(c) *Definitions.* Terms used in paragraphs (a) and (b) of this section, shall be defined as follows:

(1) *Water year.* A water year is the twelve calendar months beginning October 1.

(2) *8-River Index.* The flow determinations are made and are published by the California Department of Water Resources in Bulletin 120. The 8-River Index shall be computed as the sum of flows at the following stations:

(i) Sacramento River at Band Bridge, near Red Bluff;

(ii) Feather River, total inflow to Oroville Reservoir;

(iii) Yuba River at Smartville;

(iv) American River, total inflow to Folsom Reservoir;

(v) Stanislaus River, total inflow to New Melones Reservoir;

(vi) Tuolumne River, total inflow to Don Pedro Reservoir;

(vii) Merced River, total inflow to Exchequer Reservoir; and

(viii) San Joaquin River, total inflow to Millerton Lake.

(3) *San Joaquin Valley Index.* (i) The San Joaquin Valley Index is computed according to the following formula:

I_{SJ}=0.6X+0.2Y and 0.2Z

where I_{SJ}=San Joaquin Valley Index

X=Current year's April–July San Joaquin Valley unimpaired runoff

Y=Current year's October–March San Joaquin Valley unimpaired runoff

Z=Previous year's index in MAF, not to exceed 0.9 MAF

(ii) *Measuring San Joaquin Valley unimpaired runoff.* San Joaquin Valley unimpaired runoff for the current water year is a forecast of the sum of the following locations: Stanislaus River, total flow to New Melones Reservoir; Tuolumne River, total inflow to Don Pedro Reservoir; Merced River, total flow to Exchequer Reservoir; San Joaquin River, total inflow to Millerton Lake.

(4) *Salinity.* Salinity is the total concentration of dissolved ions in water. It shall be measured by specific conductance in accordance with the procedures set forth in 40 CFR 136.3, Table 1B, Parameter 64.

[60 FR 4707, Jan. 24, 1995]

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

Sec.

132.1 Scope, purpose, and availability of documents.
132.2 Definitions.
132.3 Adoption of criteria.
132.4 State adoption and application of methodologies, policies and procedures.
132.5 Procedures for adoption and EPA review.
132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

TABLES TO PART 132

APPENDIX A TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE METHODOLOGIES FOR DEVELOPMENT OF AQUATIC LIFE CRITERIA AND VALUES
APPENDIX B TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE
APPENDIX C TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE METHODOLOGY FOR DEVELOPMENT OF HUMAN HEALTH CRITERIA AND VALUES
APPENDIX D TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE METHODOLOGY FOR THE DEVELOPMENT OF WILDLIFE CRITERIA
APPENDIX E TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE ANTIDEGRADATION POLICY
APPENDIX F TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE IMPLEMENTATION PROCEDURES

AUTHORITY: 33 U.S.C. 1251 *et seq.*

SOURCE: 60 FR 15387, Mar. 23, 1995, unless otherwise noted.

§ 132.1 Scope, purpose, and availability of documents.

(a) This part constitutes the Water Quality Guidance for the Great Lakes System (Guidance) required by section 118(c)(2) of the Clean Water Act (33 U.S.C. 1251 *et seq.*) as amended by the Great Lakes Critical Programs Act of 1990 (Pub. L. 101–596, 104 Stat. 3000 *et seq.*). The Guidance in this part identifies minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System to protect human health, aquatic life, and wildlife.

(b) The U.S. Environmental Protection Agency, Great Lakes States, and

Great Lakes Tribes will use the Guidance in this part to evaluate the water quality programs of the States and Tribes to assure that they are protective of water quality. State and Tribal programs do not need to be identical to the Guidance in this part, but must contain provisions that are consistent with (as protective as) the Guidance in this part. The scientific, policy and legal basis for EPA's development of each section of the final Guidance in this part is set forth in the preamble, Supplementary Information Document, Technical Support Documents, and other supporting documents in the public docket. EPA will follow the guidance set out in these documents in reviewing the State and Tribal water quality programs in the Great Lakes for consistency with this part.

(c) The Great Lakes States and Tribes must adopt provisions consistent with the Guidance in this part applicable to waters in the Great Lakes System or be subject to EPA promulgation of its terms pursuant to this part.

(d) EPA understands that the science of risk assessment is rapidly improving. Therefore, to ensure that the scientific basis for the methodologies in appendices A through D are always current and peer reviewed, EPA will review the methodologies and revise them, as appropriate, every 3 years.

(e) Certain documents referenced in the appendixes to this part with a designation of NTIS and/or ERIC are available for a fee upon request to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Alternatively, copies may be obtained for a fee upon request to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, Ohio 43212. When ordering, please include the NTIS or ERIC/CSMEE accession number.

§ 132.2 Definitions.

The following definitions apply in this part. Terms not defined in this section have the meaning given by the Clean Water Act and EPA implementing regulations.

Acute-chronic ratio (ACR) is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

Acute toxicity is concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism.

Adverse effect is any deleterious effect to organisms due to exposure to a substance. This includes effects which 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.

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

Bioaccumulation factor (BAF) is the ratio (in L/kg) of a substance's concentration in 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.

Bioaccumulative chemical of concern (BCC) is any chemical that has the potential to cause adverse effects which, upon entering the surface waters, by itself or as its toxic transformation product, accumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or inhibit bioaccumulation, in accordance with the methodology in appendix B of this part. Chemicals with half-lives of less than eight weeks in the water column, sediment, and biota are not BCCs. The minimum BAF information needed to define an organic chemical as a BCC is either a field-measured BAF or a BAF derived using the BSAF methodology. The minimum BAF information needed to define an inorganic chemical, including an

organometal, as a BCC is either a field-measured BAF or a laboratory-measured BCF. BCCs include, but are not limited to, the pollutants identified as BCCs in section A of Table 6 of this part.

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

Bioconcentration factor (BCF) is the ratio (in L/kg) of a substance's concentration in 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 (BSAF) is the ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in 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 is a substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Chronic toxicity is concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure.

Connecting channels of the Great Lakes are the Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border.

Criterion continuous concentration (CCC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect.

Criterion maximum concentration (CMC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50 percent of a group of organisms under specified conditions.

Endangered or threatened species are those species that are listed as endangered or threatened under section 4 of the Endangered Species Act.

Existing Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a ''discharge of pollutants'' (as defined in 40 CFR 122.2) to the Great Lakes System, that is not a new Great Lakes discharger.

Federal Indian reservation, Indian reservation, or *reservation* means all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.

Final acute value (FAV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher GMAVs, or (b) the SMAV of an important and/or critical species, if the SMAV is lower than the calculated estimate.

Final chronic value (FCV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, (b) the quotient of an FAV divided by an appropriate acute-chronic ratio, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Final plant value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important.

Genus mean acute value (GMAV) is the geometric mean of the SMAVs for the genus.

Genus mean chronic value (GMCV) is the geometric mean of the SMCVs for the genus.

Great Lakes means Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior; and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border).

Great Lakes States and Great Lakes Tribes, or Great Lakes States and Tribes means the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin, and any Indian Tribe as defined in this part which is located in whole or in part within the drainage basin of the Great Lakes, and for which EPA has approved water quality standards under section 303 of the Clean Water Act or which EPA has authorized to administer an NPDES program under section 402 of the Clean Water Act.

Great Lakes System means all the streams, rivers, lakes and other bodies of water within the drainage basin of the Great Lakes within the United States.

Human cancer criterion (HCC) is a Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human cancer value (HCV) is the maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC) is a Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV) is the maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Indian Tribe or *Tribe* means any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal Indian reservation.

LC50 is a statistically or graphically estimated concentration that is expected to be lethal to 50 percent of a group of organisms under specified conditions.

Load allocation (LA) is the portion of a receiving water's loading capacity that is attributed either to one of its existing or future nonpoint sources or to natural background sources, as more fully defined at 40 CFR 130.2(g). Nonpoint sources include: in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff.

Loading capacity is the greatest amount of loading that a water can receive without violating water quality standards.

Lowest observed adverse effect level (LOAEL) is 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.

Method detection level is the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure set forth in appendix B of 40 CFR part 136.

Minimum Level (ML) is the concentration at which the entire analytical system must give a recognizable signal and acceptable calibration point. The ML is the concentration in a sample that is equivalent to the concentration of the lowest calibration standard analyzed by a specific analytical procedure, assuming that all the method-specified sample weights, volumes and processing steps have been followed.

New Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a ''discharge of pollutants'' (as defined in 40 CFR 122.2) to the Great Lakes System, the construction of which commenced after March 23, 1997.

No observed adverse effect level (NOAEL) is 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.

No observed effect concentration (NOEC) is the highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

Open waters of the Great Lakes (OWGLs) means all of the waters within Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, Lake Ontario, and Lake Superior lakeward from a line drawn across the mouth of tributaries to the Lakes, including all waters enclosed by constructed breakwaters, but not including the connecting channels.

Quantification level is a measurement of the concentration of a contaminant obtained by using a specified laboratory procedure calibrated at a specified concentration above the method detection level. It is considered the lowest concentration at which a particular contaminant can be quantitatively measured using a specified laboratory procedure for monitoring of the contaminant.

Quantitative structure activity relationship (QSAR) or structure activity relationship (SAR) is a mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Risk associated dose (RAD) is a dose of a known or presumed carcinogenic substance in (mg/kg)/day which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Species mean acute value (SMAV) is the geometric mean of the results of all acceptable flow-through acute toxicity tests (for which the concentrations of the test material were measured) with the most sensitive tested life stage of the species. For a species for which no such result is available for the most sensitive tested life stage, the SMAV is the geometric mean of the results of all acceptable acute toxicity tests with the most sensitive tested life stage.

Species mean chronic value (SMCV) is the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests.

Stream design flow is the stream flow that represents critical conditions, upstream from the source, for protection of aquatic life, human health, or wildlife.

Threshold effect is an effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Tier I criteria are numeric values derived by use of the Tier I methodologies in appendixes A, C and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, 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 in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that are used to implement narrative water quality criteria.

Total maximum daily load (TMDL) is the sum of the individual wasteload allocations for point sources and load allocations for nonpoint sources and natural background, as more fully defined at 40 CFR 130.2(i). A TMDL sets and allocates the maximum amount of a pollutant that may be introduced into a water body and still assure attainment

and maintenance of water quality standards.

Tributaries of the Great Lakes System means all waters of the Great Lakes System that are not open waters of the Great Lakes, or connecting channels.

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

Uptake is acquisition of a substance from the environment by an organism as a result of any active or passive process.

Wasteload allocation (WLA) is the portion of a receiving water's loading capacity that is allocated to one of its existing or future point sources of pollution, as more fully defined at 40 CFR 130.2(h). In the absence of a TMDL approved by EPA pursuant to 40 CFR 130.7 or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F of this part, a WLA is the allocation for an individual point source, that ensures that the level of water quality to be achieved by the point source is derived from and complies with all applicable water quality standards.

Wet weather point source means any discernible, confined and discrete conveyance from which pollutants are, or may be, discharged as the result of a wet weather event. Discharges from wet weather point sources shall include only: discharges of storm water from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8); storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14); discharges of storm water and sanitary wastewaters (domestic, commercial, and industrial) from a combined sewer overflow; or any other stormwater discharge for which a permit is required under section 402(p) of the Clean Water Act. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet weather point source.

§ 132.3 Adoption of criteria.

The Great Lakes States and Tribes shall adopt numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act applicable to waters of the Great Lakes System in accordance with § 132.4(d) that are consistent with:

(a) The acute water quality criteria for protection of aquatic life in Table 1 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(b) The chronic water quality criteria for protection of aquatic life in Table 2 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(c) The water quality criteria for protection of human health in Table 3 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part; and

(d) The water quality criteria for protection of wildlife in Table 4 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part.

§ 132.4 State adoption and application of methodologies, policies and procedures.

(a) The Great Lakes States and Tribes shall adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 301, 303, and 402 of the Clean Water Act that are consistent with:

(1) The definitions in § 132.2;

(2) The Methodologies for Development of Aquatic Life Criteria and Values in appendix A of this part;

(3) The Methodology for Development of Bioaccumulation Factors in appendix B of this part;

(4) The Methodologies for Development of Human Health Criteria and Values in appendix C of this part;

(5) The Methodology for Development of Wildlife Criteria in appendix D of this part;

(6) The Antidegradation Policy in appendix E of this part; and

(7) The Implementation Procedures in appendix F of this part.

(b) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part when

adopting or revising numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act for the Great Lakes System.

(c) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies and procedures consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part to develop numeric criteria and values when implementing narrative water quality criteria adopted for purposes of section 303(c) of the Clean Water Act.

(d) The water quality criteria and values adopted or developed pursuant to paragraphs (a) through (c) of this section shall apply as follows:

(1) The acute water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(2) The chronic water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(3) The water quality criteria and values for protection of human health, or site-specific modifications thereof, shall apply as follows:

(i) Criteria and values derived as HCV-Drinking and HNV-Drinking shall apply to the Open Waters of the Great Lakes, all connecting channels of the Great Lakes, and all other waters of the Great Lakes System that have been designated as public water supplies by any State or Tribe in accordance with 40 CFR 131.10.

(ii) Criteria and values derived as HCV-Nondrinking and HNV-Nondrinking shall apply to all waters of the Great Lakes System other than those in paragraph (d)(3)(i) of this section.

(4) Criteria for protection of wildlife, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(e) The Great Lakes States and Tribes shall apply implementation procedures consistent with the procedures in appendix F of this part for all applicable purposes under the Clean Water Act, including developing total maximum daily loads for the purposes of section 303(d) and water quality-based effluent limits for the purposes of section 402, in establishing controls on the discharge of any pollutant to the Great Lakes System by any point source with the following exceptions:

(1) The Great Lakes States and Tribes are not required to apply these implementation procedures in establishing controls on the discharge of any pollutant by a wet weather point source. Any adopted implementation procedures shall conform with all applicable Federal, State and Tribal requirements.

(2) The Great Lakes States and Tribes may, but are not required to, apply procedures consistent with procedures 1, 2, 3, 4, 5, 7, 8, and 9 of appendix F of this part in establishing controls on the discharge of any pollutant set forth in Table 5 of this part. Any procedures applied in lieu of these implementation procedures shall conform with all applicable Federal, State, and Tribal requirements.

(f) The Great Lakes States and Tribes shall apply an antidegradation policy consistent with the policy in appendix E for all applicable purposes under the Clean Water Act, including 40 CFR 131.12.

(g) For pollutants listed in Table 5 of this part, the Great Lakes States and Tribes shall:

(1) Apply any methodologies and procedures acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria; and

(2) Apply the implementation procedures in appendix F of this part or alternative procedures consistent with all applicable Federal, State, and Tribal laws.

(h) For any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:

(1) Apply an alternative methodology or procedure acceptable under 40 CFR part 131 when developing water quality criteria; or

(2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

(i) Nothing in this part shall prohibit the Great Lakes States and Tribes from adopting numeric water quality criteria, narrative criteria, or water quality values that are more stringent than criteria or values specified in § 132.3 or that would be derived from application of the methodologies set forth in appendixes A, B, C, and D of this part, or to adopt antidegradation standards and implementation procedures more stringent than those set forth in appendixes E and F of this part.

§ 132.5 Procedures for adoption and EPA review.

(a) Except as provided in paragraph (c) of this section, the Great Lakes States and Tribes shall adopt and submit for EPA review and approval the criteria, methodologies, policies, and procedures developed pursuant to this part no later than September 23, 1996.

(b) The following elements must be included in each submission to EPA for review:

(1) The criteria, methodologies, policies, and procedures developed pursuant to this part;

(2) Certification by the Attorney General or other appropriate legal authority pursuant to 40 CFR 123.62 and 40 CFR 131.6(e) as appropriate;

(3) All other information required for submission of National Pollutant Discharge Elimination System (NPDES) program modifications under 40 CFR 123.62; and

(4) General information which will aid EPA in determining whether the criteria, methodologies, policies and procedures are consistent with the requirements of the Clean Water Act and this part, as well as information on general policies which may affect their application and implementation.

(c) The Regional Administrator may extend the deadline for the submission required in paragraph (a) of this section if the Regional Administrator believes that the submission will be consistent with the requirements of this part and can be reviewed and approved pursuant to this section no later than March 23, 1997.

(d) If a Great Lakes State or Tribe makes no submission pursuant to this part to EPA for review, the requirements of this part shall apply to discharges to waters of the Great Lakes System located within the State or Federal Indian reservation upon EPA's publication of a final rule indicating the effective date of the part 132 requirements in the identified jurisdictions.

(e) If a Great Lakes State or Tribe submits criteria, methodologies, policies, and procedures pursuant to this part to EPA for review that contain substantial modifications of the State or Tribal NPDES program, EPA shall issue public notice and provide a minimum of 30 days for public comment on such modifications. The public notice shall conform with the requirements of 40 CFR 123.62.

(f) After review of State or Tribal submissions under this section, and following the public comment period in subparagraph (e) of this section, if any, EPA shall either:

(1) Publish notice of approval of the submission in the FEDERAL REGISTER within 90 days of such submission; or

(2) Notify the State or Tribe within 90 days of such submission that EPA has determined that all or part of the submission is inconsistent with the requirements of the Clean Water Act or this part and identify any necessary changes to obtain EPA approval. If the State or Tribe fails to adopt such changes within 90 days after the notification, EPA shall publish a notice in the FEDERAL REGISTER identifying the approved and disapproved elements of the submission and a final rule in the FEDERAL REGISTER identifying the provisions of part 132 that shall apply to discharges within the State or Federal Indian reservation.

