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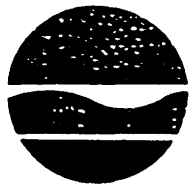

John P. Cahill
Commissioner

MEMORANDUM

***** N O T I C E *****

This document has been developed to provide Department staff with guidance on how to ensure compliance with statutory and regulatory requirements, including case law interpretations, and to provide consistent treatment of similar situations. This document may also be used by the public to gain technical guidance and insight regarding how the department staff may analyze an issue and factors in their consideration of particular facts and circumstances. This guidance document is not a fixed rule under the State Administrative Procedure Act section 102(2)(a)(i). Furthermore, nothing set forth herein prevents staff from varying from this guidance as the specific facts and circumstances may dictate, provided staff's actions comply with applicable statutory and regulatory requirements. This document does not create any enforceable rights for the benefit of any party.

Previous Date: New FEB 26 1998

TO: Regional Water Engineers, Bureau Directors, Section Chiefs

SUBJECT: Division of Water Technical and Operational Guidance Series 1.1.5

PROCEDURES FOR DERIVING AMBIENT WATER QUALITY STANDARDS AND GUIDANCE VALUES FOR THE PROTECTION OF WILDLIFE

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PURPOSE

The water quality regulations, 6NYCRR Part 702, contain general provisions for the derivation of standards and guidance values to protect wildlife. This TOGS provides detailed scientific procedures for the derivation of such values. As described below, these procedures call for the use of a bioaccumulation factor (BAF); detailed guidance for deriving BAFs is provided in Division of Water TOGS Number 1.1.4.

DISCUSSION

In 1995, under the Great Lakes Water Quality Initiative (GLI), U.S. EPA (1995a,b) developed detailed procedures for the derivation of ambient water quality criteria to protect piscivorous wildlife. That effort represents a thorough state-of-the-art analysis of the procedures needed to protect wildlife.

An essential feature of the procedures is the selection of "representative species" to determine the greatest exposures (fish consumption per unit body weight) to bioaccumulative contaminants in the aquatic food web. The species U.S. EPA selected for the Great Lakes System were the bald eagle, herring gull, belted kingfisher, mink and river otter. The Department considered the appropriateness of these representative species for the derivation of statewide values and concluded that they are representative of species highly exposed to such substances and that the particular species actually are present throughout much of the State.

The Department considers U.S. EPA's procedures appropriate for deriving statewide values. Their procedures form the basis of the guidance in the remainder of this document. Terminology has been modified for conformance with the Department's existing language in regulation and for statewide applicability.

GUIDANCE

I. INTRODUCTION

A standard or guidance value to protect wildlife is the concentration of a substance, that if not exceeded, is likely to protect avian and mammalian wildlife populations inhabiting the State from adverse effects resulting from the ingestion of water and aquatic prey taken from surface waters. These values are based on existing toxicological studies of the substance of concern and quantitative information about the exposure of wildlife species to the substance (i.e., food and water consumption rates). Because toxicological and exposure data for individual wildlife species are limited, a wildlife value can be derived using interspecies conversion procedures. Separate avian and mammalian values are developed using taxonomic-class-specific toxicity data and exposure data for five representative wildlife species in a threshold model similar to that used to derive noncancer human health criteria.

II. CALCULATION OF WILDLIFE STANDARDS AND GUIDANCE VALUES

A. Equation for Avian and Mammalian Wildlife Values. Standards and guidance values to protect wildlife are calculated using the equation presented below.

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

Where:

WV = Wildlife Value in milligrams of substance per liter (mg/L).

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

TD = Test Dose in milligrams of substance per kilogram per day (mg/kg-d) for the test species. This should be either a NOAEL or a LOAEL. Although a TD directly derived from representative species is preferred, a TD derived from other species is acceptable. Such TD is extrapolated to the representative species using the factor UF_A as described below.

UF_A = Uncertainty Factor (UF) for extrapolating toxicity data across species (unitless). A species-specific UF should 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 (BAF) for wildlife food in trophic level I in liters per kilogram (L/kg), developed using Division of Water TOGS No.1.1.4, Procedures for Deriving Bioaccumulation Factors. For consumption of piscivorous birds by other birds (e.g., herring gull by eagles), the BAF is derived by multiplying the trophic level 3 BAF for fish by a biomagnification factor to account for the biomagnification from fish to the consumed birds.

B. Calculation of Wildlife Values for Representative Species. As discussed above, three avian species (eagle, kingfisher and herring gull) and two mammalian species (mink and otter) are

used as representative species for protection. The TD obtained from toxicity data for each taxonomic class is used to calculate WVs for each of the five representative species.

