3745-1-43 **Methodology for the development of wildlife criteria for the lake Erie drainage basin.**

[Comment: For dates of non-regulatory government publications, publications of recognized organizations and associations, federal rules and federal statutory provisions referenced in this rule, see rule 3745-1-03 of the Administrative Code.]

This rule applies to water bodies located in the lake Erie drainage basin. This rule establishes a methodology which is required when developing tier I wildlife criteria for bioaccumulative chemicals of concern (BCCs).

(A) General provisions.

(1) A tier I wildlife criterion is the concentration of a substance which is likely to, if not exceeded, protect avian and mammalian wildlife populations inhabiting the lake Erie drainage basin from adverse effects resulting from the ingestion of water and aquatic prey taken from surface waters of the lake Erie drainage basin. These criteria are based on existing toxicological studies of the substance of concern and quantitative information about the exposure of wildlife species to the substance through food and water consumption. Separate avian and mammalian values are developed using taxonomic class-specific toxicity data and exposure data for five representative wildlife species. The wildlife species selected are representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience the highest exposures to bioaccumulative contaminants through the aquatic food web; they are the bald eagle, herring gull, belted kingfisher, mink, and river otter.

(2) Rule 3745-1-39 of the Administrative Code describes the procedures for calculating site-specific wildlife criteria.

(3) The term "wildlife value" (WV) is used to denote the value for each representative species which results from using the equation in this rule, the value obtained from averaging species values within a class, or any value derived from application of the site-specific procedure provided in rule 3745-1-39 of the Administrative Code. The WVs calculated for the representative species are used to calculate taxonomic class-specific WVs. The WV is the concentration of a substance which, if not exceeded, should better protect the taxon in question.

(4) "Tier I wildlife criterion," or "tier I criterion" is used to denote the number derived from data meeting the tier I minimum database requirements, and which will be protective of the two classes of wildlife.

(B) Calculation of wildlife values for tier I criteria.

(1) Equation for avian and mammalian wildlife values. Tier I wildlife values for BCCs shall be calculated using the following equation:

$$WV = \frac{\dfrac{TD}{UF_A \times UF_S \times UF_L} \times Wt}{W + \sum(F_{TLi} \times BAF_{TLi}^{WL})}$$

Where:

WV = wildlife value in milligrams of substance per liter (mg/l).

TD = test dose in milligrams of substance per kilograms per day (mg/kg-d) for the test species. This shall be either a NOAEL or a LOAEL.

UF_A = uncertainty factor for extrapolating toxicity data across species (unitless). A species-specific UF shall be selected and applied to each representative species, consistent with the equation.

UF_s = UF for extrapolating from subchronic to chronic exposures (unitless).

UF_L = UF for LOAEL to NOAEL extrapolations (unitless).

Wt = average weight in kilograms (kg) for the representative species.

W = average daily volume of water consumed in liters per day (l/d) by the representative species.

F_{TLi} = average daily amount of food consumed from trophic level I in kilograms per day (kg/d) by the representative species.

BAF^{WL}_{TLi} = bioaccumulation factor for wildlife food in trophic level I in liters per kilogram (l/kg), developed using the BAF methodology contained in rule 3745-1-41 of the Administrative Code. For consumption of piscivorous birds by other birds (e.g., herring gull by eagles), the BAF shall be derived by multiplying the trophic level three BAF for fish by a biomagnification factor to account for the biomagnification from fish to the consumed birds.

(2) Identification of representative species for protection. For bioaccumulative chemicals, piscivorous species are identified as the focus of concern for wildlife criteria development in the Great Lakes. Three avian species (eagle, kingfisher and herring gull) and two mammalian species (mink and otter) serve as representative species for protection. The TD obtained from toxicity data for each taxonomic class shall be used to calculate WVs for each of the five representative species.

(3) Calculation of avian and mammalian wildlife values and tier I criterion

derivation. The avian WV is the geometric mean of the WVs calculated for the three representative avian species. The mammalian WV is the geometric mean of the WVs calculated for the two representative mammalian species. The lower of the mammalian and avian WVs shall be selected as the tier I criterion.

(C) Parameters of the effect component of the wildlife criteria methodology.

(1) Definitions. The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of this rule:

(a) Acceptable endpoints. For the purpose of wildlife criteria derivation, acceptable subchronic and chronic endpoints are those which affect reproductive or developmental success, organismal viability or growth, or any other endpoint which is, or is directly related to, parameters that influence population dynamics.