(g) EPA's approval or disapproval of a State or Tribal submission shall be based on the requirements of this part and of the Clean Water Act. EPA's determination whether the criteria, methodologies, policies, and procedures in a State or Tribal submission are consistent with the requirements of this part will be based on whether:

(1) *For pollutants listed in Tables 1, 2, 3, and 4 of this part.* The Great Lakes State or Tribe has adopted numeric water quality criteria as protective as each of the numeric criteria in Tables 1, 2, 3, and 4 of this part, taking into account any site-specific criteria modifications in accordance with procedure 1 of appendix F of this part;

(2) *For pollutants other than those listed in Tables 1, 2, 3, 4, and 5 of this part.* The Great Lakes State or Tribe demonstrates that either:

(i) It has adopted numeric criteria in its water quality standards that were derived, or are as protective as or more protective than could be derived, using the methodologies in appendixes A, B, C, and D of this part, and the site-specific criteria modification procedures in accordance with procedure 1 of appendix F of this part; or

(ii) It has adopted a procedure by which water quality-based effluent limits and total maximum daily loads are developed using the more protective of:

(A) Numeric criteria adopted by the State into State water quality standards and approved by EPA prior to March 23, 1997; or

(B) Water quality criteria and values derived pursuant to §132.4(c); and

(3) *For methodologies, policies, and procedures.* The Great Lakes State or Tribe has adopted methodologies, policies, and procedures as protective as the corresponding methodology, policy, or procedure in §132.4. The Great Lakes State or Tribe may adopt provisions that are more protective than those contained in this part. Adoption of a more protective element in one provision may be used to offset a less protective element in the same provision as long as the adopted provision is as protective as the corresponding provision in this part; adoption of a more protective element in one provision, however, is not justification for adoption of a less protective element in another provision of this part.

(h) A submission by a Great Lakes State or Tribe will need to include any provisions that EPA determines, based on EPA's authorities under the Clean Water Act and the results of consultation under section 7 of the Endangered Species Act, are necessary to ensure that water quality is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat.

(i) EPA's approval of the elements of a State's or Tribe's submission will constitute approval under section 118 of the Clean Water Act, approval of the submitted water quality standards pursuant to section 303 of the Clean Water Act, and approval of the submitted modifications to the State's or Tribe's NPDES program pursuant to section 402 of the Clean Water Act.

§132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

TABLES TO PART 132

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water

EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Chemical	CMC (µg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 339.8	1.000
Chromium (VI)	[a,b] 16.02	0.982
Cyanide	[c] 22	n/a
Dieldrin	[d] 0.24	n/a
Endrin	[d] 0.086	n/a
Lindane	[d] 0.95	n/a
Mercury (II)	[a,b] 1.694	0.85
Parathion	[d] 0.065	n/a
Selenium	[a,b] 19.34	0.922

[a] $CMC = CMC^{tr}$.
[b] $CMC^{d} = (CMC^{tr})$ CF. The CMC^{d} shall be rounded to two significant digits.
[c] CMC should be considered free cyanide as CN.
[d] $CMC = CMC^{t}$.

Notes:
The term "n/a" means not applicable.
CMC is Criterion Maximum Concentration.
CMC^{tr} is the CMC expressed as total recoverable.
CMC^{d} is the CMC expressed as a dissolved concentration.
CMC^{t} is the CMC expressed as a total concentration.

(b)

Chemical	m_A	b_A	Conversion factor (CF)
Cadmium [a,b]	1.128	−3.6867	0.85
Chromium (III) [a,b]	0.819	+3.7256	0.316
Copper [a,b]	0.9422	−1.700	0.960
Nickel [a,b]	0.846	+2.255	0.998
Pentachlorophenol [c]	1.005	−4.869	n/a
Zinc [a,b]	0.8473	+0.884	0.978

[a] $CMC^{tr} = \exp\{ m_A [\ln(\text{hardness})] + b_A \}$.

[b] $CMC_d=(CMC_{tr})$ CF. The CMC_d shall be rounded to two significant digits.
[c] $CMC_t=\exp\ m_A\ \{\ [pH]+b_A\}$. The CMC_t shall be rounded to two significant digits.

Notes:
The term ''exp'' represents the base e exponential function.
The term ''n/a'' means not applicable.
CMC is Criterion Maximum Concentration.
CMC_{tr} is the CMC expressed as total recoverable.
CMC_d is the CMC expressed as a dissolved concentration.
CMC_t is the CMC expressed as a total concentration.

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water

EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Chemical	CCC (µg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 147.9	1.000
Chromium (VI)	[a,b] 10.98	0.962
Cyanide	[c] 5.2	n/a
Dieldrin	[d] 0.056	n/a
Endrin	[d] 0.036	n/a
Mercury (II)	[a,b] 0.9081	0.85
Parathion	[d] 0.013	n/a
Selenium	[a,b] 5	0.922

[a] $CCC=CCC_{tr}$.
[b] $CCC_d=(CCC_{tr})$ CF. The CCC_d shall be rounded to two significant digits.
[c] CCC should be considered free cyanide as CN.
[d] $CCC=CCC_t$.

Notes:
The term ''n/a'' means not applicable.
CCC is Criterion Continuous Concentration.
CCC_{tr} is the CCC expressed as total recoverable.
CCC_d is the CCC expressed as a dissolved concentration.
CCC_t is the CCC expressed as a total concentration.

(b)

Chemical	m_c	b_c	Conversion factor (CF)
Cadmium[a,b]	0.7852	−2.715	0.850
Chromium (III)[a,b]	0.819	+0.6848	0.860
Copper[a,b]	0.8545	−1.702	0.960
Nickel[a,b]	0.846	+0.0584	0.997
Pentachlorophenol[c]	1.005	−5.134	n/a
Zinc[a,b]	0.8473	+0.884	0.986

[a] $CCC_{tr}=\exp\ \{\ m_c[\ln\ (\text{hardness})]+b_c\}$.
[b] $CCC_d=(CCC_{tr})$ (CF). The CCC_d shall be rounded to two significant digits.
[c] $CMC_t=\exp\ \{\ m_A[pH]+b_A\}$. The CMC_t shall be rounded to two significant digits.

Notes:
The term ''exp'' represents the base e exponential function.
The term ''n/a'' means not applicable.
CCC is Criterion Continuous Concentration.
CCC_{tr} is the CCC expressed as total recoverable.
CCC_d is the CCC expressed as a dissolved concentration.
CCC_t is the CCC expressed as a total concentration.

TABLE 3.—WATER QUALITY CRITERIA FOR PROTECTION OF HUMAN HEALTH

Chemical	HNV (µg/L)		HCV (µg/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
Benzene	1.9E1	5.1E2	1.2E1	3.1E2
Chlordane	1.4E–3	1.4E–3	2.5E–4	2.5E–4
Chlorobenzene	4.7E2	3.2E3		
Cyanides	6.0E2	4.8E4		
DDT	2.0E–3	2.0E–3	1.5E–4	1.5E–4
Dieldrin	4.1E–4	4.1E–4	6.5E–6	6.5E–6
2,4-Dimethylphenol	4.5E2	8.7E3		
2,4-Dinitrophenol	5.5E1	2.8E3		
Hexachlorobenzene	4.6E–2	4.6E–2	4.5E–4	4.5E–4
Hexachloroethane	6.0	7.6	5.3	6.7
Lindane	4.7E–1	5.0E–1		
Mercury [1]	1.8E–3	1.8E–3		
Methylene chloride	1.6E3	9.0E4	4.7E1	2.6E3
2,3,7,8-TCDD	6.7E–8	6.7E–8	8.6E–9	8.6E–9
Toluene	5.6E3	5.1E4		
Toxaphene			6.8E–5	6.8E–5
Trichloroethylene			2.9E1	3.7E2

[1] Includes methylmercury.

[60 FR 15387, Mar. 23, 1995, as amended at 62 FR 11731, Mar. 12, 1997; 62 FR 52924, Oct. 9, 1997]

TABLE 4.—WATER QUALITY CRITERIA FOR PROTECTION OF WILDLIFE

Chemical	Criteria (µg/L)
DDT and metabolites	1.1E–5
Mercury (including methylmercury)	1.3E–3
PCBs (class)	1.2E–4
2,3,7,8-TCDD	3.1E–9

[60 FR 15387, Mar. 23, 1995, as amended at 62 FR 11731, Mar. 12, 1997]

Table 5.—Pollutants Subject to Federal, State, and Tribal Requirements

Alkalinity
Ammonia
Bacteria
Biochemical oxygen demand (BOD)
Chlorine
Color
Dissolved oxygen
Dissolved solids
pH
Phosphorus

Salinity
Temperature
Total and suspended solids
Turbidity

Table 6.—Pollutants of Initial Focus in the Great Lakes Water Quality Initiative

A. Pollutants that are bioaccumulative chemicals of concern (BCCs):
Chlordane
4,4′-DDD; p,p′-DDD; 4,4′-TDE; p,p′-TDE
4,4′-DDE; p,p′-DDE
4,4′-DDT; p,p′-DDT
Dieldrin
Hexachlorobenzene
Hexachlorobutadiene; hexachloro-1, 3-butadiene
Hexachlorocyclohexanes; BHCs
alpha-Hexachlorocyclohexane; alpha-BHC
beta-Hexachlorocyclohexane; beta-BHC
delta-Hexachlorocyclohexane; delta-BHC
Lindane; gamma-hexachlorocyclohexane; gamma-BHC
Mercury
Mirex
Octachlorostyrene
PCBs; polychlorinated biphenyls
Pentachlorobenzene
Photomirex
2,3,7,8-TCDD; dioxin
1,2,3,4-Tetrachlorobenzene
1,2,4,5-Tetrachlorobenzene Toxaphene
B. Pollutants that are not bioaccumulative chemicals of concern:
Acenaphthene
Acenaphthylene
Acrolein; 2-propenal
Acrylonitrile
Aldrin
Aluminum
Anthracene
Antimony
Arsenic
Asbestos
1,2-Benzanthracene; benz[a]anthracene
Benzene
Benzidine
Benzo[a]pyrene; 3,4-benzopyrene
3,4-Benzofluoranthene; benzo[b]fluoranthene
11,12-Benzofluoranthene; benzo[k]fluoranthene
1,12-Benzoperylene; benzo[ghi]perylene
Beryllium
Bis(2-chloroethoxy) methane
Bis(2-chloroethyl) ether
Bis(2-chloroisopropyl) ether
Bromoform; tribomomethane
4-Bromophenyl phenyl ether
Butyl benzyl phthalate
Cadmium
Carbon tetrachloride; tetrachloromethane
Chlorobenzene
p-Chloro-m-cresol; 4-chloro-3-methylphenol
Chlorodibromomethane
Chlorethane
2-Chloroethyl vinyl ether
Chloroform; trichloromethane
2-Chloronaphthalene
2-Chlorophenol
4-Chlorophenyl phenyl ether
Chlorpyrifos
Chromium
Chrysene
Copper
Cyanide
2,4-D; 2,4-Dichlorophenoxyacetic acid
DEHP; di(2-ethylhexyl) phthalate
Diazinon
1,2:5,6-Dibenzanthracene; dibenz[a,h]anthracene
Dibutyl phthalate; di-n-butyl phthalate
1,2-Dichlorobenzene
1,3-Dichlorobenzene
1,4-Dichlorobenzene
3,3′-Dichlorobenzidine
Dichlorobromomethane; bromodichloromethane
1,1-Dichloroethane
1,2-Dichloroethane
1,1-Dichloroethylene; vinylidene chloride
1,2-trans-Dichloroethylene
2,4-Dichlorophenol
1,2-Dichloropropane
1,3-Dichloropropene; 1,3-dichloropropylene
Diethyl phthalate
2,4-Dimethylphenol; 2,4-xylenol
Dimethyl phthalate
4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol
2,4-Dinitrophenol
2,4-Dinitrotoluene
2,6-Dinitrotoluene
Dioctyl phthalate; di-n-octyl phthalate
1,2-Diphenylhydrazine
Endosulfan; thiodan
alpha-Endosulfan
beta-Endosulfan
Endosulfan sulfate
Endrin
Endrin aldehyde
Ethylbenzene
Fluoranthene
Fluorene; 9H-fluorene
Fluoride
Guthion
Heptachlor
Heptachlor epoxide
Hexachlorocyclopentadiene
Hexachloroethane
Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene
Isophorone
Lead
Malathion
Methoxychlor
Methyl bromide; bromomethane
Methyl chloride; chloromethane
Methylene chloride; dichloromethane
Napthalene
Nickel
Nitrobenzene
2-Nitrophenol
4-Nitrophenol

N-Nitrosodimethylamine
N-Nitrosodiphenylamine
N-Nitrosodipropylamine; N-nitrosodi-n-propylamine
Parathion
Pentachlorophenol
Phenanthrene
Phenol
Iron
Pyrene
Selenium
Silver
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
Thallium
Toluene; methylbenzene
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethylene; trichloroethene
2,4,6-Trichlorophenol
Vinyl chloride; chloroethylene; chloroethene
Zinc

APPENDIX A TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE METHODOLOGIES FOR DEVELOPMENTS OF AQUATIC LIFE CRITERIA AND VALUES

METHODOLOGY FOR DERIVING AQUATIC LIFE CRITERIA: TIER I

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

I. Definitions

A. *Material of Concern.* When defining the material of concern the following should be considered:

1. Each separate chemical that does not ionize substantially in most natural bodies of water should usually be considered a separate material, except possibly for structurally similar organic compounds that only exist in large quantities as commercial mixtures of the various compounds and apparently have similar biological, chemical, physical, and toxicological properties.

2. For chemicals that ionize substantially in most natural bodies of water (e.g., some phenols and organic acids, some salts of phenols and organic acids, and most inorganic salts and coordination complexes of metals and metalloid), all forms that would be in chemical equilibrium should usually be considered one material. Each different oxidation state of a metal and each different non-ionizable covalently bonded organometallic compound should usually be considered a separate material.

3. The definition of the material of concern should include an operational analytical component. Identification of a material simply as ''sodium,'' for example, implies ''total sodium,'' but leaves room for doubt. If ''total'' is meant, it must be explicitly stated. Even ''total'' has different operational definitions, some of which do not necessarily measure ''all that is there'' in all samples. Thus, it is also necessary to reference or describe the analytical method that is intended. The selection of the operational analytical component should take into account the analytical and environmental chemistry of the material and various practical considerations, such as labor and equipment requirements, and whether the method would require measurement in the field or would allow measurement after samples are transported to a laboratory.

a. The primary requirements of the operational analytical component are that it be appropriate for use on samples of receiving water, that it be compatible with the available toxicity and bioaccumulation data without making extrapolations that are too hypothetical, and that it rarely result in underprotection or overprotection of aquatic organisms and their uses. Toxicity is the property of a material, or combination of materials, to adversely affect organisms.

b. Because an ideal analytical measurement will rarely be available, an appropriate compromise measurement will usually have to be used. This compromise measurement must fit with the general approach that if an ambient concentration is lower than the criterion, unacceptable effects will probably not occur, i.e., the compromise measure must not err on the side of underprotection when measurements are made on a surface water. What is an appropriate measurement in one situation might not be appropriate for another. For example, because the chemical and physical properties of an effluent are usually quite different from those of the receiving water, an analytical method that is appropriate for analyzing an effluent might not be appropriate for expressing a criterion, and vice versa. A criterion should be based on an appropriate analytical measurement, but the criterion is not rendered useless if an ideal measurement either is not available or is not feasible.

NOTE: The analytical chemistry of the material might have to be taken into account when defining the material or when judging the acceptability of some toxicity tests, but a criterion must not be based on the sensitivity of an analytical method. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods.

4. It is now the policy of EPA that the use of dissolved metal to set and measure compliance with water quality standards is the recommended approach, because dissolved metal more closely approximates the bioavailable fraction of metal in the water column that does total recoverable metal. One reason is that a primary mechanism for

water column toxicity is adsorption at the gill surface which requires metals to be in the dissolved form. Reasons for the consideration of total recoverable metals criteria include risk management considerations not covered by evaluation of water column toxicity. A risk manager may consider sediments and food chain effects and may decide to take a conservative approach for metals, considering that metals are very persistent chemicals. This approach could include the use of total recoverable metal in water quality standards. A range of different risk management decisions can be justified. EPA recommends that State water quality standards be based on dissolved metal. EPA will also approve a State risk management decision to adopt standards based on total recoverable metal, if those standards are otherwise approvable under this program.

B. *Acute Toxicity*. Concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism. (Concurrent toxicity is an adverse effect to an organism that results from, and occurs during, its exposure to one or more test materials.) Exposure constitutes contact with a chemical or physical agent. Acute exposure, however, is exposure of an organism for any short period which usually does not constitute a substantial portion of its life span.

C. *Chronic Toxicity*. Concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure. Chronic exposure is exposure of an organism for any long period or for a substantial portion of its life span.

II. Collection of Data

A. Collect all data available on the material concerning toxicity to aquatic animals and plants.

B. All data that are used should be available in typed, dated, and signed hard copy (e.g., publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. In some cases, it might be appropriate to obtain written information from the investigator, if possible. Information that is not available for distribution shall not be used.

C. Questionable data, whether published or unpublished, must not be used. For example, data must be rejected if they are from tests that did not contain a control treatment, tests in which too many organisms in the control treatment died or showed signs of stress or disease, and tests in which distilled or deionized water was used as the dilution water without the addition of appropriate salts.

D. Data on technical grade materials may be used if appropriate, but data on formulated mixtures and emulsifiable concentrates of the material must not be used.

E. For some highly volatile, hydrolyzable, or degradable materials, it might be appropriate to use only results of flow-through tests in which the concentrations of test material in test solutions were measured using acceptable analytical methods. A flow-through test is a test with aquatic organisms in which test solutions flow into constant-volume test chambers either intermittently (e.g., every few minutes) or continuously, with the excess flowing out.

F. Data must be rejected if obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35 g/kg.

2. Species that do not have reproducing wild populations in North America.

3. Organisms that were previously exposed to substantial concentrations of the test material or other contaminants.

4. Saltwater species except for use in deriving acute-chronic ratios. An ACR is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

G. Questionable data, data on formulated mixtures and emulsifiable concentrates, and data obtained with species non-resident to North America or previously exposed organisms may be used to provide auxiliary information but must not be used in the derivation of criteria.

III. Required Data

A. Certain data should be available to help ensure that each of the major kinds of possible adverse effects receives adequate consideration. An adverse effect is a change in an organism that is harmful to the organism. Exposure means contact with a chemical or physical agent. Results of acute and chronic toxicity tests with representative species of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of appropriate untested species. Fewer data concerning toxicity to aquatic plants are usually available because procedures for conducting tests with plants and interpreting the results of such tests are not as well developed.