For most substances for which wildlife values are derived, use of the representative species described in this document is likely to result in a value that is protective for most species of wildlife. However, there may be situations in which substitution of one or more species for the representative species is appropriate to ensure protection. Such situations can include (1) where another species, which may have lower exposure, is shown to be inherently more susceptible to a substance than the representative species and (2) where another species' exposure to a substance is higher than the representative species. The second situation can occur for substances with low BAFs. For these substances, representative species may be selected with greater emphasis on drinking water and less on fish consumption rates.

C. Calculation of Avian and Mammalian Wildlife Values and Derivation of Wildlife Standard or Guidance Value. 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. Where both mammalian and avian values can be derived, the lower of the two is selected as the wildlife standard or guidance value.

III. PARAMETERS OF THE EFFECT COMPONENT OF THE PROCEDURES FOR DERIVING WILDLIFE STANDARDS AND GUIDANCE VALUES

A. Definitions. The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of these procedures.

Acceptable endpoints. For the purpose of wildlife standard and guidance value 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.

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.

Lowest-observed-adverse-effect-level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No-observed-adverse-effect-level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

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.

B. Toxicity Database. Representative species include both mammals and birds. To provide the greatest assurance of protection, a standard or guidance value should be based on data from both classes, and selected as the more stringent of the mammalian and avian values. Where data only provide for the derivation of a value for one class, a standard or guidance value may be derived, but may not be protective for wildlife of the other class.

Study duration is an important consideration in evaluating data. Longer studies are preferred over shorter studies, which involve greater uncertainty as they may not identify the full extent of adverse effects.

A TD value is needed for calculation of a standard or guidance value. In reviewing the toxicity data available, the following order of preference should be applied to select the appropriate TD to be used for calculation of individual WVs. Data from peer-reviewed field studies of wildlife species of adequate quality take precedence over other types of studies. An acceptable field study should 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 should 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 should be reviewed to corroborate the final wildlife standard or guidance value, to assess the reasonableness of the toxicity value used, and to assess the appropriateness of any uncertainty factors that are applied. When evaluating the studies from which a test dose is derived in general, the following guidelines should be met:

1. 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.

2. Preference should be given to studies that assess effects on developmental or reproductive endpoints because, in general, these are more important endpoints in ensuring that a population's productivity is maintained. The Wildlife TSD (U.S. EPA, 1995b) provides additional discussion on the selection of an appropriate toxicity study.

Note to Reader:

As indicated above, a standard or guidance value can be based on a determination for one taxonomic class and with studies of short duration. Federal regulations, however, require that New York State derive a standard or guidance value under certain circumstances. The federal requirement applies only within the Great Lakes System and is contingent upon the availability of an existing minimum toxicity database. This minimum database consists of:

1. enough information to generate a subchronic or chronic dose-response curve for any given substance for both mammalian and avian species;

2. data from at least one well-conducted mammalian study of 90 days or greater designed to observe subchronic or chronic effets as defined in this TOGS; and

3. data from at least one well-conducted avian study of 70 days or greater designed to observe subchronic or chronic effects as defined in this TOGS.

Where this database is available, the Department intends to derive a standard or guidance value. Where not available (for example, no avian study), the Department will exercise its judgement concerning the need for the value and the certainty of protection.

The above mentioned Federal regulations also contain a procedural requirement regarding interclass extrapolation:

The interspecies uncertainty factor, UF_A, shall only be used for extrapolating toxicity data across species within a taxonomic class except as provided below. 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.

C. Selection of TD Data.

In selecting data to be used in the derivation of WVs, the evaluation of acceptable endpoints, as defined in Section III.A of this TOGS, will 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.

1. 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, should be used for the calculation of WVs.

2. 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 should be used.

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

D. Exposure Assumptions in the Determination of the TD.

1. 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 should be used to convert the TD to the appropriate units prior to calculating a WV.

2. If the TD is given in milligrams of toxicant per liter of water consumed by the test animals (mg/L), the TD should 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).

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

E. Drinking and Feeding Rates.

1. 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 are obtained from the study from which the TD was derived. If not already determined, body weight, and drinking and feeding rates are to be converted to a wet weight basis.

2. If the study does not provide the needed values, the values should be determined from appropriate scientific literature. For studies done with domestic laboratory animals, either the Registry of Toxic Effects of Chemical Substances (National Institute for Occupational Safety and Health, the latest edition, Cincinnati, OH), or Recommendations for and Documentation of Biological Values for Use in Risk

Assessment (U.S. EPA, 1988) should be consulted. When these references do not contain exposure information for the species used in a given study, either the allometric equations from Calder and Braun (1983) and Nagy (1987), which are presented below, or the exposure estimation methods presented in Chapter 4 of the Wildlife Exposure Factors Handbook (U.S. EPA, 1993), should be applied to approximate the needed feeding or drinking rates. Additional discussion and recommendations are provided in the Wildlife TSD (U.S. EPA, 1995b). The choice of the methods described above is at the discretion of the Department.

