is the concentration of a substance that if not exceeded, protects Illinois wild and domestic animals from adverse effects, such as functional impairment or pathological lesions, resulting from ingestion of surface waters of the State or ingestion of aquatic organisms taken from surface waters of the State.

- a) For those substances for which a NOAEL has been derived from studies of mammalian or avian species exposed to the substance via oral routes including gavage, the lowest NOAEL among species must be used in calculating the WDAPC. Additional considerations in selecting NOAEL include:
  - 1) If the NOAEL is given in milligrams of toxicant per liter of water consumed (mg/L), before calculating the WDAPC, the NOAEL must be multiplied by the daily average volume of water consumed by the test animals in liters per day (L/d) and divided by the average weight of the test animals in kilograms (kg).
  - 2) If the NOAEL is given in milligrams of toxicant per kilogram of food consumed (mg/kg), before calculating the WDAPC, the NOAEL must be multiplied by the average amount of food in kilograms consumed daily by

- the test animals (kg/d) and divided by the average weight of the test animals in kilograms (kg).
- 3) If the animals used in a study were not exposed to the toxicant each day of the test period, the NOAEL must be multiplied by the ratio of days of exposure to the total days in the test period.
- 4) If more than one NOAEL is available for the same animal species, the geometric mean of the NOAELs must be used to calculate the WDAPC.
- b) For those substances for which a NOAEL is not available but the lowest observed adverse effect level (LOAEL) has been derived from studies of animal species exposed to the substance via oral routes including gavage, one-tenth of the LOAEL must be substituted for the NOAEL.
- c) The LOAEL must be selected in the same manner as that specified for the NOAEL in subsection (a).
- d) The WDAPC, measured in milligrams per liter (mg/L), is calculated according to the equation:

$$WDAPC = [0.1 \text{ NOAEL x Wt}]/[W + (F \text{ x BCF})]$$

NOAEL is derived from mammalian or avian studies as specified in subsections (a) and (b), and is measured in units of milligrams of substance per kilogram of body weight per day (mg/kg-d);

Wt = Average weight in kilograms (kg) of the test animals;

W = Average daily volume of water in liters consumed per day (L/d) by the test animals;

F = Average daily amount of food consumed by the test animals in kilograms (kg/d);

BCF = Aquatic life Bioconcentration Factor with units of liter per kilogram (L/kg), as derived in Sections 302.660 through 302.666; and

The 0.1 represents an uncertainty factor to account for species variability.

e) If no studies pertaining to the toxic substance in question can be found by the Agency, no criterion can be determined.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

#### Section 302.642 The Human Threshold Criterion

The Human Threshold Criterion (HTC) of a substance is that concentration or level of a substance at which humans are protected from adverse effects resulting from incidental exposure to, or ingestion of, surface waters of the State and from ingestion of aquatic organisms taken from surface waters of the State. HTCs are derived for those toxic substances for which there exists a threshold dosage or concentration below which no adverse effect or response is likely to occur.

(Source: Added at 14 III. Reg. 2899, effective February 13, 1990)

## Section 302.645 Determining the Acceptable Daily Intake

The Acceptable Daily Intake (ADI) is the maximum amount of a substance that, if ingested daily for a lifetime, results in no adverse effects to humans. Subsections (a) through (e) list, in the order of preference, methods for determining the acceptable daily intake.

a) The lowest of the following ADI values:

1) For substances listed with a maximum contaminant level in 40 CFR 141 (incorporated by reference in 35 Ill. Adm. Code 301.106) or in 35 Ill. Adm. Code 611, the ADI equals the product of multiplying the maximum contaminant level given in milligrams per liter (mg/L) by 2 liters per day (L/d).

2) For substances listed with a maximum allowable concentration standard in 35 Ill. Adm. Code Subtitle F, the acceptable daily intake equals the product of multiplying the public health enforcement standard given in milligrams per liter (mg/L) by 2 liters per day (L/d).

b) For substances for which a no observed adverse effect level (NOAEL-H) for humans exposed to the substance in drinking water has been derived, the acceptable daily intake equals the product of multiplying one-tenth of the NOAEL-H given in milligrams of toxicant per liter of water consumed (mg/L) by 2 liters per day (L/d). The lowest NOAEL-H must be used in the calculation of the acceptable daily intake.

c) For substances for which the lowest observed adverse effect level (LOAEL-H) for humans exposed to the substance in drinking water has been derived, one-hundredth of the LOAEL-H may be substituted for the NOAEL-H in subsection (b).