B. To derive a Great Lakes Tier I criterion for aquatic organisms and their uses, the following must be available:

1. Results of acceptable acute (or chronic) tests (see section IV or VI of this appendix) with at least one species of freshwater animal in at least eight different families such that all of the following are included:

a. The family Salmonidae in the class Osteichthyes;

b. One other family (preferably a commercially or recreationally important, warmwater species) in the class Osteichthyes (e.g., bluegill, channel catfish);

c. A third family in the phylum Chordata (e.g., fish, amphibian);

d. A planktonic crustacean (e.g., a cladoceran, copepod);

e. A benthic crustacean (e.g., ostracod, isopod, amphipod, crayfish);

f. An insect (e.g., mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge);

g. A family in a phylum other than Arthropoda or Chordata (e.g., Rotifera, Annelida, Mollusca);

h. A family in any order of insect or any phylum not already represented.

2. Acute-chronic ratios (see section VI of this appendix) with at least one species of aquatic animal in at least three different families provided that of the three species:

a. At least one is a fish;

b. At least one is an invertebrate; and

c. At least one species is an acutely sensitive freshwater species (the other two may be saltwater species).

3. Results of at least one acceptable test with a freshwater algae or vascular plant is desirable but not required for criterion derivation (see section VIII of this appendix). If plants are among the aquatic organisms most sensitive to the material, results of a test with a plant in another phylum (division) should also be available.

C. If all required data are available, a numerical criterion can usually be derived except in special cases. For example, derivation of a chronic criterion might not be possible if the available ACRs vary by more than a factor of ten with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic (see sections V and VII of this appendix), more data will be required.

D. Confidence in a criterion usually increases as the amount of available pertinent information increases. Thus, additional data are usually desirable.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the material to a variety of species of aquatic animals are used to calculate the Final Acute Value (FAV). The calculated Final Acute Value is a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher Genus Mean Acute Values (GMAVs). An acute test is a comparative study in which organisms, that are subjected to different treatments, are observed for a short period usually not constituting a substantial portion of their life span. However, in some cases, the Species Mean Acute Value (SMAV) of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FAV, then the SMAV replaces the calculated FAV in order to provide protection for that important species.

B. Acute toxicity tests shall be conducted using acceptable procedures. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 729, Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians.

C. Except for results with saltwater annelids and mysids, results of acute tests during which the test organisms were fed should not be used, unless data indicate that the food did not affect the toxicity of the test material. (NOTE: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

D. Results of acute tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between acute toxicity and organic carbon or particulate matter, or unless data show that organic carbon or particulate matter, etc., do not affect toxicity.

E. Acute values must be based upon endpoints which reflect the total severe adverse impact of the test material on the organisms used in the test. Therefore, only the following kinds of data on acute toxicity to aquatic animals shall be used:

1. Tests with daphnids and other cladocerans must be started with organisms less than 24 hours old and tests with midges must be started with second or third instar larvae. It is preferred that the results should be the 48-hour EC50 based on the total percentage of organisms killed and immobilized. If such an EC50 is not available for a test, the 48-hour LC50 should be used in place of the desired 48-hour EC50. An EC50 or LC50 of longer than 48 hours can be used as long as the animals were not fed and the control animals were acceptable at the end of the test. An EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50% of a group of organisms under specified conditions. An LC50 is a statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions.

2. It is preferred that the results of a test with embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on the percentage of organisms with incompletely developed shells plus the percentage of organisms killed. If such an EC50 is not

available from a test, of the values that are available from the test, the lowest of the following should be used in place of the desired 96-hour EC50: 48- to 96-hour EC50s based on percentage of organisms with incompletely developed shells plus percentage of organisms killed, 48- to 96-hour EC50s based upon percentage of organisms with incompletely developed shells, and 48-hour to 96-hour LC50s. (NOTE: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

3. It is preferred that the result of tests with all other aquatic animal species and older life stages of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized plus percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from a test the lower of the following should be used in place of the desired 96-hour EC50: the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized and the 96-hour LC50.

4. Tests whose results take into account the number of young produced, such as most tests with protozoans, are not considered acute tests, even if the duration was 96 hours or less.

5. If the tests were conducted properly, acute values reported as ''greater than'' values and those which are above the solubility of the test material should be used, because rejection of such acute values would bias the Final Acute Value by eliminating acute values for resistant species.

F. If the acute toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section V of this appendix.

G. The agreement of the data within and between species must be considered. Acute values that appear to be questionable in comparison with other acute and chronic data for the same species and for other species in the same genus must not be used. For example, if the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing circumstances.

H. If the available data indicate that one or more life stages are at least a factor of two more resistant than one or more other life stages of the same species, the data for the more resistant life stages must not be used in the calculation of the SMAV because a species cannot be considered protected from acute toxicity if all of the life stages are not protected.

I. For each species for which at least one acute value is available, the SMAV shall be calculated as the geometric mean of the results of all acceptable flow-through acute toxicity tests in which the concentrations of test material were measured with the most sensitive tested life stage of the species. For a species for which no such result is available, the SMAV shall be calculated as the geometric mean of all acceptable acute toxicity tests with the most sensitive tested life stage, i.e., results of flow-through tests in which the concentrations were not measured and results of static and renewal tests based on initial concentrations (nominal concentrations are acceptable for most test materials if measured concentrations are not available) of test material. A renewal test is a test with aquatic organisms in which either the test solution in a test chamber is removed and replaced at least once during the test or the test organisms are transferred into a new test solution of the same composition at least once during the test. A static test is a test with aquatic organisms in which the solution and organisms that are in a test chamber at the beginning of the test remain in the chamber until the end of the test, except for removal of dead test organisms.

NOTE 1: Data reported by original investigators must not be rounded off. Results of all intermediate calculations must not be rounded off to fewer than four significant digits.

NOTE 2: The geometric mean of N numbers is the Nth root of the product of the N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers is the square root of the product of the two numbers, and the geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithms used.

NOTE 3: Geometric means, rather than arithmetic means, are used here because the distributions of sensitivities of individual organisms in toxicity tests on most materials and the distributions of sensitivities of species within a genus are more likely to be lognormal than normal. Similarly, geometric means are used for ACRs because quotients are likely to be closer to lognormal than normal distributions. In addition, division of the geometric mean of a set of numerators by the geometric mean of the set of denominators will result in the

geometric mean of the set of corresponding quotients.

J. For each genus for which one or more SMAVs are available, the GMAV shall be calculated as the geometric mean of the SMAVs available for the genus.

K. Order the GMAVs from high to low.

L. Assign ranks, R, to the GMAVs from ''1'' for the lowest to ''N'' for the highest. If two or more GMAVs are identical, assign them successive ranks.

M. Calculate the cumulative probability, P, for each GMAV as R/(N+1).

N. Select the four GMAVs which have cumulative probabilities closest to 0.05 (if there are fewer than 59 GMAVs, these will always be the four lowest GMAVs).

O. Using the four selected GMAVs, and Ps, calculate

$$S^2 = \frac{\sum\left((\ln \mathrm{GMAV})^2\right) - \frac{\left(\sum(\ln \mathrm{GMAV})\right)^2}{4}}{\sum(\mathrm{P}) - \frac{\left(\sum\left(\sqrt{\mathrm{P}}\right)\right)^2}{4}}$$

$$L = \frac{\sum(\ln \mathrm{GMAV}) - S\left(\sum\left(\sqrt{\mathrm{P}}\right)\right)}{4}$$

$$A = S\left(\sqrt{0.05}\right) + L$$

$$FAV = e^{A}$$

NOTE: Natural logarithms (logarithms to base e, denoted as ln) are used herein merely because they are easier to use on some hand calculators and computers than common (base 10) logarithms. Consistent use of either will produce the same result.

P. If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured is lower than the calculated Final Acute Value (FAV), then that geometric mean must be used as the FAV instead of the calculated FAV.

Q. See section VI of this appendix.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly related to a water quality characteristic, the relationship shall be taken into account as described in sections V.B through V.G of this appendix or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

B. For each species for which comparable acute toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the acute toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

NOTE: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section.

C. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For

example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be useful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. In addition, acute values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus should not be used. For example, if after adjustment for the water quality characteristic, the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing justification. If useful slopes are not available for at least one fish and one invertebrate or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between acute toxicity and the water quality characteristic, return to section IV.G of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

D. For each species, calculate the geometric mean of the available acute values and then divide each of the acute values for the species by the geometric mean for the species. This normalizes the acute values so that the geometric mean of the normalized values for each species individually and for any combination of species is 1.0.

E. Similarly normalize the values of the water quality characteristic for each species individually using the same procedure as above.

F. Individually for each species perform a least squares regression of the normalized acute values of the water quality characteristic. The resulting slopes and 95 percent confidence limits will be identical to those obtained in section V.B. of this appendix. If, however, the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

G. Treat all of the normalized data as if they were all for the same species and perform a least squares regression of all of the normalized acute values on the corresponding normalized values of the water quality characteristic to obtain the pooled acute slope, V, and its 95 percent confidence limits. If all of the normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

H. For each species calculate the geometric mean, W, of the acute toxicity values and the geometric mean, X, of the values of the water quality characteristic. (These were calculated in sections V.D and V.E of this appendix).

I. For each species, calculate the logarithm, Y, of the SMAV at a selected value, Z, of the water quality characteristic using the equation:

$$Y=\ln W-V(\ln X-\ln Z)$$

J. For each species calculate the SMAV at X using the equation:

$$SMAV=e^{Y}$$

NOTE: Alternatively, the SMAVs at Z can be obtained by skipping step H above, using the equations in steps I and J to adjust each acute value individually to Z, and then calculating the geometric mean of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted acute values for each species.

K. Obtain the FAV at Z by using the procedure described in sections IV.J through IV.O of this appendix.

L. If, for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values at Z from flow-through tests in which the concentrations of the test material were measured is lower than the FAV at Z, then the geometric mean must be used as the FAV instead of the FAV.

M. The Final Acute Equation is written as:

$$FAV=e^{(V[\ln(waterqualitycharacteristic)]+A-V[\ln Z])},$$

where:

V=pooled acute slope, and A=ln(FAV at Z).

Because V, A, and Z are known, the FAV can be calculated for any selected value of the water quality characteristic.

VI. Final Chronic Value

A. Depending on the data that are available concerning chronic toxicity to aquatic animals, the Final Chronic Value (FCV) can be calculated in the same manner as the FAV or by dividing the FAV by the Final Acute-Chronic Ratio (FACR). In some cases, it might not be possible to calculate a FCV. The FCV is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, or (b) the quotient of an FAV divided by an appropriate ACR, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

NOTE: As the name implies, the ACR is a way of relating acute and chronic toxicities.

B. Chronic values shall be based on results of flow-through (except renewal is acceptable for daphnids) chronic tests in which the concentrations of test material in the test solutions were properly measured at appropriate times during the test. A chronic test is a comparative study in which organisms, that

are subjected to different treatments, are observed for a long period or a substantial portion of their life span.

C. Results of chronic tests in which survival, growth, or reproduction in the control treatment was unacceptably low shall not be used. The limits of acceptability will depend on the species.

D. Results of chronic tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between chronic toxicity and organic carbon or particulate matter, or unless data show that organic carbon, particulate matter, etc., do not affect toxicity.

E. Chronic values must be based on endpoints and lengths of exposure appropriate to the species. Therefore, only results of the following kinds of chronic toxicity tests shall be used:

1. Life-cycle toxicity tests consisting of exposures of each of two or more groups of individuals of a species to a different concentration of the test material throughout a life cycle. To ensure that all life stages and life processes are exposed, tests with fish should begin with embryos or newly hatched young less than 48 hours old, continue through maturation and reproduction, and should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Tests with daphnids should begin with young less than 24 hours old and last for not less than 21 days, and for ceriodaphnids not less than seven days. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 1193 Guide for conducting renewal life-cycle toxicity tests with *Daphnia magna* and ASTM Standard E 1295 Guide for conducting three-brood, renewal toxicity tests with *Ceriodaphnia dubia*. Tests with mysids should begin with young less than 24 hours old and continue until seven days past the median time of first brood release in the controls. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female. For mysids, data should be obtained and analyzed on survival, growth, and young per female.

2. Partial life-cycle toxicity tests consist of exposures of each of two more groups of individuals of a species of fish to a different concentration of the test material through most portions of a life cycle. Partial life-cycle tests are allowed with fish species that require more than a year to reach sexual maturity, so that all major life stages can be exposed to the test material in less than 15 months. A life-cycle test is a comparative study in which organisms, that are subjected to different treatments, are observed at least from a life stage in one generation to the same life-stage in the next generation. Exposure to the test material should begin with immature juveniles at least two months prior to active gonad development, continue through maturation and reproduction, and end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability.

3. Early life-stage toxicity tests consisting of 28- to 32-day (60 days post hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

NOTE: Results of an early life-stage test are used as predictions of results of life-cycle and partial life-cycle tests with the same species. Therefore, when results of a life-cycle or partial life-cycle test are available, results of an early life-stage test with the same species should not be used. Also, results of early life-stage tests in which the incidence of mortalities or abnormalities increased substantially near the end of the test shall not be used because the results of such tests are possibly not good predictions of comparable life-cycle or partial life-cycle tests.

F. A chronic value may be obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test or by analyzing chronic data using regression analysis.

1. A lower chronic limit is the highest tested concentration:

a. In an acceptable chronic test;

b. Which did not cause an unacceptable amount of adverse effect on any of the specified biological measurements; and

c. Below which no tested concentration caused an unacceptable effect.

2. An upper chronic limit is the lowest tested concentration:

a. In an acceptable chronic test;

b. Which did cause an unacceptable amount of adverse effect on one or more of the specified biological measurements; and,

c. Above which all tested concentrations also caused such an effect.

NOTE: Because various authors have used a variety of terms and definitions to interpret and report results of chronic tests, reported results should be reviewed carefully. The amount of effect that is considered unacceptable is often based on a statistical hypothesis test, but might also be defined in terms of a specified percent reduction from the

controls. A small percent reduction (e.g., three percent) might be considered acceptable even if it is statistically significantly different from the control, whereas a large percent reduction (e.g., 30 percent) might be considered unacceptable even if it is not statistically significant.

G. If the chronic toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section VII of this appendix.

H. If chronic values are available for species in eight families as described in section III.B.1 of this appendix, a SMCV shall be calculated for each species for which at least one chronic value is available by calculating the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests. Appropriate GMCVs shall also be calculated. A GMCV is the geometric mean of the SMCVs for the genus. The FCV shall be obtained using the procedure described in sections IV.J through IV.O of this appendix, substituting SMCV and GMCV for SMAV and GMAV respectively. See section VI.M of this appendix.

NOTE: Section VI.I through VI.L are for use when chronic values are not available for species in eight taxonomic families as described in section III.B.1 of this appendix.

I. For each chronic value for which at least one corresponding appropriate acute value is available, calculate an ACR, using for the numerator the geometric mean of the results of all acceptable flow-through (except static is acceptable for daphnids and midges) acute tests in the same dilution water in which the concentrations are measured. For fish, the acute test(s) should be conducted with juveniles. The acute test(s) should be part of the same study as the chronic test. If acute tests were not conducted as part of the same study, but were conducted as part of a different study in the same laboratory and dilution water, then they may be used. If no such acute tests are available, results of acute tests conducted in the same dilution water in a different laboratory may be used. If no such acute tests are available, an ACR shall not be calculated.

J. For each species, calculate the SMACR as the geometric mean of all ACRs available for that species. If the minimum ACR data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used along with the freshwater data.

K. For some materials, the ACR seems to be the same for all species, but for other materials the ratio seems to increase or decrease as the SMAV increases. Thus the FACR can be obtained in three ways, depending on the data available:

1. If the species mean ACR seems to increase or decrease as the SMAVs increase, the FACR shall be calculated as the geometric mean of the ACRs for species whose SMAVs are close to the FAV.

2. If no major trend is apparent and the ACRs for all species are within a factor of ten, the FACR shall be calculated as the geometric mean of all of the SMACRs.

3. If the most appropriate SMACRs are less than 2.0, and especially if they are less than 1.0, acclimation has probably occurred during the chronic test. In this situation, because continuous exposure and acclimation cannot be assured to provide adequate protection in field situations, the FACR should be assumed to be two, so that the FCV is equal to the Criterion Maximum Concentration (CMC). (See section X.B of this appendix.)

If the available SMACRs do not fit one of these cases, a FACR may not be obtained and a Tier I FCV probably cannot be calculated.

L. Calculate the FCV by dividing the FAV by the FACR.

$$FCV = FAV \div FACR$$

If there is a Final Acute Equation rather than a FAV, see also section V of this appendix.

M. If the SMCV of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV, then that SMCV must be used as the FCV instead of the calculated FCV.

N. See section VIII of this appendix.

VII. Final Chronic Equation

A. A Final Chronic Equation can be derived in two ways. The procedure described in section VII.A of this appendix will result in the chronic slope being the same as the acute slope. The procedure described in sections VII.B through N of this appendix will usually result in the chronic slope being different from the acute slope.

1. If ACRs are available for enough species at enough values of the water quality characteristic to indicate that the ACR appears to be the same for all species and appears to be independent of the water quality characteristic, calculate the FACR as the geometric mean of the available SMACRs.

2. Calculate the FCV at the selected value Z of the water quality characteristic by dividing the FAV at Z (see section V.M of this appendix) by the FACR.

3. Use V=pooled acute slope (see section V.M of this appendix), and

L=pooled chronic slope.

4. See section VII.M of this appendix.

B. When enough data are available to show that chronic toxicity to at least one species is related to a water quality characteristic,

the relationship should be taken into account as described in sections C through G below or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

C. For each species for which comparable chronic toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the chronic toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

NOTE: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in section V of this appendix.

D. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be more useful if it is consistent with other information and if the two points cover a broad range of the water quality characteristic. In addition, chronic values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus in most cases should not be used. For example, if after adjustment for the water quality characteristic, the chronic values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is, in most cases, absent countervailing circumstances, appropriate. If a useful chronic slope is not available for at least one species or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between chronic toxicity and the water quality characteristic, it might be appropriate to assume that the chronic slope is the same as the acute slope, which is equivalent to assuming that the ACR is independent of the water quality characteristic. Alternatively, return to section VI.H of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

E. Individually for each species, calculate the geometric mean of the available chronic values and then divide each chronic value for a species by the mean for the species. This normalizes the chronic values so that the geometric mean of the normalized values for each species individually, and for any combination of species, is 1.0.

F. Similarly, normalize the values of the water quality characteristic for each species individually.

G. Individually for each species, perform a least squares regression of the normalized chronic toxicity values on the corresponding normalized values of the water quality characteristic. The resulting slopes and the 95 percent confidence limits will be identical to those obtained in section VII.B of this appendix. Now, however, if the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

H. Treat all of the normalized data as if they were all the same species and perform a least squares regression of all of the normalized chronic values on the corresponding normalized values of the water quality characteristic to obtain the pooled chronic slope, L, and its 95 percent confidence limits.

If all normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

I. For each species, calculate the geometric mean, M, of the toxicity values and the geometric mean, P, of the values of the water quality characteristic. (These are calculated in sections VII.E and F of this appendix.)

J. For each species, calculate the logarithm, Q, of the SMCV at a selected value, Z, of the water quality characteristic using the equation:

$$Q=\ln M—L(\ln P-\ln Z)$$

NOTE: Although it is not necessary, it is recommended that the same value of the water quality characteristic be used here as was used in section V of this appendix.

K. For each species, calculate a SMCV at Z using the equation:

$$SMCV=e^{Q}$$

NOTE: Alternatively, the SMCV at Z can be obtained by skipping section VII.J of this appendix, using the equations in sections VII.J and K of this appendix to adjust each chronic value individually to Z, and then calculating the geometric means of the adjusted values for each species individually. This alternative procedure allows an examination of

the range of the adjusted chronic values for each species.

L. Obtain the FCV at Z by using the procedure described in sections IV.J through O of this appendix.

M. If the SMCV at Z of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV at Z, then that SMCV shall be used as the FCV at Z instead of the calculated FCV.

N. The Final Chronic Equation is written as:

$$FCV = e^{(L[\ln(\text{waterqualitycharacteristic})] + \ln S - L[\ln Z])}$$

Where:

L=pooled chronic slope and S = FCV at Z.

Because L, S, and Z are known, the FCV can be calculated for any selected value of the water quality characteristic.

VIII. Final Plant Value

A. A Final Plant Value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important. Appropriate measures of the toxicity of the material to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals. Although procedures for conducting and interpreting the results of toxicity tests with plants are not well-developed, results of tests with plants usually indicate that criteria which adequately protect aquatic animals and their uses will, in most cases, also protect aquatic plants and their uses.

B. A plant value is the result of a 96-hour test conducted with an alga or a chronic test conducted with an aquatic vascular plant.

NOTE: A test of the toxicity of a metal to a plant shall not be used if the medium contained an excessive amount of a complexing agent, such as EDTA, that might affect the toxicity of the metal. Concentrations of EDTA above 200 μg/L should be considered excessive.

C. The FPV shall be obtained by selecting the lowest result from a test with an important aquatic plant species in which the concentrations of test material are measured and the endpoint is biologically important.

IX. Other Data

Pertinent information that could not be used in earlier sections might be available concerning adverse effects on aquatic organisms. The most important of these are data on cumulative and delayed toxicity, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically important. Delayed toxicity is an adverse effect to an organism that results from, and occurs after the end of, its exposure to one or more test materials. Especially important are data for species for which no other data are available. Data from behavioral, biochemical, physiological, microcosm, and field studies might also be available. Data might be available from tests conducted in unusual dilution water (see sections IV.D and VI.D of this appendix), from chronic tests in which the concentrations were not measured (see section VI.B of this appendix), from tests with previously exposed organisms (see section II.F.3 of this appendix), and from tests on formulated mixtures or emulsifiable concentrates (see section II.D of this appendix). Such data might affect a criterion if the data were obtained with an important species, the test concentrations were measured, and the endpoint was biologically important.

X. Criterion

A. A criterion consists of two concentrations: the CMC and the Criterion Continuous Concentration (CCC).

B. The CMC is equal to one-half the FAV. The CMC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

C. The CCC is equal to the lowest of the FCV or the FPV (if available) unless other data (see section IX of this appendix) show that a lower value should be used. The CCC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect. If toxicity is related to a water quality characteristic, the CCC is obtained from the Final Chronic Equation or FPV (if available) that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (see section IX) show that a lower value should be used.

D. Round both the CMC and the CCC to two significant digits.

E. The criterion is stated as:

The procedures described in the Tier I methodology indicate that, except possibly where a commercially or recreationally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) μg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) μg/L more than once every three years on the average.

Where:

(1) = insert name of material
(2) = insert the CCC
(3) = insert the CMC

If the CMC averaging period of one hour or the CCC averaging period of four days is inappropriate for the pollutant, or if the once-

in-three-year allowable excursion frequency is inappropriate for the pollutant or for the sites to which a criterion is applied, then the State may specify alternative averaging periods or frequencies. The choice of an alternative averaging period or frequency shall be justified by a scientifically defensible analysis demonstrating that the alternative values will protect the aquatic life uses of the water. Appropriate laboratory data and/or well-designed field biological surveys shall be submitted to EPA as justification for differing averaging periods and/or frequencies of exceedance.

XI. Final Review

A. The derivation of the criterion should be carefully reviewed by rechecking each step of the Guidance in this part. Items that should be especially checked are:

1. If unpublished data are used, are they well documented?
2. Are all required data available?
3. Is the range of acute values for any species greater than a factor of 10?
4. Is the range of SMAVs for any genus greater than a factor of 10?
5. Is there more than a factor of 10 difference between the four lowest GMAVs?
6. Are any of the lowest GMAVs questionable?
7. Is the FAV reasonable in comparison with the SMAVs and GMAVs?
8. For any commercially or recreationally important species of the Great Lakes System, is the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured lower than the FAV?
9. Are any of the chronic values used questionable?
10. Are any chronic values available for acutely sensitive species?
11. Is the range of acute-chronic ratios greater than a factor of 10?
12. Is the FCV reasonable in comparison with the available acute and chronic data?
13. Is the measured or predicted chronic value for any commercially or recreationally important species of the Great Lakes System below the FCV?
14. Are any of the other data important?
15. Do any data look like they might be outliers?
16. Are there any deviations from the Guidance in this part? Are they acceptable?

B. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, shall be derived consistent with the Guidance in this part.

METHODOLOGY FOR DERIVING AQUATIC LIFE VALUES: TIER II

XII. Secondary Acute Value

If all eight minimum data requirements for calculating an FAV using Tier I are not met, a Secondary Acute Value (SAV) for the waters of the Great Lakes System shall be calculated for a chemical as follows:

To calculate a SAV, the lowest GMAV in the database is divided by the Secondary Acute Factor (SAF) (Table A–1 of this appendix) corresponding to the number of satisfied minimum data requirements listed in the Tier I methodology (section III.B.1 of this appendix). (Requirements for definitions, data collection and data review, contained in sections I, II, and IV shall be applied to calculation of a SAV.) If all eight minimum data requirements are satisfied, a Tier I criterion calculation may be possible. In order to calculate a SAV, the database must contain, at a minimum, a genus mean acute value (GMAV) for one of the following three genera in the family Daphnidae—*Ceriodaphnia sp.*, *Daphnia sp.*, or *Simocephalus sp.*

If appropriate, the SAV shall be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XIII. Secondary Acute-Chronic Ratio

If three or more experimentally determined ACRs, meeting the data collection and review requirements of Section VI of this appendix, are available for the chemical, determine the FACR using the procedure described in Section VI. If fewer than three acceptable experimentally determined ACRs are available, use enough assumed ACRs of 18 so that the total number of ACRs equals three. Calculate the Secondary Acute-Chronic Ratio (SACR) as the geometric mean of the three ACRs. Thus, if no experimentally determined ACRs are available, the SACR is 18.

XIV. Secondary Chronic Value

Calculate the Secondary Chronic Value (SCV) using one of the following:

$$\text{A. } SCV = \frac{FAV}{SACR} \text{ (use FAV from Tier I)}$$

$$\text{B. } SCV = \frac{SAV}{FACR}$$

$$\text{C. } SCV = \frac{SAV}{SACR}$$

If appropriate, the SCV will be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XV. Commercially or Recreationally Important Species

If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values or chronic values from flow-through tests in which the concentrations of the test materials were measured is lower than the calculated SAV or SCV, then that geometric mean must be used as the SAV or SCV instead of the calculated SAV or SCV.

XVI. Tier II Value

A. A Tier II value shall consist of two concentrations: the Secondary Maximum Concentration (SMC) and the Secondary Continuous Concentration (SCC).

B. The SMC is equal to one-half of the SAV.

C. The SCC is equal to the lowest of the SCV or the Final Plant Value, if available, unless other data (see section IX of this appendix) show that a lower value should be used.

If toxicity is related to a water quality characteristic, the SCC is obtained from the Secondary Chronic Equation or FPV, if available, that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (See section IX of this appendix) show that a lower value should be used.

D. Round both the SMC and the SCC to two significant digits.

E. The Tier II value is stated as:

The procedures described in the Tier II methodology indicate that, except possibly where a locally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) µ g/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) µ g/L more than once every three years on the average.

Where:

(1) = insert name of material
(2) = insert the SCC
(3) = insert the SMC

As discussed above, States and Tribes have the discretion to specify alternative averaging periods or frequencies (see section X.E. of this appendix).

XVII. Appropriate Modifications

On the basis of all available pertinent laboratory and field information, determine if the Tier II value is consistent with sound scientific evidence. If it is not, another value, either higher or lower, shall be derived consistent with the Guidance in this part.

TABLE A–1.— SECONDARY ACUTE FACTORS

Number of minimum data requirements satisfied	Adjustment factor
1	21.9
2	13.0
3	8.0
4	7.0
5	6.1
6	5.2
7	4.3

APPENDIX B TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE

METHODOLOGY FOR DERIVING BIOACCUMULATION FACTORS

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

I. Introduction

A. The purpose of this methodology is to describe procedures for deriving bioaccumulation factors (BAFs) to be used in the calculation of Great Lakes Water Quality Guidance (Guidance) human health Tier I criteria and Tier II values and wildlife Tier I criteria. A subset of the human health BAFs are also used to identify the chemicals that are considered bioaccumulative chemicals of concern (BCCs).

B. Bioaccumulation reflects uptake of a substance by aquatic organisms exposed to the substance through all routes (i.e., ambient water and food), as would occur in nature. Bioconcentration reflects uptake of a substance by aquatic organisms exposed to the substance only through the ambient water. Both BAFs and bioconcentration factors (BCFs) are proportionality constants that describe the relationship between the concentration of a substance in aquatic organisms and its concentration in the ambient water. For the Guidance in this part, BAFs, rather than BCFs, are used to calculate Tier I criteria for human health and wildlife and Tier II values for human health because they better account for the total exposure of aquatic organisms to chemicals.

C. For organic chemicals, baseline BAFs can be derived using four methods. Measured baseline BAFs are derived from field-measured BAFs; predicted baseline BAFs are derived using biota-sediment accumulation factors (BSAFs) or are derived by multiplying a laboratory-measured or predicted BCF by a food-chain multiplier (FCM). The lipid content of the aquatic organisms is used to account for partitioning of organic chemicals within organisms so that data from different tissues and species can be integrated. In addition, the baseline BAF is based on the

concentration of freely dissolved organic chemicals in the ambient water to facilitate extrapolation from one water to another.

D. For inorganic chemicals, baseline BAFs can be derived using two of the four methods. Baseline BAFs are derived using either field-measured BAFs or by multiplying laboratory-measured BCFs by a FCM. For inorganic chemicals, BAFs are assumed to equal BCFs (i.e., the FCM is 1.0), unless chemical-specific biomagnification data support using a FCM other than 1.0.

E. Because both humans and wildlife consume fish from both trophic levels 3 and 4, two baseline BAFs are needed to calculate either a human health criterion or value or a wildlife criterion for a chemical. When appropriate, ingestion through consumption of invertebrates, plants, mammals, and birds in the diet of wildlife species to be protected may be taken into account.

II. Definitions

Baseline BAF. For organic chemicals, a BAF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BAF that is based on the wet weight of the tissue.

Baseline BCF. For organic chemicals, a BCF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BCF that is based on the wet weight of the tissue.

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

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

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

Bioconcentration factor (BCF). The ratio (in L/kg) of a substance's concentration in 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 (BSAF). The ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in 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.

Depuration. The loss of a substance from an organism as a result of any active or passive process.

Food-chain multiplier (FCM). The ratio of a BAF to an appropriate BCF.

Octanol-water partition coefficient (K_{OW}). The ration 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 K_{OW}, the log of the octanol-water partition coefficient is a base 10 logarithm.

Uptake. Acquisition of a substance from the environment by an organism as a result of any active or passive process.

III. Review and Selection of Data

A. *Data Sources.* Measured BAFs, BSAFs and BCFs are assembled from available sources including the following:

1. EPA Ambient Water Quality Criteria documents issued after January 1, 1980.
2. Published scientific literature.
3. Reports issued by EPA or other reliable sources.
4. Unpublished data.

One useful source of references is the Aquatic Toxicity Information Retrieval (AQUIRE) database.

B. *Field-Measured BAFs.* The following procedural and quality assurance requirements shall be met for field-measured BAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).
2. The trophic level of the fish species shall be determined.
3. The site of the field study should not be so unique that the BAF cannot be extrapolated to other locations where the criteria and values will apply.
4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.
5. The concentration of the chemical in the water shall be measured in a way that can be related to particulate organic carbon (POC) and/or dissolved organic carbon (DOC) and should be relatively constant during the steady-state time period.
6. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the ambient water shall be either measured or reliably estimated.
7. For inorganic and organic chemicals, BAFs shall be used only if they are expressed on a wet weight basis; BAFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

C. *Field-Measured BSAFs.* The following procedural and quality assurance requirements shall be met for field-measured BSAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. Samples of surface sediments (0–1 cm is ideal) shall be from locations in which there is net deposition of fine sediment and is representative of average surface sediment in the vicinity of the organism.

3. The K_{ow} s used shall be acceptable quality as described in section III.F below.

4. The site of the field study should not be so unique that the resulting BAF cannot be extrapolated to other locations where the criteria and values will apply.

5. The tropic level of the fish species shall be determined.

6. The percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

D. *Laboratory-Measured BCFs.* The following procedural and quality assurance requirements shall be met for laboratory-measured BCFs:

1. The test organism shall not be diseased, unhealthy, or adversely affected by the concentration of the chemical.

2. The total concentration of the chemical in the water shall be measured and should be relatively constant during the steady-state time period.

3. The organisms shall be exposed to the chemical using a flow-through or renewal procedure.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BCF.

5. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the test solution shall be either measured or reliably estimated.

6. Laboratory-measured BCFs should be determined using fish species, but BCFs determined with molluscs and other invertebrates may be used with caution. For example, because invertebrates metabolize some chemicals less efficiently than vertebrates, a baseline BCF determined for such a chemical using invertebrates is expected to be higher than a comparable baseline BCF determined using fish.

7. If laboratory-measured BCFs increase or decrease as the concentration of the chemical increases in the test solutions in a bioconcentration test, the BCF measured at the lowest test concentration that is above concentrations existing in the control water shall be used (i.e., a BCF should be calculated from a control treatment). The concentrations of an inorganic chemical in a bioconcentration test should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccummulation of an inorganic chemical might be overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms.

8. For inorganic and organic chemicals, BCFs shall be used only if they are expressed on a wet weight basis. BCFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

9. BCFs for organic chemicals may be based on measurement or radioactivity only when the BCF is intended to include metabolites or when there is confidence that there is no interference due to metabolites.

10. The calculation of the BCF must appropriately address growth dilution.

11. Other aspects of the methodology used should be similar to those described by ASTM (1990).

E. *Predicted BCFs.* The following procedural and quality assurance requirements shall be met for predicted BCFs:

1. The K_{ow} used shall be of acceptable quality as described in section III.F below.

2. The predicted baseline BCF shall be calculated using the equation: predicted baseline BCF = K_{ow}

where:

K_{ow} = octanol-water partition coefficient.

F. *Octanol-Water Partition Coefficient (K_{ow}).* 1. The value of K_{ow} used for an organic chemical shall be determined by giving priority to the experimental and computational techniques used as follows:

Log K_{ow} < 4:

Priority	Technique
1	Slow-stir.
1	Generator-column.
1	Shake-flask.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Calculated by the CLOGP program.

Log K_{ow} > 4:

Priority	Technique
1	Slow Stir.
1	Generator-column.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.

Priority	Technique
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Shake-flask.
5	Calculated by the CLOGP program.

2. The CLOGP program is a computer program available from Pomona College. A value of K_{ow} that seems to be different from the others should be considered an outlier and not used. The value of K_{ow} used for an organic chemical shall be the geometric mean of the available K_{ow} s with highest priority or can be calculated from the arithmetic mean of the available log K_{ow} with the highest priority. Because it is an intermediate value in the derivation of a BAF, the value used for the K_{ow} of a chemical should not be rounded to fewer than three significant digits and a value for log K_{ow} should not be rounded to fewer than three significant digits after the decimal point.

G. This methodology provides overall guidance for the derivation of BAFs, but it cannot cover all the decisions that must be made in the review and selection of acceptable data. Professional judgment is required throughout the process. A degree of uncertainty is associated with the determination of any BAF, BSAF, BCF or K_{ow}. The amount of uncertainty in a baseline BAF depends on both the quality of data available and the method used to derive the BAF.

H. Hereinafter in this methodology, the terms BAF, BSAF, BCF and K_{ow} refer to ones that are consistent with the procedural and quality assurance requirements given above.

