RSC=Relative source contribution factor of
0.8. An RSC derived from actual exposure
data may be developed using the method-
ology outlined by the 1980 National Guide-
lines (see 45 FR 79354).

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both
drinking and incidental exposure) for sur-
face waters classified as public water
supplies=two liters/day.

  or

WC_r=per capita incidental daily water inges-
tion for surface waters not used as human
drinking water sources=0.01 liters/day.

FC_{TL3}=mean consumption of trophic level 3
fish by regional sport fishers of regionally
caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4
fish by regional sport fishers of regionally
caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=human health bioaccumulation
factor for edible portion of trophic level 3
fish, as derived using the BAF method-
ology in appendix B to part 132.

BAF^{HH}_{TL4}=human health bioaccumulation
factor for edible portion of trophic level 4
fish, as derived using the BAF method-
ology in appendix B to part 132.

IV. REFERENCES

A. Howe, R.B., K.S. Crump and C. Van
Landingham. 1986. Computer Program to Ex-
trapolate Quantitative Animal Toxicity
Data to Low Doses. Prepared for EPA under
subcontract #2–251U–2745 to Research Tri-
angle Institute.

B. U.S. Environmental Protection Agency.
1980. Water Quality Criteria Availability, Ap-
pendix C Guidelines and Methodology Used
in the Preparation of Health Effects Assess-
ment Chapters of the Consent Decree Water
Quality Criteria Documents. Available from
U.S. Environmental Protection Agency, Of-
fice of Water Resource Center (WH–550A),
1200 Pennsylvania Ave., NW., Washington,
DC 20460.

C. U.S. Environmental Protection Agency.
1986. Guidelines for Carcinogen Risk Assess-
ment. Available from U.S. Environmental
Protection Agency, Office of Water Resource
Center (WH–550A), 1200 Pennsylvania Ave.,
NW., Washington, DC 20460.

APPENDIX D TO PART 132—GREAT LAKES
WATER QUALITY INITIATIVE METHOD-
OLOGY FOR THE DEVELOPMENT OF
WILDLIFE CRITERIA

Great Lakes States and Tribes shall adopt
provisions consistent with (as protective as)
this appendix.

I. INTRODUCTION

A. A Great Lakes Water Quality Wildlife
Criterion (GLWC) is the concentration of a
substance which is likely to, if not exceeded,
protect avian and mammalian wildlife popu-
lations inhabiting the Great Lakes basin
from adverse effects resulting from the in-
gestion of water and aquatic prey taken from
surface waters of the Great Lakes System.
These criteria are based on existing toxi-
cological studies of the substance of concern
and quantitative information about the ex-
posure of wildlife species to the substance
(i.e., food and water consumption rates).
Since toxicological and exposure data for in-
dividual wildlife species are limited, a GLWC
is derived using a methodology similar to
that used to derive noncancer human health
criteria (Barnes and Dourson, 1988; NAS,
1977; NAS, 1980; U.S. EPA, 1980). Separate
avian and mammalian values are developed
using taxonomic class-specific toxicity data
and exposure data for five representative
Great Lakes basin wildlife species. The wild-
life species selected are representative of
avian and mammalian species resident in the
Great Lakes basin which are likely to experi-
ence the highest exposures to bioaccumula-
tive contaminants through the aquatic food
web; they are the bald eagle, herring gull,
belted kingfisher, mink, and river otter.

B. This appendix establishes a method-
ology which is required when developing Tier
I wildlife criteria for bioaccumulative
chemicals of concern (BCCs). The use of the
equation provided in the methodology is en-
couraged, but not required, for the develop-
ment of Tier I criteria or Tier II values for
pollutants other than those identified in
Table 6–A for which Tier I criteria or Tier II
values are determined to be necessary for the
protection of wildlife in the Great Lakes
basin. A discussion of the methodology for
deriving Tier II values can be found in the
Great Lakes Water Quality Initiative Tech-
nical Support Document for Wildlife Criteria
(Wildlife TSD).