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- —For substances for which a no observed adverse effect level (NOAEL-A) has been derived from studies of mammalian test species exposed to the substance via oral routes including gavage, the acceptable daily intake equals the product of multiplying 1/100 of the NOAEL-A given in milligrams toxicant per day per kilogram of test species weight (mg/kg-d) by the average weight of an adult human of 70 kilograms (kg). The lowest NOAEL-A among animal species must be used in the calculation of the acceptable daily intake. Additional considerations in selecting the NOAEL-A include:
  - -If the NOAEL-A is given in milligrams of toxicant per liter of water consumed (mg/L), before calculating the acceptable daily intake, the NOAEL-A must be multiplied by the daily average volume of water consumed by the mammalian test species in liters per day (L/d) and divided by the average weight of the mammalian test species in kilograms (kg).
    - -If the NOAEL-A is given in milligrams of toxicant per kilogram of food consumed (mg/kg), before calculating the acceptable daily intake, the NOAEL-A must be multiplied by the average amount in kilograms of food consumed daily by the mammalian test species (kg/d) and divided by the average weight of the mammalian test species in kilograms (kg).
  - -If the mammalian test species were not exposed to the toxicant each day of the test period, the NOAEL-A must be multiplied by the ratio of days of exposure to the total days of the test period.
    - If more than one NOAEL-A is available for the same mammalian test species, the geometric mean of the NOAEL-As must be used.
- -For substances for which a NOAEL-A is not available but the lowest observed adverse effect level (LOAEL-A) has been derived from studies of mammalian test species exposed to the substance via oral routes including gavage, one-tenth of the LOAEL-A may be substituted for the NOAEL-A in subsection (d). The LOAEL-A must be selected in the same manner as that specified for the NOAEL-A in subsection (d).
- If no studies pertaining to the toxic substance in question can be found by the Agency, no criterion can be determined.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

#### **Section 302.640 Procedures for Deriving Bioaccumulation Factors**

A bioaccumulation factor (BAF) is used to relate the concentration of a substance in an aquatic organism to the concentration of the substance in the waters in which the organism resides when

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all routes of exposure (ambient water and food) are included. A BAF is used in the derivation of water quality criteria to protect human health.

- a) Selection of Data. BAFs can be obtained or developed from one of the following methods, listed in order of preference.
  - 1) Field-measured BAF.
  - 2) Field-measured biota-sediment accumulation factor (BSAF).
  - 3) Laboratory-measured bioconcentration factor (BCF).

    The concentration of particulate organic carbon (POC) and dissolved organic carbon (DOC) in the test solution must be either measured or reliably estimated.
  - 4) Predicted BCF.
    Predicted baseline BCF = Kow.
- b) Calculation of Baseline BAFs for Organic Chemicals

  The most preferred BAF or BCF from above is used to calculate a baseline BAF which in turn is utilized to derive a human health or wildlife specific BAF.
  - 1) Procedures for Determining the Necessary Elements of Baseline Calculation
    - A) Lipid Normalization (μg/g). The lipid-normalized concentration,
       C<sub>1</sub>, of a chemical in tissue is defined using the following equation:

$$C_l = \frac{C_B}{f_l}$$

Where:

 $C_b$  = concentration of the organic chemical in the tissue of aquatic biota (either whole organism or specified tissue) ( $\mu g/g$ )  $f_l$  = fraction of the tissue that is lipid

B) Bioavailability.

The fraction of the total chemical in the ambient water that is freely dissolved,  $f_{fd}$ , must be calculated using the following equation:

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$$f_{fd} = \frac{1}{\left\{1 + \left(\frac{DOC \bullet Kow}{10}\right) + (POC \bullet Kow)\right\}}$$

DOC = concentration of dissolved organic carbon (kg of dissolved organic carbon/L of water)

<u>Kow = octanol-water partition coefficient of the chemical</u> (unitless)

POC = concentration of particulate organic carbon (kg of particulate organic carbon/L of water)