IV. Four Methods for Deriving Baseline BAFs

Baseline BAFs shall be derived using the following four methods, which are listed from most preferred to least preferred:

A. A measured baseline BAF for an organic or inorganic chemical derived from a field study of acceptable quality.

B. A predicted baseline BAF for an organic chemical derived using field-measured BSAFs of acceptable quality.

C. A predicted baseline BAF for an organic or inorganic chemical derived from a BCF measured in a laboratory study of acceptable quality and a FCM.

D. A predicted baseline BAF for an organic chemical derived from a K_{ow} of acceptable quality and a FCM.

For comparative purposes, baseline BAFs should be derived for each chemical by as many of the four methods as available data allow.

V. Calculation of Baseline BAFs for Organic Chemicals

A. *Lipid Normalization.* 1. It is assumed that BAFs and BCFs for organic chemicals can be extrapolated on the basis of percent lipid from one tissue to another and from one aquatic species to another in most cases.

2. Because BAFs and BCFs for organic chemicals are related to the percent lipid, it does not make any difference whether the tissue sample is whole body or edible portion, but both the BAF (or BCF) and the percent lipid must be determined for the same tissue. The percent lipid of the tissue should be measured during the BAF or BCF study, but in some cases it can be reliably estimated from measurements on tissue from other organisms. If percent lipid is not reported for the test organisms in the original study, it may be obtained from the author; or, in the case of a laboratory study, lipid data for the same or a comparable laboratory population of test organisms that were used in the original study may be used.

3. The lipid-normalized concentration, C_l, 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) (μg/g).

f_l=fraction of the tissue that is lipid.

B. *Bioavailability.* By definition, baseline BAFs and BCFs for organic chemicals, whether measured or predicted are based on the concentration of the chemical that is freely dissolved in the ambient water in order to account for bioavailability. For the purposes of this Guidance in this part, the relationship between the total concentration of the chemical in the water (i.e., that which is freely dissolved plus that which is sorbed to particulate organic carbon or to dissolved organic carbon) to the freely dissolved concentration of the chemical in the ambient water shall be calculated using the following equation:

$$C_w^{fd} = \left(f_{fd}\right)\left(C_w^t\right)$$

Where:

C^{fd}_w=freely dissolved concentration of the organic chemical in the ambient water;

C^t_w=total concentration of the organic chemical in the ambient water;

f_{fd}=fraction of the total chemical in the ambient water that is freely dissolved.

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

$$f_{fd} = \frac{1}{1 + \frac{(DOC)(K_{ow})}{10} + (POC)(K_{ow})}$$

Where:

DOC=concentration of dissolved organic carbon, kg of dissolved organic carbon/L of water.

K_{OW}=octanol-water partition coefficient of the chemical.

POC=concentration of particulate organic carbon, kg of particulate organic carbon/L of water.

C. *Food-Chain Multiplier.* In the absence of a field-measured BAF or a predicted BAF derived from a BSAF, a FCM shall be used to calculate the baseline BAF for trophic levels 3 and 4 from a laboratory-measured or predicted BCF. For an organic chemical, the FCM used shall be derived from Table B–1 using the chemical's log K_{OW} and linear interpolation. A FCM greater than 1.0 applies to most organic chemicals with a log K_{OW} of four or more. The trophic level used shall take into account the age or size of the fish species consumed by the human, avian or mammalian predator because, for some species of fish, the young are in trophic level 3 whereas the adults are in trophic level 4.

D. *Calculation of a Baseline BAF from a Field-Measured BAF.* A baseline BAF shall be calculated from a field-measured BAF of acceptable quality using the following equation:

$$\text{Baseline BAF} = \left[\frac{\text{Measured BAF}_T^t}{f_{fd}} - 1\right]\left[\frac{1}{f_l}\right]$$

Where:

BAF^t_T=BAF based on total concentration in tissue and water.

f_l=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical that is freely dissolved in the ambient water.

The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the field-measured BAF. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured baseline BAF is available for a given species. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be calculated. If a baseline BAF based on a measured BAF is available for either trophic level 3 or 4, but not both, a measured baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B–1 for the chemical.

E. *Calculation of a Baseline BAF from a Field-Measured BSAF.* 1. A baseline BAF for organic chemical ''i'' shall be calculated from a field-measured BSAF of acceptable quality using the following equation:

$$(\text{Baseline BAF})_i = (\text{Baseline BAF})_r \cdot \frac{(BSAF)_i \cdot (K_{ow})_i}{(BSAF)_r \cdot (K_{ow})_r}$$

Where:

$(BSAF)_i$=BSAF for chemical ''i''.

$(BSAF)_r$=BSAF for the reference chemical ''r''.

$(K_{OW})_i$=octanol-water partition coefficient for chemical ''i''.

$(K_{OW})_r$=octanol-water partition coefficient for the reference chemical ''r''.

2. A BSAF shall be calculated using the following equation:

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

Where:

C_t=the lipid-normalized concentration of the chemical in tissue.

C_{SOC}=the organic carbon-normalized concentration of the chemical in sediment.

3. The organic carbon-normalized concentration of a chemical in sediment, C_{SOC}, shall be calculated using the following equation:

$$C_{SOC} = \frac{C_S}{f_{OC}}$$

Where:

C_S=concentration of chemical in sediment (μg/g sediment).

f_{OC}=fraction of the sediment that is organic carbon.

4. Predicting BAFs from BSAFs requires data from a steady-state (or near steady-state) condition between sediment and ambient water for both a reference chemical ''r'' with a field-measured BAF_l fd and other chemicals ''n=i'' for which BSAFs are to be determined.

5. The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the BSAF. For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from BSAFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs derived using BSAFs shall be calculated.

6. If a baseline BAF based on a measured BSAF is available for either trophic level 3 or 4, but not both, a baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B–1 for the chemical.

F. *Calculation of a Baseline BAF from a Laboratory-Measured BCF.* A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a laboratory-measured BCF of acceptable quality and a FCM using the following equation:

$$\text{Baseline BAF} = (\text{FCM})\left[\frac{\text{Measured BCF}_T^t}{f_{fd}} - 1\right]\left[\frac{1}{f_l}\right]$$

Where:

BCF^t_T=BCF based on total concentration in tissue and water.

f_l=fraction of the tissue that is lipid.

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 by linear interpolation for trophic level 3 or 4, as necessary.

For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from laboratory-measured BCFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs based on laboratory-measured BCFs shall be calculated.

G. *Calculation of a Baseline BAF from an Octanol-Water Partition Coefficient.* A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a K_{OW} of acceptable quality and a FCM using the following equation:

Baseline BAF=(FCM) (predicted baseline BCF)=(FCM) (K_{OW})

Where:

FCM=the food-chain multiplier obtained from Table B–1 by linear interpolation for trophic level 3 or 4, as necessary.

K_{OW}=octanol-water partition coefficient.

VI. Human Health and Wildlife BAFs for Organic Chemicals

A. To calculate human health and wildlife BAFs for an organic chemical, the K_{OW} of the chemical shall be used with a POC concentration of 0.00000004 kg/L and a DOC concentration of 0.000002 kg/L to yield the fraction freely dissolved:

$$f_{fd} = \frac{1}{1 + \frac{(DOC)(K_{ow})}{10} + (POC)(K_{ow})}$$

$$= \frac{1}{1 + \frac{(0.000002\ kg/L)(K_{ow})}{10} + (0.00000004\ kg/L)(K_{ow})}$$

$$= \frac{1}{1 + (0.00000024\ kg/L)(K_{ow})}$$

B. The human health BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

$$\text{Human Health } BAF_{TL3}^{HH} = [(\text{baseline BAF})(0.0182) + 1](f_{fd})$$

For trophic level 4:

$$\text{Human Health } BAF_{TL4}^{HH} = [(\text{baseline BAF})(0.0310) + 1](f_{fd})$$

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 for the GLI.

C. The wildlife BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

$$\text{Wildlife } BAF_{TL3}^{WL} = [(\text{baseline BAF})(0.0646) + 1](f_{fd})$$

For trophic level 4:

$$\text{Wildlife } BAF_{TL4}^{WL} = [(\text{baseline BAF})(0.1031) + 1](f_{fd})$$

Where:

0.0646 and 0.1031 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive wildlife criteria for the GLI.

VII. Human Health and Wildlife BAFs for Inorganic Chemicals

A. 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, i.e., the FCM is assumed

to be 1 for both trophic levels 3 and 4. However, a FCM greater than 1 might be applicable to some metals, such as mercury, if, for example, an organometallic form of the metal biomagnifies.

B. *BAFs for Human Health Criteria and Values.*

1. Measured BAFs and BCFs used to determine human health BAFs for inorganic chemicals shall be based on edible tissue (e.g., muscle) of freshwater fish unless it is demonstrated that whole-body BAFs or BCFs are similar to edible-tissue BAFs or BCFs. BCFs and BAFs based on measurements of aquatic plants and invertebrates should not be used in the derivation of human health criteria and values.

2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with the muscle of fish:

a. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species; and

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the human health BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable edible-portion laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the human health BAF for that chemical.

C. *BAFs for Wildlife Criteria.*

1. Measured BAFs and BCFs used to determine wildlife BAFs for inorganic chemicals shall be based on whole-body freshwater fish and invertebrate data unless it is demonstrated that edible-tissue BAFs or BCFs are similar to whole-body BAFs or BCFs.

2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with whole body of fish or invertebrates:

a. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species.

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the wildlife BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable whole-body laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the wildlife BAF for that chemical.

VIII. Final Review

For both organic and inorganic chemicals, human health and wildlife BAFs for both trophic levels shall be reviewed for consistency with all available data concerning the bioaccumulation, bioconcentration, and metabolism of the chemical. For example, information concerning octanol-water partitioning, molecular size, or other physicochemical properties that might enhance or inhibit bioaccumulation should be considered for organic chemicals. BAFs derived in accordance with this methodology should be modified if changes are justified by available data.

IX. Literature Cited

ASTM. 1990. Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. Standard E 1022. American Society for Testing and Materials, Philadelphia, PA.

TABLE B–1.—FOOD-CHAIN MULTIPLIERS FOR TROPHIC LEVELS 2, 3 & 4

Log K_{ow}	Trophic level 2	Trophic[1] level 3	Trophic level 4
2.0	1.000	1.005	1.000
2.5	1.000	1.010	1.002
3.0	1.000	1.028	1.007
3.1	1.000	1.034	1.007
3.2	1.000	1.042	1.009
3.3	1.000	1.053	1.012
3.4	1.000	1.067	1.014
3.5	1.000	1.083	1.019
3.6	1.000	1.103	1.023
3.7	1.000	1.128	1.033
3.8	1.000	1.161	1.042
3.9	1.000	1.202	1.054
4.0	1.000	1.253	1.072
4.1	1.000	1.315	1.096
4.2	1.000	1.380	1.130
4.3	1.000	1.491	1.178
4.4	1.000	1.614	1.242
4.5	1.000	1.766	1.334
4.6	1.000	1.950	1.459
4.7	1.000	2.175	1.633
4.8	1.000	2.452	1.871
4.9	1.000	2.780	2.193
5.0	1.000	3.181	2.612
5.1	1.000	3.643	3.162
5.2	1.000	4.188	3.873
5.3	1.000	4.803	4.742
5.4	1.000	5.502	5.821
5.5	1.000	6.266	7.079
5.6	1.000	7.096	8.551
5.7	1.000	7.962	10.209
5.8	1.000	8.841	12.050
5.9	1.000	9.716	13.964
6.0	1.000	10.556	15.996

TABLE B–1.—FOOD-CHAIN MULTIPLIERS FOR TROPHIC LEVELS 2, 3 & 4—Continued

Log K_{ow}	Trophic level 2	Trophic[1] level 3	Trophic level 4
6.1	1.000	11.337	17.783
6.2	1.000	12.064	19.907
6.3	1.000	12.691	21.677
6.4	1.000	13.228	23.281
6.5	1.000	13.662	24.604
6.6	1.000	13.980	25.645
6.7	1.000	14.223	26.363
6.8	1.000	14.355	26.669
6.9	1.000	14.388	26.669
7.0	1.000	14.305	26.242
7.1	1.000	14.142	25.468
7.2	1.000	13.852	24.322
7.3	1.000	13.474	22.856
7.4	1.000	12.987	21.038
7.5	1.000	12.517	18.967
7.6	1.000	11.708	16.749
7.7	1.000	10.914	14.388
7.8	1.000	10.069	12.050
7.9	1.000	9.162	9.840
8.0	1.000	8.222	7.798
8.1	1.000	7.278	6.012
8.2	1.000	6.361	4.519
8.3	1.000	5.489	3.311
8.4	1.000	4.683	2.371
8.5	1.000	3.949	1.663
8.6	1.000	3.296	1.146
8.7	1.000	2.732	0.778
8.8	1.000	2.246	0.521
8.9	1.000	1.837	0.345
9.0	1.000	1.493	0.226

[1] The FCMs for trophic level 3 are the geometric mean of the FCMs for sculpin and alewife.

APPENDIX C TO PART 132—GREAT LAKES WATER QUALITY INITIATIVE METHODOLOGIES FOR DEVELOPMENT OF HUMAN HEALTH CRITERIA AND VALUES

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

I. INTRODUCTION

Great Lakes States and Tribes shall adopt provisions consistent with this appendix C to ensure protection of human health.

A. *Goal.* The goal of the human health criteria for the Great Lakes System is the protection of humans from unacceptable exposure to toxicants via consumption of contaminated fish and drinking water and from ingesting water as a result of participation in water-oriented recreational activities.

B. *Definitions.*

Acceptable daily exposure (ADE). An estimate of the maximum daily dose of a substance which is not expected to result in adverse noncancer effects to the general human population, including sensitive subgroups.

Adverse effect. Any deleterious effect to organisms due to exposure to a substance. This includes effects which 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.

Carcinogen. A substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Human cancer criterion (HCC). A Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C.

Human cancer value (HCV). The maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC). A Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV). The maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health criteria and Values in appendix C of this part.

Linearized multi-stage model. A conservative 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, i.e., exposure to even a very small amount of the substance is assumed to produce a finite increased risk of cancer.

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.

Quantitative structure activity relationship (QSAR) or structure activity relationship (SAR). A mathematical relationship between a

property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Relative source contribution (RSC). The factor (percentage) used in calculating an HNV or HNC to account for all sources of exposure to a contaminant. The RSC reflects the percent of total exposure which can be attributed to surface water through water intake and fish consumption.

Risk associated dose (RAD). A dose of a known or presumed carcinogenic substance in (mg/kg/day) which, 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. Also known as q_1*, slope factor is the incremental rate of cancer development calculated through use of a linearized multistage model or other appropriate model. It is expressed in (mg/kg/day) of exposure to the chemical in question.

Threshold effect. An effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Uncertainty factor (UF). One of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

C. *Level of Protection.* The criteria developed shall provide a level of protection likely to be without appreciable risk of carcinogenic and/or noncarcinogenic effects. Criteria are a function of the level of designated risk or no adverse effect estimation, selection of data and exposure assumptions. Ambient criteria for single carcinogens shall not be set at a level representing a lifetime upper-bound incremental risk greater than one in 100,000 of developing cancer using the hazard assessment techniques and exposure assumptions described herein. Criteria affording protection from noncarcinogenic effects shall be established at levels that, taking into account uncertainties, are considered likely to be without an appreciable risk of adverse human health effects (i.e., acute, subchronic and chronic toxicity including reproductive and developmental effects) during a lifetime of exposure, using the risk assessment techniques and exposure assumptions described herein.

D. *Two-tiered Classification.* Chemical concentration levels in surface water protective of human health shall be derived based on either a Tier I or Tier II classification. The two Tiers are primarily distinguished by the amount of toxicity data available for deriving the concentration levels and the quantity and quality of data on bioaccumulation.

II. MINIMUM DATA REQUIREMENTS

The best available toxicity data on the adverse health effects of a chemical and the best data on bioaccumulation factors shall be used when developing human health Tier I criteria or Tier II values. The best available toxicity data shall include data from well-conducted epidemiologic and/or animal studies which provide, in the case of carcinogens, an adequate weight of evidence of potential human carcinogenicity and, in the case of noncarcinogens, a dose-response relationship involving critical effects biologically relevant to humans. Such information should be obtained from the EPA Integrated Risk Information System (IRIS) database, the scientific literature, and other informational databases, studies and/or reports containing adverse health effects data of adequate quality for use in this procedure. Strong consideration shall be given to the most currently available guidance provided by IRIS in deriving criteria or values, supplemented with any recent data not incorporated into IRIS. When deviations from IRIS are anticipated or considered necessary, it is strongly recommended that such actions be communicated to the EPA Reference Dose (RfD) and/or the Cancer Risk Assessment Verification Endeavor (CRAVE) workgroup immediately. The best available bioaccumulation data shall include data from field studies and well-conducted laboratory studies.

A. *Carcinogens.* Tier I criteria and Tier II values shall be derived using the methodologies described in section III.A of this appendix when there is adequate evidence of potential human carcinogenic effects for a chemical. It is strongly recommended that the EPA classification system for chemical carcinogens, which is described in the 1986 EPA Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1986), or future modifications thereto, be used in determining whether adequate evidence of potential carcinogenic effects exists. Carcinogens are classified, depending on the weight of evidence, as either human carcinogens, probable human carcinogens, or possible human carcinogens. The human evidence is considered inadequate and therefore the chemical cannot be classified as a human carcinogen, if one of two conditions exists: (a) there are few pertinent data, or (b) the available studies, while showing evidence of association, do not exclude chance, bias, or confounding and therefore a casual interpretation is not credible. The animal evidence is considered inadequate, and therefore the chemical cannot be classified as a probable or possible human carcinogen, when, because of major qualitative or quantitative limitations, the evidence cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

Chemicals are described as ''human carcinogens'' when there is sufficient evidence from epidemiological studies to support a causal association between exposure to the chemicals and cancer. Chemicals described as ''probable human carcinogens'' include chemicals for which the weight of evidence of human carcinogenicity based on epidemiological studies is limited. Limited human evidence is that which indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding, cannot adequately be excluded. Probable human carcinogens are also agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiologic studies. Sufficient animal evidence is data which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors: (a) in multiple species or strains; (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests (such as mutagenicity/genotoxicity tests which help determine whether the chemical interacts directly with DNA) or on chemical structure, metabolism or mode of action.