(b) Chronic effect. An adverse effect that is measured by assessing an acceptable endpoint and results from continual exposure over several generations, or at least over a significant part of the test species' projected life span or life stage.

(c) Subchronic effect. 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.

(2) Minimum toxicity database for tier I criteria development. A TD value is required for criterion calculation. To derive a tier I criterion for wildlife, the data set shall provide enough data to generate a subchronic or chronic dose-response curve for any given substance for both mammalian and avian species. In reviewing the toxicity data available which meet the minimum data requirements for each taxonomic class, the following order of preference shall be applied to select the appropriate TD to be used for calculation of individual WVs. Data from peer-reviewed field studies of wildlife species take precedence over other types of studies, where such studies are of adequate quality. An acceptable field study shall be of subchronic or chronic duration, provide a defensible, chemical-specific dose-response curve in which cause and effect are clearly established, and assess acceptable endpoints as defined in this document. When acceptable wildlife field studies are not available, or determined to be of inadequate quality, the needed toxicity information may come from peer-reviewed laboratory studies. When laboratory studies are used, preference shall be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations. All available laboratory data and field studies shall be reviewed to corroborate the final tier I criterion, to assess the reasonableness of the toxicity value used, and to assess the

appropriateness of any UFs which are applied. When evaluating the studies from which a test dose is derived in general, the following requirements shall be met:

(a) The mammalian data shall come from at least one well-conducted study of ninety days or greater designed to observe subchronic or chronic effects as defined in this document.

(b) The avian data shall come from at least one well-conducted study of seventy days or greater designed to observe subchronic or chronic effects as defined in this rule.

(c) In reviewing the studies from which a TD is derived for use in calculating a WV, studies involving exposure routes other than oral may be considered only when an equivalent oral daily dose can be estimated and technically justified because the criteria calculations are based on an oral route of exposure.

(d) In assessing the studies which meet the minimum data requirements, preference shall be given to studies which assess effects on developmental or reproductive endpoints.

(3) Selection of TD data. In selecting data to be used in the derivation of WVs, the evaluation of acceptable endpoints, as defined in paragraph (C)(1) of this rule, shall be the primary selection criterion. All data not part of the selected subset may be used to assess the reasonableness of the toxicity value and the appropriateness of the UFs which are applied, as follows:

(a) If more than one TD value is available within a taxonomic class, based on different endpoints of toxicity, that TD which is likely to reflect best potential impacts to wildlife populations through resultant changes in mortality or fecundity rates shall be used for the calculation of WVs.

(b) If more than one TD is available within a taxonomic class, based on the same endpoint of toxicity, the TD from the most sensitive species shall be used.

(c) If more than one TD based on the same endpoint of toxicity is available for a given species, the TD for that species shall be calculated using the geometric mean of those TDs.

(4) In those cases in which a TD is available in units other than milligrams of substance per kilograms per day (mg/kg/d), the following procedures shall be used to convert the TD to the appropriate units prior to calculating a WV.

(a) If the TD is given in milligrams of toxicant per liter of water consumed by the test animals (mg/l), the TD shall 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).

(b) If the TD is given in milligrams of toxicant per kilogram of food consumed by the test animals (mg/kg), the TD shall 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).

(5) Drinking and feeding rates.

(a) When drinking and feeding rates and body weight are needed to express the TD in milligrams of substance per kilograms per day (mg/kg/d), they shall be obtained from the study from which the TD was derived. If not already determined, body weight, and drinking and feeding rates shall be converted to a wet weight basis.

(b) If the study does not provide the needed values, the values shall be determined from appropriate scientific literature. For studies done with domestic laboratory animals, either the "Registry of Toxic Effects of Chemical Substances" or "Recommendations for and Documentation of Biological Values for Use in Risk Assessment" shall be consulted. When these references do not contain exposure information for the species used in a given study, either the allometric equations in this rule or the exposure estimation methods presented in chapter 4 of "The Wildlife Exposure Factors Handbook" should be applied to approximate the needed feeding or drinking rates. The choice of the methods described in this paragraph is at the discretion of the director.

(c) For mammalian species, the general allometric equations are as follows:

(i) $F = 0.0687\ (Wt)^{0.82}$

Where:

F = feeding rate of mammalian species in kilograms per day (kg/d) dry weight.

Wt = average weight in kilograms (kg) of the test animals.