- C) Food Chain Multiplier (FCM). For an organic chemical, the FCM used must be taken from Table B-1 in Appendix B of 40 CFR 132, incorporated by reference at 35 Ill. Adm. Code 301.106.
- 2) Calculation of Baseline BAFs
  - A) From Field-Measured BAF

$$Baseline\ BAF = \left\{ \left( \frac{Measured\ BAF_{tT}}{f_{fd}} \right) - 1 \right\} \bullet \left( \frac{1}{f_l} \right)$$

Where:

 $BAF_{tT} = BAF$  based on total concentration in tissue and water of study organism and site (L/kg)

 $\underline{f_l}$  = fraction of the tissue of study organism that is lipid  $\underline{f_{fd}}$  = fraction of the total chemical that is freely dissolved in the ambient water

B) From a Field-Measured Biota-Sediment Accumulation Factor (BSAF)

 $(Baseline\ BAF)_i = \frac{(Baseline\ BAF)_r \bullet (BSAF)_i \bullet (Kow)_i}{(BSAF)_r \bullet (Kow)_r}$ 

(BSAF)<sub>i</sub> = BSAF for chemical "i" (kg of organic carbon/kg of lipid)

 $(BSAF)_r = BSAF$  for the reference chemical "r" (kg of organic carbon/kg of lipid)

 $(Kow)_i$  = octanol-water partition coefficient for chemical "i", unitless

 $(Kow)_r$  = octanol-water partition coefficient for the reference chemical " $_r$ ", unitless

i) A BSAF must be calculated using the following equation:

 $BSAF = \frac{C_l}{C_{soc}}$ 

Where:

 $C_1$  = the lipid-normalized concentration of the chemical in tissue ( $\mu$ g/g)

 $\underline{C_{soc}}$  = the organic carbon-normalized concentration of the chemical in sediment ( $\mu g/g$ )

ii) The organic carbon-normalized concentration of a chemical in sediment, C<sub>soc</sub>, must be calculated using the following equation:

 $C_{soc} = \frac{C_s}{f_{oc}}$ 

Where:

 $C_s$  = concentration of chemical in sediment (mg/g sediment)

 $\underline{\mathbf{f}_{oc}}$  = fraction of the sediment that is organic carbon

C) From a Laboratory-Measured BCF

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$$Baseline \; BAF = FCM \; \bullet \left\{ \left( \frac{measured \; BCF_{tT}}{f_{fd}} \right) - 1 \right\} \bullet \left( \frac{1}{f_l} \right)$$

 $\overline{BCF_{tT}} = BCF$  based on total concentration in tissue and water.  $f_l = f_{tot}$  fraction of the tissue that is lipid

 $\underline{f_{fd}}$  = fraction of the total chemical in the test water that is freely dissolved

FCM = the food-chain multiplier obtained from Table B-1 in Appendix B to 40 CFR 132, incorporated by reference at 35 Ill. Adm. Code 310.106, by linear interpolation for trophic level 3 or 4, as necessary

### D) From a Predicted BCF

Baseline BAF =  $FCM \cdot Predicted Baseline BCF = FCM \cdot Kow$ 

Where:

FCM = the food-chain multiplier obtained from Table B-1 in Appendix B to 40 CFR 132, incorporated by reference at 35 Ill. Adm. Code 301.106, by linear interpolation for trophic level 3 or 4, as necessary

Kow = octanol-water partition coefficient

- c) Human Health BAFs for Organic Chemicals
  - 1) Fraction freely dissolved (ffd). By using the equation in subsection (b)(1)(B), the ffd to be used to calculate human health BAFs for an organic chemical must be calculated using statewide mean stream POC concentration of 0.0000002 kg/L and DOC concentration of 0.00000459 kg/L), or site-specific waterbody POC and DOC concentrations (in kg/L) if sufficient data allows:

$$f_{fd} = \frac{1}{\left\{1 + \left(\frac{DOC \bullet Kow}{10}\right) + (POC \bullet Kow)\right\}}$$

- 2) Human health BAF. The human health BAFs for an organic chemical must be calculated using the following equations:
  - A) For Trophic Level 3

 $Human \ Health \ BAF_{HHTL3} = \{(baseline \ BAF \bullet 0.0182) + 1\} \bullet f_{fd}$ 

B) For Trophic Level 4

 $\textit{Human Health BAF}_{\textit{HHTL4}} = \{(\textit{baseline BAF} \bullet 0.0310) + 1\} \bullet \textit{f}_{\textit{fd}}$ 

Where:

0.0182 and 0.0310 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive human health criteria and values

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- d) Human Health BAFs for Inorganic Chemicals. For inorganic chemicals, the baseline BAFs for trophic levels 3 and 4 are both assumed to equal the BCF determined for the chemical with fish.
  - 1) Human Health. Measured BAFs and BCFs used to determine human health BAFs for inorganic chemicals must be based on concentration in edible tissue (e.g., muscle) of freshwater fish.