''Possible human carcinogens'' are chemicals with limited evidence of carcinogenicity in animals in the absence of human data. Limited animal evidence is defined as data which suggests a carcinogenic effect but are limited because: (a) The studies involve a single species, strain, or experiment and do not meet criteria for sufficient evidence (see preceding paragraph); or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or (c) the studies indicate an increase in the incidence of benign tumors only. More specifically, this group can include a wide variety of evidence, e.g., (a) a malignant tumor response in a single well-conducted experiment that does not meet conditions for sufficient evidence, (b) tumor response of marginal statistical significance in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) response of marginal statistical significance in a tissue known to have a high or variable background rate.

1. *Tier I:* Weight of evidence of potential human carcinogenic effects sufficient to derive a Tier I HCC shall generally include human carcinogens, probable human carcinogens and can include, on a case-by-case basis, possible human carcinogens if studies have been well-conducted albeit based on limited evidence, when compared to studies used in classifying human and probable human carcinogens. The decision to use data on a possible human carcinogen for deriving Tier I criteria shall be a case-by-case determination. In determining whether to derive a Tier I HCC, additional evidence that shall be considered includes but is not limited to available information on mode of action, such as mutagenicity/genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity, and metabolism.

2. *Tier II:* Weight of evidence of possible human carcinogenic effects sufficient to derive a Tier II human cancer value shall include those possible human carcinogens for which there are at a minimum, data sufficient for quantitative risk assessment, but for which data are inadequate for Tier I criterion development due to a tumor response of marginal statistical significance or inability to derive a strong dose-response relationship. In determining whether to derive Tier II human cancer values, additional evidence that shall be considered includes but is not limited to available information on mode of action such as mutagenicity/genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity and metabolism. As with the use of data on possible human carcinogens in developing Tier I criteria, the decision to use data on possible human carcinogens to derive Tier II values shall be made on a case-by-case basis.

B. *Noncarcinogens.* All available toxicity data shall be evaluated considering the full range of possible health effects of a chemical, i.e., acute/subacute, chronic/subchronic and reproductive/developmental effects, in order to best describe the dose-response relationship of the chemical, and to calculate human noncancer criteria and values which will protect against the most sensitive endpoint(s) of toxicity. Although it is desirable to have an extensive database which considers a wide range of possible adverse effects, this type of data exists for a very limited number of chemicals. For many others, there is a range in quality and quantity of data available. To assure minimum reliability of criteria and values, it is necessary to establish a minimum database with which to develop Tier I criteria or Tier II values. The following represent the minimum data sets necessary for this procedure.

1. *Tier I:* The minimum data set sufficient to derive a Tier I human HNC shall include at least one well-conducted epidemiologic study or animal study. A well-conducted epidemiologic study for a Tier I HNC must quantify exposure level(s) and demonstrate positive association between exposure to a chemical and adverse effect(s) in humans. A

well-conducted study in animals must demonstrate a dose response relationship involving one or more critical effect(s) biologically relevant to humans. (For example, study results from an animal whose pharmacokinetics and toxicokinetics match those of a human would be considered most biologically relevant.) Ideally, the duration of a study should span multiple generations of exposed test species or at least a major portion of the lifespan of one generation. This type of data is currently very limited. By the use of uncertainty adjustments, shorter term studies (such as 90-day subchronic studies) with evaluation of more limited effect(s) may be used to extrapolate to longer exposures or to account for a variety of adverse effects. For Tier I criteria developed pursuant to this procedure, such a limited study must be conducted for at least 90 days in rodents or 10 percent of the lifespan of other appropriate test species and demonstrate a no observable adverse effect level (NOAEL). Chronic studies of one year or longer in rodents or 50 percent of the lifespan or greater in other appropriate test species that demonstrate a lowest observable adverse effect level (LOAEL) may be sufficient for use in Tier I criterion derivation if the effects observed at the LOAEL were relatively mild and reversible as compared to effects at higher doses. This does not preclude the use of a LOAEL from a study (of chronic duration) with only one or two doses if the effects observed appear minimal when compared to effect levels observed at higher doses in other studies.

2. *Tier II:* When the minimum data for deriving Tier I criteria are not available to meet the Tier I data requirements, a more limited database may be considered for deriving Tier II values. As with Tier I criteria, all available data shall be considered and ideally should address a range of adverse health effects with exposure over a substantial portion of the lifespan (or multiple generations) of the test species. When such data are lacking it may be necessary to rely on less extensive data in order to establish a Tier II value. With the use of appropriate uncertainty factors to account for a less extensive database, the minimum data sufficient to derive a Tier II value shall include a NOAEL from at least one well-conducted short-term repeated dose study. This study shall be of at least 28 days duration, in animals demonstrating a dose-response, and involving effects biologically relevant to humans. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies (greater than 28 days) may be more appropriate in some cases for derivation of Tier II values. Use of a LOAEL should be based on consideration of the following information: severity of effect, quality of the study and duration of the study.

C. *Bioaccumulation factors (BAFs).*

1. *Tier I for Carcinogens and Noncarcinogens:* To be considered a Tier I cancer or noncancer human health criterion, along with satisfying the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix, a chemical must have the following minimum bioaccumulation data. For all organic chemicals either: (a) a field-measured BAF; (b) a BAF derived using the BSAF methodology; or (c) a chemical with a BAF less than 125 regardless of how the BAF was derived. For all inorganic chemicals, including organometals such as mercury, either: (a) a field-measured BAF or (b) a laboratory-measured BCF.

2. *Tier II for Carcinogens and Noncarcinogens:* A chemical is considered a Tier II cancer or noncancer human health value if it does not meet either the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix or the minimum bioaccumulation data requirements of section II.C.1 of this appendix.

III. Principles for Development of Tier I Criteria or Tier II Values

The fundamental components of the procedure to calculate Tier I criteria or Tier II values are the same. However, certain of the aspects of the procedure designed to account for short-duration studies or other limitations in data are more likely to be relevant in deriving Tier II values than Tier I criteria.

A. *Carcinogens.*

1. A non-threshold mechanism of carcinogenesis shall be assumed unless biological data adequately demonstrate the existence of a threshold on a chemical-specific basis.

2. All appropriate human epidemiologic data and animal cancer bioassay data shall be considered. Data specific to an environmentally appropriate route of exposure shall be used. Oral exposure should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. The risk associated dose shall be set at a level corresponding to an incremental cancer risk of one in 100,000. If acceptable human epidemiologic data are available for a chemical, it shall be used to derive the risk associated dose. If acceptable human epidemiologic data are not available, the risk associated dose shall be derived from available animal bioassay data. Data from a species that is considered most biologically relevant to humans (i.e., responds most like humans) is preferred where all other considerations regarding quality of data are equal. In the absence of data to distinguish the most relevant species, data from the most sensitive species tested, i.e., the species showing a carcinogenic effect at the lowest administered dose, shall generally be used.

3. When animal bioassay data are used and a non-threshold mechanism of carcinogenicity is assumed, the data are fitted to a linearized multistage computer model (e.g., Global '86 or equivalent model). Global '86 is the linearized multistage model, derived by Howe, Crump and Van Landingham (1986), which EPA uses to determine cancer potencies. The upper-bound 95 percent confidence limit on risk (or, the lower 95 percent confidence limit on dose) at the one in 100,000 risk level shall be used to calculate a risk associated dose (RAD). Other models, including modifications or variations of the linear multistage model which are more appropriate to the available data may be used where scientifically justified.

4. If the duration of the study is significantly less than the natural lifespan of the test animal, the slope may be adjusted on a case-by-case basis to compensate for latent tumors which were not expressed (e.g., U.S. EPA, 1980) In the absence of alternative approaches which compensate for study durations significantly less than lifetime, the permitting authority may use the process described in the 1980 National Guidelines (see 45 FR 79352).

5. A species scaling factor shall be used to account for differences between test species and humans. It shall be assumed that milligrams per surface area per day is an equivalent dose between species (U.S. EPA, 1986). All doses presented in mg/kg bodyweight will be converted to an equivalent surface area dose by raising the mg/kg dose to the 2/3 power. However, if adequate pharmacokinetic and metabolism studies are available, these data may be factored into the adjustment for species differences on a case-by-case basis.

6. Additional data selection and adjustment decisions must also be made in the process of quantifying risk. Consideration must be given to tumor selection for modeling, e.g., pooling estimates for multiple tumor types and identifying and combining benign and malignant tumors. All doses shall be adjusted to give an average daily dose over the study duration. Adjustments in the rate of tumor response must be made for early mortality in test species. The goodness-of-fit of the model to the data must also be assessed.

7. When a linear, non-threshold dose response relationship is assumed, the RAD shall be calculated using the following equation:

$$RAD = \frac{0.00001}{q_1^*}$$

Where:

RAD=risk associated dose in milligrams of toxicant per kilogram body weight per day (mg/kg/day).

0.00001 (1×10^{-5})=incremental risk of developing cancer equal to one in 100,000.

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

8. If human epidemiologic data and/or other biological data (animal) indicate that a chemical causes cancer via a threshold mechanism, the risk associated dose may, on a case-by-case basis, be calculated using a method which assumes a threshold mechanism is operative.

B. *Noncarcinogens.*

1. Noncarcinogens shall generally be assumed to have a threshold dose or concentration below which no adverse effects should be observed. Therefore, the Tier I criterion or Tier II value is the maximum water concentration of a substance at or below which a lifetime exposure from drinking the water, consuming fish caught in the water, and ingesting water as a result of participating in water-related recreation activities is likely to be without appreciable risk of deleterious effects.

For some noncarcinogens, there may not be a threshold dose below which no adverse effects should be observed. Chemicals acting as genotoxic teratogens and germline mutagens are thought to possibly produce reproductive and/or developmental effects via a genetically linked mechanism which may have no threshold. Other chemicals also may not demonstrate a threshold. Criteria for these types of chemicals will be established on a case-by-case basis using appropriate assumptions reflecting the likelihood that no threshold exists.

2. All appropriate human and animal toxicologic data shall be reviewed and evaluated. To the maximum extent possible, data most specific to the environmentally relevant route of exposure shall be used. Oral exposure data should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. When acceptable human data are not available (e.g., well-conducted epidemiologic studies), animal data from species most biologically relevant to humans shall be used. In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species showing a toxic effect at the lowest administered dose (given a relevant route of exposure), should generally be used.

3. Minimum data requirements are specified in section II.B of this appendix. The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) from studies satisfying the provisions of section II.B of this appendix shall be used for criteria calculations. In the absence of a NOAEL, the LOAEL from studies satisfying the provisions of section II.B of this appendix may be

used if it is based on relatively mild and reversible effects.

4. Uncertainty factors shall 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.

a. An uncertainty factor of 10 shall generally be used when extrapolating from valid experimental results from studies on prolonged exposure to average healthy humans. This 10-fold factor is used to protect sensitive members of the human population.

b. An uncertainty factor of 100 shall generally be used when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. In comparison to a, above, this represents an additional 10-fold uncertainty factor in extrapolating data from the average animal to the average human.

c. An uncertainty factor of up to 1000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than chronic, but greater than subchronic (e.g., 90 days or more in length), or when other significant deficiencies in study quality are present, and when useful long-term human data are not available. In comparison to b, above, this represents an additional UF of up to 10-fold for less than chronic, but greater than subchronic, studies.

d. An UF of up to 3000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than subchronic (e.g., 28 days). In comparison to b above, this represents an additional UF of up to 30-fold for less than subchronic studies (e.g., 28-day). The level of additional uncertainty applied for less than chronic exposures depends on the duration of the study used relative to the lifetime of the experimental animal.

e. An additional UF of between one and ten may be used when deriving a criterion from a LOAEL. This UF accounts for the lack of an identifiable NOAEL. The level of additional uncertainty applied may depend upon the severity and the incidence of the observed adverse effect.

f. An additional UF of between one and ten may be applied when there are limited effects data or incomplete sub-acute or chronic toxicity data (e.g., reproductive/developmental data). The level of quality and quantity of the experimental data available as well as structure-activity relationships may be used to determine the factor selected.

g. When deriving an UF in developing a Tier I criterion or Tier II value, the total uncertainty, as calculated following the guidance of sections 4.a through f, cited above, shall not exceed 10,000 for Tier I criteria and 30,000 for Tier II values.

5. All study results shall be converted, as necessary, to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses shall be adjusted for continuous exposure (i.e., seven days/week, 24 hours/day, etc.).

C. *Criteria and Value Derivation.*

1. *Standard Exposure Assumptions.* The following represent the standard exposure assumptions used to calculate Tier I criteria and Tier II values for carcinogens and noncarcinogens. Higher levels of exposure may be assumed by States and Tribes pursuant to Clean Water Act (CWA) section 510, or where appropriate in deriving site-specific criteria pursuant to procedure 1 in appendix F to part 132.

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

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

—or—

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

FC = per capita daily consumption of regionally caught freshwater fish = 0.015kg/day (0.0036 kg/day for trophic level 3 and 0.0114 kg/day for trophic level 4).

BAF = bioaccumulation factor for trophic level 3 and trophic level 4, as derived using the BAF methodology in appendix B to part 132.

2. *Carcinogens.* The Tier I human cancer criteria or Tier II values shall be calculated as follows:

$$HCV = \frac{RAD \times BW}{WC + \left[\left(FC_{TL3} \times BAF_{TL3}^{HH}\right) + \left(FC_{TL4} \times BAF_{TL4}^{HH}\right)\right]}$$

Where:

HCV=Human Cancer Value in milligrams per liter (mg/L).

RAD=Risk associated dose in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a

lifetime incremental cancer risk equal to one in 100,000.

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

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

or

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

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

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

BAF^{HH}_{TL3}=bioaccumulation factor for trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=bioaccumulation factor for trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.

3. *Noncarcinogens.* The Tier I human noncancer criteria or Tier II values shall be calculated as follows:

$$HNV = \frac{ADE \times BW \times RSC}{WC + \left[\left(FC_{TL3} \times BAF^{HH}_{TL3}\right) + \left(FC_{TL4} \times BAF^{HH}_{TL4}\right)\right]}$$

Where:

HNV=Human noncancer value in milligrams per liter (mg/L).

ADE=Acceptable daily exposure in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC=Relative source contribution factor of 0.8. An RSC derived from actual exposure data may be developed using the methodology outlined by the 1980 National Guidelines (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 surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion 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 methodology 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 methodology in appendix B to part 132.

IV. References

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

B. U.S. Environmental Protection Agency. 1980. Water Quality Criteria Availability, Appendix C Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Quality Criteria Documents. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH–550A), 401 M St., SW., Washington, DC 20460.

C. U.S. Environmental Protection Agency. 1986. Guidelines for Carcinogen Risk Assessment. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH–550A), 401 M St., SW., Washington, DC 20460.

Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology 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 populations inhabiting the Great Lakes basin from adverse effects resulting from the ingestion of water and aquatic prey taken from surface waters of the Great Lakes System. 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 (i.e., food and water consumption rates).

Since toxicological and exposure data for individual 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 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.

B. This appendix establishes a methodology 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 encouraged, but not required, for the development 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 Technical 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 methodology 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 representative species which are better examples of species with the highest exposures for the given chemical. The equation presented in this methodology, however, is still encouraged. In addition, procedure 1 of appendix F of this part describes the procedures for calculating 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 equation 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^{WL}_{TLi}=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 account 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 oral 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), 401 M St. SW, 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.

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

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)
Bald eagle	4.6	0.160	TL3: 0.371; TL4: 0.0929 ..... PB: 00283; 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.

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 water quality necessary to protect existing uses shall be maintained and protected. Where designated uses of the waterbody are impaired, there shall be no lowering of the water quality with respect to the pollutant or pollutants which are causing the impairment;

B. Where, for any parameter, the quality of the waters exceed levels necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water shall be considered high quality for that parameter consistent with the definition of high quality water found at section II.A of this appendix and that quality shall be maintained and protected unless the State or Tribe finds, after full satisfaction of intergovernmental coordination and public participation provisions of the State's or Tribe's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation, the State or Tribe shall assure water quality adequate to protect existing uses fully. Further, the State or Tribe shall assure that there shall be achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost-effective and reasonable best management practices for nonpoint source control. The State or Tribe shall utilize the Antidegradation Implementation Procedures adopted pursuant to the requirements of this regulation in determining if any lowering of water quality will be allowed;

C. Where high quality waters constitute an outstanding national resource, such as waters of national and State parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected; and

D. In those cases where the potential lowering of water quality is associated with a thermal discharge, the decision to allow such degradation shall be consistent with section 316 of the Clean Water Act (CWA).

II. ANTIDEGRADATION IMPLEMENTATION PROCEDURES

A. *Definitions.*

Control Document. Any authorization issued by a State, Tribal or Federal agency to any source of pollutants to waters under its jurisdiction that specifies conditions under which the source is allowed to operate.

High quality waters. High quality waters are water bodies in which, on a parameter by parameter basis, the quality of the waters exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water.

Lake Superior Basin—Outstanding International Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to ensure that any new or increased discharges of Lake Superior bioaccumulative substances of immediate concern are subject to best technology in process and treatment requirements.

Lake Superior Basin—Outstanding National Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to prohibit new or increased discharges of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

Lake Superior bioaccumulative substances of immediate concern. A list of substances identified in the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. They include: 2, 3, 7, 8-TCDD; octachlorostyrene; hexachlorobenzene; chlordane; DDT, DDE, and other metabolites; toxaphene; PCBs; and mercury. Other chemicals may be added to the list following States' or Tribes' assessments of environmental effects and impacts and after public review and comment.

Outstanding National Resource Waters. Those waters designated as such by a Tribe or State. The State or Tribal designation shall describe the quality of such waters to serve as the benchmark of the water quality that shall be maintained and protected. Waters that may be considered for designation as Outstanding National Resource Waters include, but are not limited to, water bodies that are recognized as:

Important because of protection through official action, such as Federal or State law, Presidential or secretarial action, international treaty, or interstate compact;

Having exceptional recreational significance;

Having exceptional ecological significance;

Having other special environmental, recreational, or ecological attributes; or waters whose designation as Outstanding National Resource Waters is reasonably necessary for the protection of other waters so designated.