3. For mammalian species, the general allometric equations are:

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

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.

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

Where:

W = Drinking rate of mammalian species in liters per day (L/d).
Wt = Average weight in kilograms (kg) of the test animals.

4. For avian species, the general allometric equations are:

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

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.

$$W = 0.059 \times (Wt)^{0.67}$$

Where:

W = Drinking rate of avian species in liters per day (L/d).
Wt = Average weight in kilograms (kg) of the test animals.

F. 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 should be divided by an UF to estimate a NOAEL for use in deriving WVs. The value of the UF should not be less than one and should not exceed 10, depending on the dose-response curve and any other available data, and is represented by UF_L in the equation expressed in Section II.A of this TOGS. Guidance for selecting an appropriate UF_L, based on a review of available wildlife toxicity data, is available in the Wildlife TSD (U.S. EPA, 1995b).

G. 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 should be divided by an UF to extrapolate from subchronic to chronic levels. The value of the UF should not be less than 1 and should not exceed 10, and is represented by UF_S in the equation expressed in Section II.A of this TOGS. This factor is to be used when assessing highly bioaccumulative substances where toxicokinetic considerations suggest that a bioassay of limited length underestimates chronic effects. Guidance for selecting an appropriate UF_S, based on a review of available wildlife toxicity data, is available in the Wildlife TSD (U.S. EPA, 1995b).

Where data are of less than subchronic duration, the value of UF_A may exceed 10, but should generally not exceed 100.

H. Interspecies Extrapolations (UF_A).

1. The selection of the UF_A should 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 an UF that is intended to account for differences in toxicological sensitivity among species. Guidance for selecting an appropriate UF_A, based on a review of available wildlife toxicity data, is available in the Wildlife TSD (U.S. EPA, 1995b). Additional discussion of an interspecies UF located in appendix A to the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria (U.S. EPA, 1995c) may be useful in determining the appropriate value for UF_A.

2. The value of a UF_A should not be less than 1 and should not exceed 100, and should be applied to each of the five representative species, based on existing data and best professional judgement. The value of UF_A may differ for each of the representative species.

IV. PARAMETERS OF THE EXPOSURE COMPONENT OF THE WILDLIFE CRITERIA METHODOLOGY

A. Drinking and Feeding Rates of Representative Species.

The body weights (Wt), feeding rates (F_{Ti}), drinking rates (W), and trophic level dietary composition (as food ingestion rate and percent in diet) for each of the five representative species are presented in Table 1 of this TOGS. Guidance on incorporating the non-aquatic portion of the bald eagle and mink diets in the criteria calculations is available in the Wildlife TSD (U.S. EPA, 1995b).

B. BAFs.

Procedures for deriving bioaccumulation factors are presented in Division of Water TOGS Number 1.1.4. Trophic level 3 and 4 BAFs are used to derive WVs because these are the trophic levels at which the representative species feed.

V. SITE-SPECIFIC MODIFICATIONS

The guidance above will generally be used to derive statewide standards and guidance values to protect wildlife. Site-specific modifications to such values are allowed or may be needed as described below.

A. Any site-specific modifications that result in less stringent values should not jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of such species' critical habitat.

B. More stringent modifications should be developed to protect endangered or threatened species where such modifications are necessary to ensure that water quality is not likely to jeopardize the continued existence of such species or result in the destruction or adverse modification of such species' critical habitat.

C. Less stringent site specific modifications may be developed when a site-specific BAF is derived that is lower than the statewide BAF derived according to the procedures in TOGS Number 1.1.4. The modification should consider both the mobility of prey organisms and wildlife in defining the site for which values are developed. In addition, there should be a showing that:

1. Any increased uptake of the toxicant by prey species utilizing the site will not cause adverse effects in wildlife populations; and

2. Wildlife populations utilizing the site or downstream waters will continue to be fully protected.

D. Any modification to protect endangered or threatened wildlife species should consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed, and may be accomplished by using the following recommended method.

1. The procedures above are used, substituting appropriate species-specific toxicological, epidemiological, or exposure information, including changes to the BAF;

2. An interspecies uncertainty factor of 1 should be used where epidemiological data are available for the species in question. If necessary, species-specific exposure parameters can be derived as presented above;

3. An intraspecies uncertainty factor (to account for protection of individuals within a wildlife population) should be applied in the denominator of the effect part of the wildlife equation above in a manner consistent with the other uncertainty factors described above; and

4. The resulting wildlife value for the species in question should be compared to the two class-specific wildlife values which were previously calculated, and the lowest of the three selected as the site-specific modification.

Note: Further discussion of the use of this methodology may be found in the Wildlife TSD (U.S. EPA, 1995b).

VI. REFERENCES

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TABLE 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	Percent 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 three fish
TL4 = trophic level four fish
PB = piscivorous birds
Other = non-aquatic birds and mammals