(Source:)

# Section 302.641 Procedures for Deriving Water Quality Criteria and Values to Protect Human Health - General

- a) The human health criteria or values for a substance are those concentrations at which humans are protected from adverse effects resulting from incidental exposure to, or ingestion of, the surface waters of the State and from ingestion of aquatic organisms taken from the waters of the State. A Human Health Threshold Criterion (HHTC) or Human Health Threshold Value (HHTV) will be calculated for all substances according to Section 302.643, if data is available. Water quality criteria or values for substances that are, or may be, carcinogenic to humans will also be calculated according to procedures for the Human Health Nonthreshold Criterion (HHNC) or the Human Health Nonthreshold Value (HHNV) in Section 302.652.
- b) Minimum data requirements for BAFs for human health criteria:

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1) Tier I

- A) For all organic chemicals, either a field-measured BAF or a BAF derived using the BSAF methodology is required unless the chemical has a BAF less than 125, then a BAF derived by any methodology is required; and
- B) For all inorganic chemicals, including organometals such as mercury, either a field-measured BAF or a laboratory-measured BCF is required.
- 2) Tier II. Any bioaccumulation factor method in Section 302.640(a) may be used to derive a Tier II criterion.

(Source:)

# Section 302.643 Procedures for Determining the Human Health Threshold Criterion (HHTC) and the Human Health Threshold Value (HHTV)

The HHTC or HHTV is derived for all toxic substances from the most sensitive endpoint for which there exists a dosage or concentration below which no adverse effect or response is likely to occur.

- a) Minimum Data Requirements
  - 1) Tier I. The minimum data set sufficient to derive a Tier I HHTC must include at least one epidemiological study or one animal study of greater than 90 days duration; or
  - 2) Tier II. When the minimum data for deriving Tier I criteria are not available, a more limited database consisting of an animal study of greater than 28 days duration must be used.
- b) Principles for Development of Tier I Criteria and Tier II Values
  - 1) The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) must be used to calculate a criterion or value. In the absence of a NOAEL, a LOAEL must be used if it is based on relatively mild and reversible effects;
  - 2) Uncertainty factors (UFs) must be used to account for the uncertainties in predicting acceptable dose levels for the general human population based upon experimental animal data or limited human data:

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- A) A UF of 10 must be used when extrapolating from experimental results of studies on prolonged exposure to average healthy humans;
- B) A UF of 100 must be used when extrapolating from results of longterm studies on experimental animals;
- C) A UF of up to 1000 must be used when extrapolating from animal studies for which the exposure duration is less than chronic, but greater than subchronic;
- D) A UF of up to 3000 must be used when extrapolating from animal studies for which the exposure duration is less than subchronic;
- E) An additional UF of between one and ten must be used when deriving a criterion from a LOAEL. The level of additional uncertainty applied will depend upon the severity and the incidence of the observed adverse effect;
- F) An additional UF of between one and ten must be applied when there are limited effects data or incomplete sub-acute or chronic toxicity data;
- The total uncertainty ( $\Sigma$  of the uncertainty factors) must not exceed 10,000 for Tier I criterion and 30,000 for Tier II value; and
- 4) All study results must be converted to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses must be adjusted for continuous exposure.
- c) Tier I Criteria and Tier II Value Derivation
  - 1) Determining the Acceptable Daily Exposure (ADE)

 $ADE = \frac{Test \ Level}{\sum UFs \ from \ subsection \ (b)(2)}$ 

Where:

acceptable daily exposure is in milligrams toxicant per kilogram body weight per day (mg/kg/day)

2) Determining the Human Health Threshold Criterion (HHTC) or the Human Health Threshold Value (HHTV)