Significant Lowering of Water Quality. A significant lowering of water quality occurs when there is a new or increased loading of any BCC from any regulated existing or new facility, either point source or nonpoint source for which there is a control document or reviewable action, as a result of any activity including, but not limited to:

(1) Construction of a new regulated facility or modification of an existing regulated facility such that a new or modified control document is required;

(2) Modification of an existing regulated facility operating under a current control document such that the production capacity of the facility is increased;

(3) Addition of a new source of untreated or pretreated effluent containing or expected to contain any BCC to an existing wastewater treatment works, whether public or private;

(4) A request for an increased limit in an applicable control document;

(5) Other deliberate activities that, based on the information available, could be reasonably expected to result in an increased loading of any BCC to any waters of the Great Lakes System.

b. Notwithstanding the above, changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review. These changes include, but are not limited to:

(1) Normal operational variability;

(2) Changes in intake water pollutants;

(3) Increasing the production hours of the facility, (e.g., adding a second shift); or

(4) Increasing the rate of production.

C. Also, excluded from an antidegradation review are new effluent limits based on improved monitoring data or new water quality criteria or values that are not a result of changes in pollutant loading.

B. For all waters, the Director shall ensure that the level of water quality necessary to protect existing uses is maintained. In order to achieve this requirement, and consistent with 40 CFR 131.10, water quality standards use designations must include all existing uses. Controls shall be established as necessary on point and nonpoint sources of pollutants to ensure that the criteria applicable to the designated use are achieved in the water and that any designated use of a downstream water is protected. Where water quality does not support the designated uses of a waterbody or ambient pollutant concentrations exceed water quality criteria applicable to that waterbody, the Director shall not allow a lowering of water quality for the pollutant or pollutants preventing the attainment of such uses or exceeding such criteria.

C. For Outstanding National Resource Waters:

1. The Director shall ensure, through the application of appropriate controls on pollutant sources, that water quality is maintained and protected.

2. Exception. A short-term, temporary (i.e., weeks or months) lowering of water quality may be permitted by the Director.

D. For high quality waters, the Director shall ensure that no action resulting in a lowering of water quality occurs unless an antidegradation demonstration has been completed pursuant to section III of this appendix and the information thus provided is

determined by the Director pursuant to section IV of this appendix to adequately support the lowering of water quality.

1. The Director shall establish conditions in the control document applicable to the regulated facility that prohibit the regulated facility from undertaking any deliberate action, such that there would be an increase in the rate of mass loading of any BCC, unless an antidegradation demonstration is provided to the Director and approved pursuant to section IV of this appendix prior to commencement of the action. Imposition of limits due to improved monitoring data or new water quality criteria or values, or changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review.

2. For BCCs known or believed to be present in a discharge, from a point or nonpoint source, a monitoring requirement shall be included in the control document. The control document shall also include a provision requiring the source to notify the Director or any increased loadings. Upon notification, the Director shall require actions as necessary to reduce or eliminate the increased loading.

3. Fact Sheets prepared pursuant to 40 CFR 124.8 and 124.56 shall reflect any conditions developed under sections II.D.1 or II.D.2 of this appendix and included in a permit.

E. *Special Provisions for Lake Superior.* The following conditions apply in addition to those specified in section II.B through II.C of this appendix for waters of Lake Superior so designated.

1. A State or Tribe may designate certain specified areas of the Lake Superior Basin as Lake Superior Basin—Outstanding National Resource Waters for the purpose of prohibiting the new or increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

2. States and Tribes may designate all waters of the Lake Superior Basin as Outstanding International Resource Waters for the purpose of restricting the increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources consistent with the requirements of sections III.C and IV.B of this appendix.

F. *Exemptions.* Except as the Director may determine on a case-by-case basis that the application of these procedures is required to adequately protect water quality, or as the affected waterbody is an Outstanding National Resource Water as defined in section II.A of this appendix, the procedures in this part do not apply to:

1. Short-term, temporary (i.e., weeks or months) lowering of water quality;

2. Bypasses that are not prohibited at 40 CFR 122.41(m); and

3. Response actions pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), as amended, or similar Federal, State or Tribal authorities, undertaken to alleviate a release into the environment of hazardous substances, pollutants or contaminants which may pose an imminent and substantial danger to public health or welfare.

III. Antidegradation Demonstration

Any entity seeking to lower water quality in a high quality water or create a new or increased discharge of Lake Superior bioaccumulative substances of immediate concern in a Lake Superior Outstanding International Resource Water must first, as required by sections II.D or II.E.2 of this appendix, submit an antidegradation demonstration for consideration by the Director. States and Tribes should tailor the level of detail and documentation in antidegradation reviews, to the specific circumstances encountered. The antidegradation demonstration shall include the following:

A. *Pollution Prevention Alternatives Analysis.* Identify any cost-effective pollution prevention alternatives and techniques that are available to the entity, that would eliminate or significantly reduce the extent to which the increased loading results in a lowering of water quality.

B. *Alternative or Enhanced Treatment Analysis.* Identify alternative or enhanced treatment techniques that are available to the entity that would eliminate the lowering of water quality and their costs relative to the cost of treatment necessary to achieve applicable effluent limitations.

C. *Lake Superior.* If the States or Tribes designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, then any entity proposing a new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern to the Lake Superior Basin shall identify the best technology in process and treatment to eliminate or reduce the extent of the lowering of water quality. In this case, the requirements in section III.B of this appendix do not apply.

D. *Important Social or Economic Development Analysis.* Identify the social or economic development and the benefits to the area in which the waters are located that will be foregone if the lowering of water quality is not allowed.

E. *Special Provision for Remedial Actions.* Entities proposing remedial actions pursuant to the CERCLA, as amended, corrective actions pursuant to the Resource Conservation and Recovery Act, as amended, or similar actions pursuant to other Federal or State environmental statutes may submit information to the Director that demonstrates that the action utilizes the most cost effective

pollution prevention and treatment techniques available, and minimizes the necessary lowering of water quality, in lieu of the information required by sections III.B through III.D of this appendix.

IV. Antidegradation Decision

A. Once the Director determines that the information provided by the entity proposing to increase loadings is administratively complete, the Director shall use that information to determine whether or not the lowering of water quality is necessary, and, if it is necessary, whether or not the lowering of water quality will support important social and economic development in the area. If the proposed lowering of water quality is either not necessary, or will not support important social and economic development, the Director shall deny the request to lower water quality. If the lowering of water quality is necessary, and will support important social and economic development, the Director may allow all or part of the proposed lowering to occur as necessary to accommodate the important social and economic development. In no event may the decision reached under this section allow water quality to be lowered below the minimum level required to fully support existing and designated uses. The decision of the Director shall be subject to the public participation requirements of 40 CFR 25.

B. If States designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, any entity requesting to lower water quality in the Lake Superior Basin as a result of the new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern shall be required to install and utilize the best technology in process and treatment as identified by the Director.

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Procedure 1: Site-specific Modifications to Criteria and Values

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

A. Requirements for Site-specific Modifications to Criteria and Values. Criteria and values may be modified on a site-specific basis to reflect local environmental conditions as restricted by the following provisions. Any such modifications must be protective of designated uses and aquatic life, wildlife or human health and be submitted to EPA for approval. In addition, any site-specific modifications that result in less stringent criteria must be based on a sound scientific rationale and shall not be likely to jeopardize the continued existence of endangered or threatened species listed or proposed under section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications shall be developed to protect endangered or threatened species listed or proposed under section 4 of the ESA, 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. More stringent modifications may also be developed to protect candidate (C1) species being considered by the U.S. Fish and Wildlife Service (FWS) for listing under section 4 of the ESA, where such modifications are necessary to protect such species.

1. *Aquatic Life.*

a. Aquatic life criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act (CWA) section 510.

Guidance on developing site-specific criteria in these instances is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

b. Less stringent site-specific modifications to chronic or acute aquatic life criteria or values may be developed when:

i. The local water quality characteristics such as Ph, hardness, temperature, color, etc., alter the biological availability or toxicity of a pollutant; or

ii. The sensitivity of the aquatic organisms species that ''occur at the site'' differs from the species actually tested in developing the criteria. The phrase ''occur at the site'' includes the species, genera, families, orders, classes, and phyla that: are usually present at the site; are present at the site only seasonally due to migration; are present intermittently because they periodically return to or extend their ranges into the site; were present at the site in the past, are not currently present at the site due to degraded conditions, and are expected to return to the site when conditions improve; are present in nearby bodies of water, are not currently present at the site due to degraded conditions, and are expected to be present at the site when conditions improve. The taxa that ''occur at the site'' cannot be determined merely by sampling downstream and/or upstream of the site at one point in time. ''Occur at the site'' does not include taxa that were once present at the site but cannot exist at the site now due to permanent physical alteration of the habitat at the site resulting, for example, from dams, etc.

c. Less stringent modifications also may be developed to acute and chronic aquatic life criteria or values to reflect local physical and hydrological conditions.

Guidance on developing site-specific criteria is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

d. Any modifications to protect threatened or endangered aquatic species required by procedure 1.A of this appendix may be accomplished using either of the two following procedures:

i. If the Species Mean Acute Value (SMAV) for a listed or proposed species, or for a surrogate of such species, is lower than the calculated Final Acute Value (FAV), such lower SMAV may be used instead of the calculated FAV in developing site-specific modified criteria; or,

ii. The site-specific criteria may be calculated using the recalculation procedure for site-specific modifications described in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

2. *Wildlife.*

a. Wildlife water quality criteria may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510.

b. Less stringent site-specific modifications to wildlife water quality criteria may be developed when a site-specific bioaccumulation factor (BAF) is derived which is lower than the system-wide BAF derived under appendix B of this part. The modification must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed. In addition, there must be a showing that:

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

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

c. Any modification to protect endangered or threatened wildlife species required by procedure 1.A of this appendix must 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.

i. The methodology presented in appendix D to part 132 is used, substituting appropriate species-specific toxicological, epidemiological, or exposure information, including changes to the BAF;

ii. 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 in Appendix D of this part;

iii. 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 in appendix D of this part in a manner consistent with the other uncertainty factors described in appendix D of this part; and

iv. 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 shall be selected as the site-specific modification.

NOTE: Further discussion on the use of this methodology may be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria.

3. *BAFs.*

a. BAFs may be modified on a site-specific basis to larger values, pursuant to the authority reserved to the States and Tribes under CWA section 510, where reliable data show that local bioaccumulation is greater than the system-wide value.

b. BAFs may be modified on a site-specific basis to lower values, where scientifically defensible, if:

i. The fraction of the total chemical that is freely dissolved in the ambient water is different than that used to derive the system-wide BAFs (i.e., the concentrations of particulate organic carbon and the dissolved organic carbon are different than those used to derive the system-wide BAFs);

ii. Input parameters of the Gobas model, such as the structure of the aquatic food web and the disequilibrium constant, are different at the site than those used to derive the system-wide BAFs;

iii. The percent lipid of aquatic organisms that are consumed and occur at the site is different than that used to derive the system-wide BAFs; or

iv. Site-specific field-measured BAFs or biota-sediment accumulation factor (BSAFs) are determined.

If site-specific BAFs are derived, they shall be derived using the methodology in appendix B of this part.

c. Any more stringent modifications to protect threatened or endangered species required by procedure 1.A of this appendix shall be derived using procedures set forth in the methodology in appendix B of this part.

4. *Human Health.*

a. Human health criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510. Human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations.

b. Less stringent site-specific modifications to human health criteria or values may be developed when:

i. local fish consumption rates are lower than the rate used in deriving human health

criteria or values under appendix C of this part; and/or

ii. a site-specific BAF is derived which is lower than that used in deriving human health criteria or values under appendix C of this part.

B. *Notification Requirements.* When a State proposes a site-specific modification to a criterion or value as allowed in section 4.A above, the State should notify the other Great Lakes States of such a proposal and, for less stringent criteria, supply appropriate justification.

C. *References.*

U.S. EPA. 1984. Water Quality Standards Handbook—Revised. Chapter 3 and Appendices. U.S. Environmental Protection Agency, Office of Water Resource Center (RC–4100), 401 M Street, SW., Washington, DC 20960.

PROCEDURE 2: VARIANCES FROM WATER QUALITY STANDARDS FOR POINT SOURCES

The Great Lakes States or Tribes may adopt water quality standards (WQS) variance procedures and may grant WQS variances for point sources pursuant to such procedures. Variance procedures shall be consistent with (as protective as) the provisions in this procedure.

A. *Applicability.* A State or Tribe may grant a variance to a WQS which is the basis of a water quality-based effluent limitation included in a National Pollutant Discharge Elimination System (NPDES) permit. A WQS variance applies only to the permittee requesting the variance and only to the pollutant or pollutants specified in the variance. A variance does not affect, or require the State or Tribe to modify, the corresponding water quality standard for the waterbody as a whole.

1. This provision shall not apply to new Great Lakes dischargers or recommencing dischargers.

2. A variance to a water quality standard shall not be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under Section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat.

3. A WQS variance shall not be granted if standards will be attained by implementing effluent limits required under sections 301(b) and 306 of the Clean Water Act (CWA) and by the permittee implementing cost-effective and reasonable best management practices for nonpoint source control.

B. *Maximum Timeframe for Variances.* A WQS variance shall not exceed five years or the term of the NPDES permit, whichever is less. A State or Tribe shall review, and modify as necessary, WQS variances as part of each water quality standards review pursuant to section 303(c) of the CWA.

C. *Conditions to Grant a Variance.* A variance may be granted if:

1. The permittee demonstrates to the State or Tribe that attaining the WQS is not feasible because:

a. Naturally occurring pollutant concentrations prevent the attainment of the WQS;

b. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the WQS, unless these conditions may be compensated for by the discharge of sufficient volume of effluent to enable WQS to be met without violating State or Tribal water conservation requirements;

c. Human-caused conditions or sources of pollution prevent the attainment of the WQS and cannot be remedied, or would cause more environmental damage to correct than to leave in place;

d. Dams, diversions or other types of hydrologic modifications preclude the attainment of the WQS, and it is not feasible to restore the waterbody to its original condition or to operate such modification in a way that would result in the attainment of the WQS;

e. Physical conditions related to the natural features of the waterbody, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of WQS; or

f. Controls more stringent than those required by sections 301(b) and 306 of the CWA would result in substantial and widespread economic and social impact.

2. In addition to the requirements of C.1, above, the permittee shall also:

a. Show that the variance requested conforms to the requirements of the State's or Tribe's antidegradation procedures; and

b. Characterize the extent of any increased risk to human health and the environment associated with granting the variance compared with compliance with WQS absent the variance, such that the State or Tribe is able to conclude that any such increased risk is consistent with the protection of the public health, safety and welfare.

D. *Submittal of Variance Application.* The permittee shall submit an application for a variance to the regulatory authority issuing the permit. The application shall include:

1. All relevant information demonstrating that attaining the WQS is not feasible based on one or more of the conditions in section C.1 of this procedure; and,

2. All relevant information demonstrating compliance with the conditions in section C.2 of this procedure.

E. *Public Notice of Preliminary Decision.* Upon receipt of a complete application for a variance, and upon making a preliminary decision regarding the variance, the State or

Tribe shall public notice the request and preliminary decision for public comment pursuant to the regulatory authority's Administrative Procedures Act and shall notify the other Great Lakes States and Tribes of the preliminary decision. This public notice requirement may be satisfied by including the supporting information for the variance and the preliminary decision in the public notice of a draft NPDES permit.

F. *Final Decision on Variance Request.* The State or Tribe shall issue a final decision on the variance request within 90 days of the expiration of the public comment period required in section E of this procedure. If all or part of the variance is approved by the State or Tribe, the decision shall include all permit conditions needed to implement those parts of the variance so approved. Such permit conditions shall, at a minimum, require:

1. Compliance with an initial effluent limitation which, at the time the variance is granted, represents the level currently achievable by the permittee, and which is no less stringent than that achieved under the previous permit;

2. That reasonable progress be made toward attaining the water quality standards for the waterbody as a whole through appropriate conditions;

3. When the duration of a variance is shorter than the duration of a permit, compliance with an effluent limitation sufficient to meet the underlying water quality standard, upon the expiration of said variance; and

4. A provision that allows the permitting authority to reopen and modify the permit based on any State or Tribal triennial water quality standards revisions to the variance.

The State shall deny a variance request if the permittee fails to make the demonstrations required under section C of this procedure.

G. *Incorporating Variance into Permit.* The State or Tribe shall establish and incorporate into the permittee's NPDES permit all conditions needed to implement the variance as determined in section F of this procedure.

H. *Renewal of Variance.* A variance may be renewed, subject to the requirements of sections A through G of this procedure. As part of any renewal application, the permittee shall again demonstrate that attaining WQS is not feasible based on the requirements of section C of this procedure. The permittee's application shall also contain information concerning its compliance with the conditions incorporated into its permit as part of the original variance pursuant to sections F and G of this procedure. Renewal of a variance may be denied if the permittee did not comply with the conditions of the original variance.

I. *EPA Approval.* All variances and supporting information shall be submitted by the State or Tribe to the appropriate EPA regional office and shall include:

1. Relevant permittee applications pursuant to section D of this procedure;

2. Public comments and records of any public hearings pursuant to section E of this procedure;

3. The final decision pursuant to section F of this procedure; and,

4. NPDES permits issued pursuant to section G of this procedure.

5. Items required by sections I.1 through I.3. of this procedure shall be submitted by the State within 30 days of the date of the final variance decision. The item required by section I.4 of this procedure shall be submitted in accordance with the State or Tribe Memorandum of Agreement with the Regional Administrator pursuant to 40 CFR 123.24.

6. EPA shall review the State or Tribe submittal for compliance with the CWA pursuant to 40 CFR 123.44, and 40 CFR 131.21.

J. *State WQS Revisions.* All variances shall be appended to the State or Tribe WQS rules.

Procedure 3: Total Maximum Daily Loads, Wasteload Allocations for Point Sources, Load Allocations for Nonpoint Sources, Wasteload Allocations in the Absence of a TMDL, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure 3 for the purpose of developing Total Maximum Daily Loads (TMDLs), Wasteload Allocations (WLAs) in the Absence of TMDLs, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits (WQBELs), except as specifically provided.