C. In the event that this methodology is
used to develop criteria for pollutants other
than BCCs, or in the event that the Tier II
methodology described in the Wildlife TSD is
used to derive Tier II values, the method-
ology for deriving bioaccumulation factors
under appendix B to part 132 must be used in
either derivation. For chemicals which do
not biomagnify to the extent of BCCs, it may
be appropriate to select different representa-
tive species which are better examples of
species with the highest exposures for the
given chemical. The equation presented in
this methodology, however, is still encour-
aged. In addition, procedure 1 of appendix F
of this part describes the procedures for cal-
culating site-specific wildlife criteria.

D. The term ''wildlife value'' (WV) is used
to denote the value for each representative
species which results from using the equa-
tion presented below, the value obtained
from averaging species values within a class,
or any value derived from application of the
site-specific procedure provided in procedure

1 of appendix F of this part. 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.

E. "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. It is synonymous with the term "GLWC," and the two are used interchangeably.

II. CALCULATION OF WILDLIFE VALUES FOR TIER I CRITERIA

Table 4 of Part 132 and Table D–1 of this appendix contain criteria calculated by EPA using the methodology provided below.

A. *Equation for Avian and Mammalian Wildlife Values.* Tier I wildlife values for the pollutants designated BCCs pursuant to part 132 are to be calculated using the equation presented below.

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

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 shall be either a NOAEL or a LOAEL.

UF_A=Uncertainty Factor (UF) 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_{TLi}^{WL}=Bioaccumulation factor (BAF) for wildlife food in trophic level i in liters per kilogram (L/kg), developed using the BAF methodology in appendix B to part 132, Methodology for Development of 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 ac-

count for the biomagnification from fish to the consumed birds.

B. *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. An analysis of known or estimated exposure components for avian and mammalian wildlife species is presented in the Wildlife TSD. This analysis identifies three avian species (eagle, kingfisher and herring gull) and two mammalian species (mink and otter) 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.

C. *Calculation of Avian and Mammalian Wildlife Values and GLWC 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 must be selected as the GLWC.

III. PARAMETERS OF THE EFFECT COMPONENT OF THE WILDLIFE CRITERIA METHODOLOGY

A. *Definitions.* The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of this methodology.

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.

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. *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 must 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 GLWC, 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 must be met:

1. The mammalian data must come from at least one well-conducted study of 90 days or greater designed to observe subchronic or chronic effects as defined in this document.

2. The avian data must come from at least one well-conducted study of 70 days or greater designed to observe subchronic or chronic effects as defined in this document.

3. 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 daily dose can be estimated and technically justified because the criteria calculations are based on an oral route of exposure.

4. In assessing the studies which meet the minimum data requirements, preference should be given to studies which 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 provides additional discussion on the selection of an appropriate toxicity study.

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 appendix, 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, shall 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 shall 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 shall 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 shall 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 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).

3. 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).

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 shall 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. The choice of the methods described above is at the discretion of the State or Tribe.

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

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

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.

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

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:

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

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.

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

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 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 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 appendix. Guidance for selecting an appropriate UF$_L$, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

G. *Subchronic to Chronic Extrapolations (US$_S$)*. 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 should not exceed 10, and is represented by UF$_S$ in the equation expressed in Section II.A of this appendix. 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.

H. *Interspecies Extrapolations (UF$_A$)*. 1. 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 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. Additional discussion of an interspecies UF located in appendix A to the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria may be useful in determining the appropriate value for UF$_A$.

2. For the derivation of Tier I criteria, a UF$_A$ shall not be less than one and should not exceed 100, and shall be applied to each of the five representative species, based on existing data and best professional judgment. The value of UF$_A$ may differ for each of the representative species.

3. 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 below. 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.

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$_{Tli}$), 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 D–2 of this appendix. Guidance on incorporating the non-aquatic portion of the bald eagle and mink diets in the criteria calculations is available in the Wildlife TSD.