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$$HHTC \ or \ HHTV = \frac{ADE \bullet BW \bullet RSC}{\{WC + (FC_{TL3} \bullet BAF_{HHTL3}) + (FC_{TL4} \bullet BAF_{HHTL4})\}}$$

Where:

HHTC or HHTV is in milligrams per liter (mg/L)

ADE = acceptable daily intake in milligrams toxicant per kilogram body weight per day (mg/kg/day)

 $\underline{RSC}$  = relative source contribution factor of 0.2 (default) or calculated  $\leq \underline{0.8}$ 

BW = weight of an average adult human (BW = 80 kg)

WC = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = 2.5 liters/day; or per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day

 $\overline{FC}_{TL3}$  = mean consumption of trophic level 3 fish by regional sport fishers of regionally caught freshwater fish = 0.0039 kg/day

 $FC_{TL4}$  = mean consumption of trophic level 4 fish by regional sport fishers of regionally caught freshwater fish = 0.0051 kg/day

 $\overline{BAF_{HHTL3}}$  = human health bioaccumulation factor for edible portion of trophic level 3 fish, as derived using the BAF methodology in Section 302.640 (L/kg).

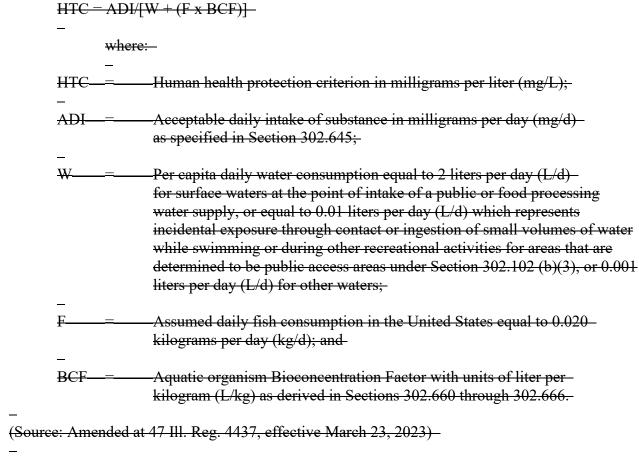
BAF<sub>HHTL4</sub> = human health bioaccumulation factor for edible portion of trophic level 4 fish, as derived using the BAF methodology in Section 302.640 (L/kg)

(Source:)

### Section 302.648 Determining the Human Threshold Criterion

The HTC is calculated according to the equation:

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Section 302.651——The Human Nonthreshold Criterion

The Human Nonthreshold Criterion (HNC) of a substance is the concentration or level of a substance at which humans are protected from an unreasonable risk of disease caused by a nonthreshold toxic mechanism as a result of incidental exposure to or ingestion of surface waters of the State or ingestion of aquatic organisms taken from surface waters of the State. HNCs are derived for those toxic substances for which any exposure, regardless of extent, carries some risk of damage as specified in subsections (a) and (b).

a) For single substances, a risk level of one in one million (1 in 1,000,000) must be allowed (i.e., considered acceptable) to determine an HNC.

b) For mixtures of substances, an additive risk level of one in one hundred thousand (1 in 100,000) must be allowed (i.e., considered acceptable) to determine an HNC.

(Source: Amended at 47 III. Reg. 4437, effective March 23, 2023)

Section 302.654 Determining the Risk Associated Intake

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The Risk Associated Intake (RAI) is the maximum amount of a substance that if ingested daily for a lifetime, is expected to result in the risk of one additional case of human cancer in a population of one million. Where more than one carcinogenic chemical is present, the RAI must be based on an allowed additive risk of one additional case of cancer in a population of one hundred thousand. The RAI must be derived as specified in subsections (a) through (c).

- a) For those substances for which a human epidemiologic study has been performed, the RAI equals the product of the dose from exposure in units of milligrams of toxicant per kilogram body weight per day (mg/kg-d) that results in a 70-year lifetime cancer probability of one in one million, times the average weight of an adult human of 70 kilograms (kg). The resulting RAI is expressed in milligrams toxicant per day (mg/d). If more than one human epidemiologic study is available, the lowest exposure level resulting in a 70-year lifetime probability of cancer equal to a ratio of one in one hundred thousand must be used in calculating the RAI.
- b) In the absence of an epidemiologic study, for those toxic substances for which a carcinogenic potency factor (CPF) has been derived from studies of mammalian test species, the risk associated intake is calculated from the equation:

RAI - K/CPF

Where:

RAI - Risk associated intake in milligrams per day (mg/d);

K = A constant consisting of the product of the average weight of an adult human, assumed to be 70 kg, and the allowed cancer risk level of one in one million (1/1,000,000); and

CPF – Carcinogenic Potency Factor is the risk of one additional cancer per unit dose from exposure. The CPF is expressed in units of inverse milligrams per kilogram day (1/mg/kg-d) as derived in subsections (b)(1) through (b)(7).