(ii) $W = 0.099\ (Wt)^{0.90}$

Where:

W = drinking rate of mammalian species in liters per day (l/d).

Wt = average weight in kilograms (kg) of the test animals.

(d) For avian species, the general allometric equations are:

(i) $F = 0.0582 (Wt)^{0.65}$

Where:

F = feeding rate of avian species in kilograms per day (kg/d) dry weight.

Wt = average weight in kilograms (kg) of the test animals.

(ii) $W = 0.059 (Wt)^{0.67}$

Where:

W = drinking rate of avian species in liters per day (l/d).

Wt = average weight in kilograms (kg) of the test animals.

(6) LOAEL to NOAEL extrapolations (UF_L). In those cases in which a NOAEL is unavailable as the TD and a LOAEL is available, the LOAEL may be used to estimate the NOAEL. If used, the LOAEL shall be divided by an UF to estimate a NOAEL for use in deriving WVs. The value of the UF shall not be less than one and shall not exceed ten, depending on the dose-response curve and any other available data, and is represented by UF_L in the equation expressed in paragraph (B)(1) of this rule.

(7) Subchronic to chronic extrapolations (UF_s). In instances where only subchronic data are available, the TD may be derived from subchronic data. In such cases, the TD shall be divided by an UF to extrapolate from subchronic to chronic levels. The value of the UF shall not be less than one and shall not exceed ten, and is represented by UF_s in the equation expressed in paragraph (B)(1) of this rule. This factor shall be used when assessing highly bioaccumulative substances where toxicokinetic considerations suggest that a bioassay of limited length underestimates chronic effects.

(8) Interspecies extrapolations (UF_A).

(a) The selection of the UF_A shall be based on the available toxicological data and on available data concerning the physicochemical, toxicokinetic, and toxicodynamic properties of the substance in question and the amount and quality of available data. This value is a UF that is intended to account for differences in toxicological sensitivity among species.

(b) For the derivation of tier I criteria, a UF_A shall not be less than one and shall not exceed one hundred, and shall be applied to each of the five

representative species, based on existing data and the director's best professional judgement. The value of UF_A may differ for each of the representative species.

(c) For tier I wildlife criteria, the UF_A shall be used only for extrapolating toxicity data across species within a taxonomic class, except as provided in this paragraph. The tier I UF_A is not intended for interclass extrapolations because of the poorly defined comparative toxicokinetic and toxicodynamic parameters between mammals and birds. However, an interclass extrapolation employing a UF_A may be used for a given chemical if it can be supported by a validated biologically-based dose-response model or by an analysis of interclass toxicological data, considering acceptable endpoints, for a chemical analog that acts under the same mode of toxic action.

(D) Parameters of the exposure component of the wildlife criteria methodology.

(1) Drinking and feeding rates of representative species. The body weights (Wt), feeding rates (F_{TLi}), drinking rates (W), and trophic level dietary composition (as food ingestion rate and per cent in diet) for each of the five representative species are presented in table 43-1 of this rule.

(2) BAFs. The methodology for development of bioaccumulation factors is in rule 3745-1-41 of the Administrative Code. Trophic level three and four BAFs are used to derive WVs because these are the trophic levels at which the representative species feed.

(E) Application of criteria. The wildlife criterion shall be applied as a thirty-day average concentration outside the mixing zone.

Table 43-1. Exposure parameters for the five representative species identified for protection.

Species	Adult body weight	Water ingestion rate	Food ingestion rate of prey in each trophic level	Trophic level of prey
Units	kg	l/day	kg/day	Per cent of diet
Mink	0.80	0.081	TL3: 0.159 Other: 0.0177	TL3: 90 % Other: 10 %
Otter	7.4	0.600	TL3: 0.977 TL4: 0.244	TL3: 80 % TL4: 20 %
Kingfisher	0.15	0.017	TL3: 0.0672	TL3: 100 %
Herring gull	1.1	0.063	TL3: 0.192 TL4: 0.0480 Other: 0.0267	Fish: 90 % TL3: 80 % TL4: 20 % Other: 10 %
Bald eagle	4.6	0.160	TL3: 0.371 TL4: 0.0929 PB: 0.0283 Other: 0.0121	Fish: 92 % TL3: 80 % TL4: 20 % Birds: 8 % PB: 70 % Non-aquatic: 30 %

Note: TL3 = trophic level 3 fish
TL4 = trophic level 4 fish
PB = piscivorous birds
Other = non-aquatic birds and mammals

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