B. *BAFs*. The Methodology for Development of Bioaccumulation Factors is presented in appendix B to part 132. Trophic level 3 and 4 BAFs are used to derive Wvs because these are the trophic levels at which the representative species feed.

V. REFERENCES

A. Barnes, D.G. and M. Dourson. 1988. Reference Dose (RfD): Description and Use in Health Risk Assessments. Regul. Toxicol. Pharmacol. 8:471–486.

B. Calder III, W.A. and E.J. Braun. 1983. Scaling of Osmotic Regulation in Mammals and Birds. American Journal of Physiology. 244:601–606.

C. Nagy, K.A. 1987. Field Metabolic Rate and Food Requirement Scaling in Mammals and Birds. Ecological Monographs. 57(2):111–128.

D. National Academy of Sciences. 1977. Chemical Contaminants: Safety and Risk Assessment, *in* Drinking Water and Health, Volume 1. National Academy Press.

E. National Academy of Sciences. 1980. Problems of Risk Estimation, *in* Drinking Water and Health, Volume 3. National Academy Press.

F. National Institute for Occupational Safety and Health. Latest edition. Registry of Toxic Effects of Chemical Substances. Division of Standards Development and Technology Transfer. (Available only on microfiche or as an electronic database.)

G. U.S. EPA. 1980. Appendix C. Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents, pp. 79347–79357 *in* Water Quality Criteria Documents; Availability. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH–550A), 1200 Pennsylvania Ave., NW, Washington, DC 20460.

H. U.S. EPA. 1988. Recommendations for, and documentation of, biological values for use in risk assessment. NTIS–PB88–179874.

I. U.S. EPA. 1993. Wildlife Exposure Factors Handbook, Volumes I and II. EPA/600/R–93/187a and b.

Tables to Appendix D to Part 132

TABLE D–1—TIER I GREAT LAKES WILDLIFE CRITERIA

Substance	Criterion (μg/L)
DDT & Metabolites	1.1E–5
Mercury	1.3E–3
PCBs (total)	7.4E–5
2,3,7,8-TCDD	3.1E–9

TABLE D–2—EXPOSURE PARAMETERS FOR THE FIVE REPRESENTATIVE SPECIES IDENTIFIED FOR PROTECTION

Species (units)	Adult body weight (kg)	Water ingestion rate (L/day)	Food ingestion rate of prey in each trophic level (kg/day)	Trophic level of prey (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	Fish: 90—TL3: 80; TL4: 20.
			Other: 0.0267	Other: 10.
Bald eagle	4.6	0.160	TL3: 0.371; TL4: 0.0929	Fish: 92—TL3: 80; TL4: 20.
			PB: 00283; Other: 0.0121	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.

APPENDIX E TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE ANTIDEGRADATION POLICY

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) appendix E to part 132.

The State or Tribe shall adopt an antidegradation standard applicable to all waters of the Great Lakes System and identify the methods for implementing such a standard. Consistent with 40 CFR 131.12, an acceptable antidegradation standard and implementation procedure are required elements of a State's or Tribe's water quality standards program. Consistent with 40 CFR 131.6, a complete water quality standards submission needs to include both an antidegradation standard and antidegradation implementation procedures.

At a minimum, States and Tribes shall adopt provisions in their antidegradation standard and implementation methods consistent with sections I, II, III and IV of this appendix, applicable to pollutants identified as bioaccumulative chemicals of concern (BCCs).

I. ANTIDEGRADATION STANDARD

This antidegradation standard shall be applicable to any action or activity by any source, point or nonpoint, of pollutants that is anticipated to result in an increased loading of BCCs to surface waters of the Great Lakes System and for which independent regulatory authority exists requiring compliance with water quality standards. Pursuant to this standard:

A. Existing instream water uses, as defined pursuant to 40 CFR 131, and the level of