- 1) Only those studies that fulfill the data requirement criteria of Section 302.606 must be used in calculating the CPF.
- The linear no-threshold dose-response relationship developed in the same manner as in the USEPA document "Mutagenicity and Carcinogenicity Assessment of 1,3-butadiene", incorporated by reference in 35 Ill. Adm. Code 301.106, must be used in obtaining the unit risk, defined as the 95th percentile upper bound risk of one additional cancer resulting from a lifetime exposure to a unit concentration of the substance being considered. The CPF must be estimated from the unit risk in compliance

with subsection (b)(7). In calculating a CPF, the Agency must review alternate scientifically valid protocols if so requested.

3) If in a study of a single species more than one type of tumor is induced by exposure to the toxic substance, the highest of the CPFs is used.

4) If two or more studies vary in either species, strain, or sex of the test animal, or tumor type, the highest CPF is used.

5) If more than one tumor of the same type is found in some of the test animals, these should be pooled so that the dose-response relationship is dose versus number of tumors per animal. The potency estimate for this dose-response relationship is used if it is higher than estimates resulting from other methods.

6) If two or more studies are identical regarding species, strain, and sex of the test animal, and tumor type, the highest of the CPFs is used.

7) Calculation of an equivalent dose between animal species and humans using a surface area conversion, and conversion of units of exposure to dose in milligrams of toxicant per kilogram of body weight per day (mg/kg-d), must be performed as specified in the USEPA document "Mutagenicity and Carcinogenicity Assessment of 1,3 butadiene", incorporated by reference in 35 Ill. Adm. Code 301.106.

e) If both a human epidemiologic study and a study of mammalian test species are available for use in subsections (a) and (b), the risk associated intake is determined as follows:

1) When the human epidemiologic study provides evidence of a carcinogenic effect on humans, the RAI is calculated from the human epidemiology study as specified in subsection (a).

2) When the mammalian study provides evidence of a carcinogenic effect on humans, but the human epidemiologic study does not, a cancer risk to humans is assumed and the risk associated intake is calculated as specified in subsection (b).

(Source: Amended at 47 III. Reg. 4437, effective March 23, 2023)

Section 302.652 Procedures for Determining the Human Health Nonthreshold

Criterion (HHNC) or the Human Health Nonthreshold Value

(HHNV)

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An HHNC or HHNV must be derived for those toxic substances for which any exposure, regardless of extent, carries some risk of damage from cancer or a nonthreshold toxic mechanism. For single or combinations of substances, a risk level of 1 in 100,000 (or 10<sup>-5</sup>) must be used to determine an HHNC or HHNV.

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- a) Minimum Data Requirements. Minimal experimental or epidemiological data requirements are incorporated in the cancer classification determined by USEPA in Appendix C II A to 40 CFR 132, incorporated by reference at 35 Ill. Adm. Code 301.106.
- b) Principles for Development of Criteria or Values
- \_
- 1) Animal data are fitted to a linearized multistage computer model (Global 1986 in "Mutagenicity and Carcinogenicity Assessment for 1, 3-Butadiene" September 1985 EPA/600/8-85/004A, incorporated by reference at 35 Ill. Adm. Code 301.106 or scientifically justified equivalents). The upper-bound 95 percent confidence limit on risk at the 1 in 100,000 risk level must be used to calculate a risk associated dose (RAD); and
- A species scaling factor must be used to account for differences between test species and humans. Milligrams per surface area per day is an equivalent dose between species. All doses presented in mg/kg body weight will be converted to an equivalent surface area dose by raising the mg/kg dose to the 3/4 power.
- c) Determining the Risk-Associated Dose (RAD). The RAD must be calculated using the following equation:
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$$RAD = \frac{0.00001}{q_l *}$$

Where:

RAD = risk-associated dose in milligrams of toxicant or combinations of toxicants per kilogram body weight per day (mg/kg/day)

0.00001 (1 X 10<sup>-5</sup>) = incremental risk of developing cancer equal to 1 in 100,000

 $q_1^*$  = slope factor (mg/kg/day)-1

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d) Determining the Human Health Nonthreshold Criterion (HHNC) or the Human Health Nonthreshold Value (HHNV)

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$$\frac{RAD \bullet BW}{\{WC + (FC_{TL3} \bullet BAF_{HHTL3}) + (FC_{TL4} \bullet BAF_{HHTL4})\}}$$

Where:

HHNC or HHNV is in milligrams per liter (mg/L)

RAD = risk-associated dose of a substance or combination of substances in milligrams per day (mg/d) which is associated with a lifetime cancer risk level equal to a ratio of 1 to 100,000

BW = weight of an average human (BW = 80 kg)

WC = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = 2.5 liters/day, or per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day

 $\overline{FC_{TL3}}$  = mean consumption of trophic level 3 of regionally caught freshwater fish = 0.0039 kg/day

 $FC_{TL4}$  = mean consumption of trophic level 4 of regionally caught freshwater fish = 0.0051 kg/day

BAF<sub>HHTL3</sub>, BAF<sub>HHTL4</sub> = bioaccumulation factor for trophic levels 3 and 4 as derived in Section 302.640 (L/kg)

(Source:)

### Section 302.657 Determining the Human Nonthreshold Criterion

The HNC is calculated according to the equation:

$$\frac{HNC - RAI/[W + (F \times BCF)]}{}$$

where:

HNC = Human Nonthreshold Protection Criterion in milligrams per liter (mg/L);

RAI — Risk Associated Intake of a substance in milligrams per day (mg/d) that is associated with a lifetime cancer risk level equal to a ratio of one to 1,000,000 as derived in Section 302.654;

Per capita daily water consumption equal to 2 liters per day (L/d)
for surface waters at the point of intake of a public or food processing
water supply, or equal to 0.01 liters per day (L/d) which represents
incidental exposure through contact or ingestion of small volumes of water
while swimming or during other recreational activities for areas which are
determined to be public access areas under Section 302.102(b)(3), or
0.001 liters per day (L/d) for other waters;

F — Assumed daily fish consumption in the United States equal to 0.020 kilograms per day (kg/d); and

BCF — Aquatic Life Bioconcentration Factor with units of liter perkilogram (L/kg) as derived in Section 302.663.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

# Section 302.658 Stream Flow for Application of Human <u>Health</u> Nonthreshold Criterion

The HHNC applies at all times except during periods when flows are less than the harmonic mean flow (Qhm), as determined by:

$$Qhm = \frac{N}{\sum \left(\frac{1}{Qi}\right)}$$

Where:

Qhm = harmonic mean flow,

N = number of daily values for streamflows, and

Qi = daily streamflow value on day i.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

#### Section 302.660 Bioconcentration Factor

A Bioconcentration Factor is used to relate substance residue in aquatic organisms to the concentration of the substance in the waters in which the organisms reside.

(Source: Added at 14 III. Reg. 2899, effective February 13, 1990)

#### **Section 302.663 Determination of Bioconcentration Factors**

A Bioconcentration Factor equals the concentration of a substance in all or part of an aquatic organism in milligrams per kilogram of wet tissue weight (mg/kg), divided by the concentration of the substance in the water to which the organism is exposed in milligrams of the substance per liter of water (mg/L).

- a) The Bioconcentration Factor is calculated from a field study if the following conditions are met:
  - 1) Data are available to show that the concentration of the substance in the water to which the organism was exposed remained constant over the range of territory inhabited by the organism and for a period of time exceeding 28 days;
  - 2) Competing mechanisms for removal of the substance from solution did not affect the bioavailability of the substance; and
  - 3) The concentration of the substance to which the organism was exposed is less than the lowest concentration causing any adverse effects on the organism.
- b) In the absence of a field-derived Bioconcentration Factor, the Bioconcentration Factor is calculated from a laboratory test if the following conditions are met:
  - 1) The Bioconcentration Factor was calculated from measured concentrations of the toxic substance in the test solution;
  - 2) The laboratory test was of sufficient duration to have reached steady state, which is defined as a less than 10 percent change in the calculated Bioconcentration Factor over a 2-day period or 16 percent of the test duration, whichever is longer. In the absence of a laboratory test that has reached steady state, the Bioconcentration Factor may be calculated from a laboratory test with a duration greater than 28 days if more than one test is available for the same species of organism;
  - 3) The concentration of the toxic substance to which the test organism was exposed is less than the lowest concentration causing any adverse effects on the organism;
  - 4) If more than one Bioconcentration Factor for the same species is available, the geometric mean of the Bioconcentration Factors is used; and

- 5) The Bioconcentration Factor is calculated on a wet tissue weight basis. A Bioconcentration Factor calculated using dry tissue weight must be converted to a wet tissue weight basis by multiplying the dry weight bioconcentration value by 0.1 for plankton and by 0.2 for individual species of fish and invertebrates.
- c) In the absence of any Bioconcentration Factors measured from field studies as specified in subsection (a) or laboratory studies that have reached steady state as specified in subsection (b), the Bioconcentration Factor is calculated according to the equation:

$$\log BCF = A + B \log Kow$$

BCF = Bioconcentration Factor;

Kow = The octanol/water partition coefficient measured as specified in ASTM E 1147, incorporated by reference in 35 Ill. Adm. Code 301.106 (If the Kow is not available from laboratory testing, it must be calculated from structure-activity relationships or available regression equations.); and

The constants A = -0.23 and B = 0.76 must be used unless a change in the value of the constants is requested (The Agency must honor requests for changes only if the changes are accompanied by scientifically valid supporting data.).

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

### **Section 302.666 Utilizing the Bioconcentration Factor**

The Bioconcentration Factor derived in Section 302.663 is used to calculate water quality criteria for a substance as specified below:

- a) When calculating a WDAPC as described in Section 302.633, the geometric mean of all available steady-state, whole-body Bioconcentration Factors for fish and shellfish species that constitute or represent a portion of the diet of indigenous wild and domestic animal species is used. Additional considerations in deriving a Bioconcentration Factor include:
  - An edible portion Bioconcentration Factor is converted to a whole-body Bioconcentration Factor for a fish or shellfish species by multiplying the edible portion Bioconcentration Factor by the ratio of the percent lipid in the whole body to the percent lipid in the edible portion of the same species.

- 2) A Bioconcentration Factor calculated as described in Section 302.663(c) is converted to a whole-body Bioconcentration Factor by multiplying the calculated Bioconcentration Factor by the ratio of the percent lipid in the whole body to 7.6.
- b) When calculating either a human threshold criterion or a human nonthreshold criterion as described in Sections 302.642 through 302.648 or Sections 302.651 through 302.657, respectively, the geometric mean of all available edible portion Bioconcentration Factors for fish and shellfish species consumed by humans is used. Additional considerations in deriving a Bioconcentration Factor include:
  - 1) Edible portions include:
    - A) Decapods -- muscle tissue.
    - B) Bivalve mollusks -- total living tissue.
    - C) Scaled fish -- boneless, scaleless filets including skin except for bloater chubs in which the edible portion is the whole body, excluding head, scales, and viscera.
    - D) Smooth-skinned fish -- boneless, skinless filets.
  - A whole-body Bioconcentration Factor is converted to an edible portion Bioconcentration Factor by multiplying the whole-body Bioconcentration Factor of a species by the ratio of the percent lipid in the edible portion to the percent lipid in the whole body of the same species.
  - 3) A Bioconcentration Factor calculated as described in Section 302.663 is converted to an edible portion Bioconcentration Factor by multiplying the calculated Bioconcentration Factor by the ratio of the percent lipid in the edible portion to 7.6.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)

### Section 302.669 Listing of Derived Criteria

- a) The Agency must develop and maintain a listing of toxicity criteria <u>or values</u> pursuant to this Subpart. This list must be made available to the public and updated whenever a new criterion is derived and must be published when updated in the Illinois Register.
- b) A criterion published pursuant to subsection (a) may be proposed to the Board for adoption as a numeric water quality standard.

c) The Agency must maintain for inspection all information, including assumptions, toxicity data, and calculations, used to derive any toxicity criterion listed pursuant to subsection (a) until adopted by the Board as a water quality standard.

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)