A. Where a State or Tribe develops an assessment and remediation plan that the State or Tribe certifies meets the requirements of sections B through F of this procedure and public participation requirements applicable to TMDLs, and that has been approved by EPA as meeting those requirements under 40 CFR 130.6, the assessment and remediation plan may be used in lieu of a TMDL for purposes of appendix F to part 132. Assessment and remediation plans under this procedure may include, but are not limited to, Lakewide Management Plans, Remedial Action Plans, and State Water Quality Management Plans. Also, any part of an assessment and remediation plan that also satisfies one or more requirements under Clean Water Act (CWA) section 303(d) or implementing regulations may be incorporated by reference into a TMDL as appropriate. Assessment and remediation plans under this

section should be tailored to the level of detail and magnitude for the watershed and pollutant being assessed.

B. *General Conditions of Application.* Except as provided in §132.4, the following are conditions applicable to establishing TMDLs for all pollutants and pollutant parameters in the Great Lakes System, with the exception of whole effluent toxicity, unless otherwise provided in procedure 6 of appendix F. Where specified, these conditions also apply to wasteload allocations (WLAs) calculated in the absence of TMDLs and to preliminary WLAs for purposes of determining the needs for WQBELs under procedure 5 of appendix F.

1. *TMDLs Required.* TMDLs shall, at a minimum, be established in accordance with the listing and priority setting process established in section 303(d) of the CWA and at 40 CFR 130.7. Where water quality standards cannot be attained immediately, TMDLs must reflect reasonable assurances that water quality standards will be attained in a reasonable period of time. Some TMDLs may be based on attaining water quality standards over a period of time, with specific controls on individual sources being implemented in stages. Determining the reasonable period of time in which water quality standards will be met is a case-specific determination considering a number of factors including, but not limited to: receiving water characteristics; persistence, behavior and ubiquity of pollutants of concern; type of remediation activities necessary; available regulatory and non-regulatory controls; and individual State or Tribal requirements for attainment of water quality standards.

2. *Attainment of Water Quality Standards.* A TMDL must ensure attainment of applicable water quality standards, including all numeric and narrative criteria, Tier I criteria, and Tier II values for each pollutant or pollutants for which a TMDL is established.

3. *TMDL Allocations.*

a. TMDLs shall include WLAs for point sources and load allocations (LAs) for nonpoint sources, including natural background, such that the sum of these allocations is not greater than the loading capacity of the water for the pollutant(s) addressed by the TMDL, minus the sum of a specified margin of safety (MOS) and any capacity reserved for future growth.

b. Nonpoint source LAs shall be based on:

i. Existing pollutant loadings if changes in loadings are not reasonably anticipated to occur;

ii. Increases in pollutant loadings that are reasonably anticipated to occur;

iii. Anticipated decreases in pollutant loadings if such decreased loadings are technically feasible and are reasonably anticipated to occur within a reasonable time period as a result of implementation of best management practices or other load reduction measures. In determining whether anticipated decreases in pollutant loadings are technically feasible and can reasonably be expected to occur within a reasonable period of time, technical and institutional factors shall be considered. These decisions are case-specific and should reflect the particular TMDL under consideration.

c. WLAs. The portion of the loading capacity not assigned to nonpoint sources including background, or to an MOS, or reserved for future growth is allocated to point sources. Upon reissuance, NPDES permits for these point sources must include effluent limitations consistent with WLAs in EPA-approved or EPA-established TMDLs.

d. Monitoring. For LAs established on the basis of subsection b.iii above, monitoring data shall be collected and analyzed in order to validate the TMDL's assumptions, to varify anticipated load reductions, to evaluate the effectiveness of controls being used to implement the TMDL, and to revise the WLAs and LAs as necessary to ensure that water quality standards will be achieved within the time-period established in the TMDL.

4. *WLA Values.* If separate EPA-approved or EPA-established TMDLs are prepared for different segments of the same watershed, and the separate TMDLs each include WLAs for the same pollutant for one or more of the same point sources, then WQBELs for that pollutant for the point source(s) shall be consistent with the most stringent of those WLAs in order to ensure attainment of all applicable water quality standards.

5. *Margin of Safety (MOS).* Each TMDL shall include a MOS sufficient to account for technical uncertainties in establishing the TMDL and shall describe the manner in which the MOS is determined and incorporated into the TMDL. The MOS may be provided by leaving a portion of the loading capacity unallocated or by using conservative modeling assumptions to establish WLAs and LAs. If a portion of the loading capacity is left unallocated to provide a MOS, the amount left unallocated shall be described. If conservative modeling assumptions are relied on to provide a MOS, the specific assumptions providing the MOS shall be identified.

6. *More Stringent Requirements.* States and Tribes may exercise authority reserved to them under section 510 of the CWA to develop more stringent TMDLs (including WLAs and LAs) than are required herein, provided that all LAs in such TMDLs reflect actual nonpoint source loads or those loads that can reasonably be expected to occur within a reasonable time-period as a result of implementing nonpoint source controls.

7. *Accumulation in Sediments.* TMDLs shall reflect, where appropriate and where sufficient data are available, contributions to the water column from sediments inside and outside of any applicable mixing zones. TMDLs

shall be sufficiently stringent so as to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life.

8. *Wet Weather Events.* Notwithstanding the exception provided for the establishment of controls on wet weather point sources in §132.4(e)(1), TMDLs shall reflect, where appropriate and where sufficient data are available, discharges resulting from wet weather events. This procedure does not provide specific procedures for considering discharges resulting from wet weather events. However, some of the provisions of procedure 3 may be deemed appropriate for considering wet weather events on a case-by-case basis.

9. *Background Concentration of Pollutants.* The representative background concentration of pollutants shall be established in accordance with this subsection to develop TMDLs, WLAs calculated in the absence of a TMDL, or preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F. Background loadings may be accounted for in a TMDL through an allocation to a single ''background'' category or through individual allocations to the various background sources.

a. *Definition of Background.* ''Background'' represents all loadings that: (1) flow from upstream waters into the specified watershed, waterbody or waterbody segment for which a TMDL, WLA in the absence of a TMDL or preliminary WLA for the purpose of determining the need for a WQBEL is being developed; (2) enter the specified watershed, waterbody or waterbody segment through atmospheric deposition or sediment release or resuspension; or (3) occur within the watershed, waterbody or waterbody segment as a result of chemical reactions.

b. *Data considerations.* When determining what available data are acceptable for use in calculating background, the State or Tribe should use best professional judgment, including consideration of the sampling location and the reliability of the data through comparison to reported analytical detection levels and quantification levels. When data in more than one of the data sets or categories described in section B.9.c.i through B.9.c.iii below exist, best professional judgment should be used to select the one data set that most accurately reflects or estimates background concentrations. Pollutant degradation and transport information may be considered when utilizing pollutant loading data.

c. *Calculation requirements.* Except as provided below, the representative background concentration for a pollutant in the specified watershed, waterbody or waterbody segment shall be established on a case-by-case basis as the geometric mean of:

i. Acceptable available water column data; or

ii. Water column concentrations estimated through use of acceptable available caged or resident fish tissue data; or

iii. Water column concentrations estimated through use of acceptable available or projected pollutant loading data.

d. *Detection considerations.*

i. Commonly accepted statistical techniques shall be used to evaluate data sets consisting of values both above and below the detection level.

ii. When all of the acceptable available data in a data set or category, such as water column, caged or resident fish tissue or pollutant loading data, are below the level of detection for a pollutant, then all the data for that pollutant in that data set shall be assumed to be zero.

10. *Effluent Flow.* If WLAs are expressed as concentrations of pollutants, the TMDL shall also indicate the point source effluent flows assumed in the analyses. Mass loading limitations established in NPDES permits must be consistent with both the WLA and assumed effluent flows used in establishing the TMDL.

11. *Reserved Allocations.* TMDLs may include reserved allocations of loading capacity to accommodate future growth and additional sources. Where such reserved allocations are not included in a TMDL, any increased loadings of the pollutant for which the TMDL was developed that are due to a new or expanded discharge shall not be allowed unless the TMDL is revised in accordance with these proceudres to include an allocation for the new or expanded discharge.

C. [Reserved]

D. *Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources: WLAs in the Absence of a TMDL; and Preliminary WLAs for Purposes of Determining the Need for WQBELs for OWGL.* This section addresses conditions for deriving TMDLs for Open Waters of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes. State and Tribal procedures to derive TMDLs under this section must be consistent with (as protective as) the general conditions in section B of this procedure, CWA section 303(d), existing regulations (40 CFR 130.7), section C of this procedure, and sections D.1. through D.4 below. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F must be consistent with sections B.9, C.1, C3 through C.6, and D. 1 through D.4 of this procedure.

1. Individual point source WLAs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall assume no greater dilution than one part effluent to 10 parts receiving water for implementation of numeric and

narrative chronic criteria and values (including, but not limited to human cancer criteria, human cancer values, human noncancer values, human noncancer criteria, wildlife criteria, and chronic aquatic life criteria and values) unless an alternative mixing zone is demonstrated as appropriate in a mixing zone demonstration conducted pursuant to section F of this procedure. In no case shall a mixing zone be granted that exceeds the area where discharge-induced mixing occurs.

2. Appropriate mixing zone assumptions to be used in calculating load allocations for nonpoint sources shall be determined, consistent with applicable State or Tribal requirements, on a case-by-case basis.

3. WLAs and preliminary WLAs based on acute aquatic life criteria or values shall not exceed the Final Acute Value (FAV), unless a mixing zone demonstration is conducted and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where acute mixing zones overlap.

4. In no case shall a mixing zone be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

E. *Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources; WLAs in the Absence of a TMDL; and Preliminary WLAs for the Purposes of Determining the Need for WQBELs for Great Lakes Systems Tributaries and Connecting Channels.* This section describes conditions for deriving TMDLs for tributaries and connecting channels of the Great Lakes System that exhibit appreciable flows relative to their volumes. State and Tribal procedures to derive TMDLs must be consistent with the general conditions listed in section B of this procedure, section C of this procedure, existing TMDL regulations (40 CFR 130.7) and specific conditions E.1 through E.5. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of this appendix for discharges to tributaries and connecting channels must be consistent with sections B.9, C.1, C.3 through C.6, and E.1 through E.5 of this procedure.

1. *Stream Design.* These design flows must be used unless data exist to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions. For purposes of calculating a TMDL, WLAs in the absence of a TMDL, or preliminary WLAs for the purposes of determining reasonable potential under procedure 5 of this appendix, using a steady-state model, the stream design flows shall be:

a. The 7-day, 10-year stream design flow (7Q10), or the 4-day, 3-year biologically-based stream design flow for chronic aquatic life criteria or values;

b. The 1-day, 10-year stream design flow (1Q10), for acute aquatic life criteria or values;

c. The harmonic mean flow for human health criteria or values;

d. The 90-day, 10-year flow (90Q10) for wildlife criteria.

e. TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for the purpose of determining the need for WQBELs calculated using dynamic modelling do not need to incorporate the stream design flows specified in sections E.1.a through E.1.d of this procedure.

2. *Loading Capacity.* The loading capacity is the greatest amount of loading that a water can receive without violating water quality standards. The loading capacity is initially calculated at the farthest downstream location in the watershed drainage basin. The maximum allowable loading consistent with the attainment of each applicable numeric criterion or value for a given pollutant is determined by multiplying the applicable criterion or value by the flow at the farthest downstream location in the tributary basin at the design flow condition described above. This loading is then compared to the loadings at sites within the basin to assure that applicable numeric criteria or values for a given pollutant are not exceeded at all applicable sites. The lowest load is then selected as the loading capacity.

3. *Polluant Degradation.* TMDLs, WLAs in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall be based on the assumption that a pollutant does not degrade. However, the regulatory authority may take into account degradation of the pollutant if each of the following conditions are met.

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered;

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

4. *Acute Aquatic Life Criteria and Values.* WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purpose of determining the need for WQBELs based on acute aquatic life criteria or values shall not exceed the FAV,

unless a mixing zone demonstration is completed and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where any applicable acute mixing zones overlap. This acute WLA review shall include, but not be limited to, consideration of:

a. The expected dilution under all effluent flow and concentration conditions at stream design flow;

b. Maintenance of a zone of passage for aquatic organisms; and

c. Protection of critical aquatic habitat.

In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

5. *Chronic Mixing Zones.* WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purposes of determining the need for WQBELs for protection of aquatic life, wildlife and human health from chronic effects shall be calculated using a dilution fraction no greater than 25 percent of the stream design flow unless a mixing zone demonstration pursuant to section F of this procedure is conducted and approved. A demonstration for a larger mixing zone may be provided, if approved and implemented in accordance with section F of this procedure. In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

F. *Mixing Zone Demonstration Requirements.*

1. For purposes of establishing a mixing zone other than as specified in sections D and E above, a mixing zone demonstration must:

a. Describe the amount of dilution occurring at the boundaries of the proposed mixing zone and the size, shape, and location of the area of mixing, including the manner in which diffusion and dispersion occur;

b. For sources discharging to the open waters of the Great Lakes (OWGLs), define the location at which discharge-induced mixing ceases;

c. Document the substrate character and geomorphology within the mixing zone;

d. Show that the mixing zone does not interfere with or block passage of fish or aquatic life;

e. Show that the mixing zone will be allowed only to the extent that the level of the pollutant permitted in the waterbody would not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

f. Show that the mixing zone does not extend to drinking water intakes;

g. Show that the mixing zone would not otherwise interfere with the designated or existing uses of the receiving water or downstream waters;

h. Document background water quality concentrations;

i. Show that the mixing zone does not promote undesirable aquatic life or result in a dominance of nuisance species; and

j. Provide that by allowing additional mixing/dilution:

i. Substances will not settle to form objectionable deposits;

ii. Floating debris, oil, scum, and other matter in concentrations that form nuisances will not be produced; and

iii. Objectionable color, odor, taste or turbidity will not be produced.

2. In addition, the mixing zone demonstration shall address the following factors:

a. Whether or not adjacent mixing zones overlap;

b. Whether organisms would be attracted to the area of mixing as a result of the effluent character; and

c. Whether the habitat supports endemic or naturally occurring species.

3. The mixing zone demonstration must be submitted to EPA for approval. Following approval of a mixing zone demonstration consistent with sections F.1 and F.2, adjustment to the dilution ratio specified in section D.1 of this procedure shall be limited to the dilution available in the area where discharger-induced mixing occurs.

4. The mixing zone demonstration shall be based on the assumption that a pollutant does not degrade within the proposed mixing zone, unless:

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered; and

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

PROCEDURE 4: ADDITIVITY

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

A. The Great Lakes States and Tribes shall adopt provisions to protect human health from the potential adverse additive effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. For the chlorinated dibenzo-p-

dioxins (CDDs) and chlorinated dibenzofurans (CDFs) listed in Table 1, potential adverse additive effects in effluents shall be accounted for in accordance with section B of this procedure.

B. *Toxicity Equivalency Factors (TEFs)/Bioaccumulation Equivalency Factors (BEFs).*

1. The TEFs in Table 1 and BEFs in Table 2 shall be used when calculating a 2,3,7,8-TCDD toxicity equivalence concentration in effluent to be used when implementing both human health noncancer and cancer criteria. The chemical concentration of each CDDs and CDFs in effluent shall be converted to a 2,3,7,8-TCDD toxicity equivalence concentration in effluent by (a) multiplying the chemical concentration of each CDDs and CDFs in the effluent by the appropriate TEF in Table 1 below, (b) multiplying each product from step (a) by the BEF for each CDDs and CDFs in Table 2 below, and (c) adding all final products from step (b). The equation for calculating the 2,3,7,8-TCDD toxicity equivalence concentration in effluent is:

$$(TEC)_{tcdd} = \sum (C)_x (TEF)_x (BEF)_x$$

where:

$(TEC)_{tcdd}$=2,3,7,8-TCDD toxicity equivalence concentration in effluent

$(C)_x$=concentration of total chemical x in effluent

$(TEF)_x$=TCDD toxicity equivalency factor for x

$(BEF)_x$=TCDD bioaccumulation equivalency factor for x

2. The 2,3,7,8-TCDD toxicity equivalence concentration in effluent shall be used when developing waste load allocations under procedure 3, preliminary waste load allocations for purposes of determining reasonable potential under procedure 5, and for purposes of establishing effluent quality limits under procedure 5.

TABLE 1.—TOXICITY EQUIVALENCY FACTORS FOR CDDS AND CDFS

Congener	TEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.5
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.001
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.5
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.001

TABLE 2.—BIOACCUMULATION EQUIVALENCY FACTORS FOR CDDS AND CDFS

Congener	BEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.9
1,2,3,4,7,8-HxCDD	0.3
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.05
OCDD	0.01
2,3,7,8-TCDF	0.8
1,2,3,7,8-PeCDF	0.2
2,3,4,7,8-PeCDF	1.6
1,2,3,4,7,8-HxCDF	0.08
1,2,3,6,7,8-HxCDF	0.2
2,3,4,6,7,8-HxCDF	0.7
1,2,3,7,8,9-HxCDF	0.6
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.4
OCDF	0.02

PROCEDURE 5: REASONABLE POTENTIAL TO EXCEED WATER QUALITY STANDARDS

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure. If a permitting authority determines that a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value, the permitting authority shall incorporate a water quality-based effluent limitation (WQBEL) in an NPDES permit for the discharge of that pollutant. When facility-specific effluent monitoring data are available, the permitting authority shall make this determination by developing preliminary effluent limitations (PEL) and comparing those effluent limitations to the projected effluent quality (PEQ) of the discharge in accordance with the following procedures. In all cases, the permitting authority shall use any valid, relevant, representative information that indicates a reasonable potential to exceed any Tier I criterion or Tier II value.

A. *Developing Preliminary Effluent Limitations on the Discharge of a Pollutant From a Point Source.*

1. The permitting authority shall develop preliminary wasteload allocations (WLAs) for the discharge of the pollutant from the point source to protect human health, wildlife, acute aquatic life, and chronic aquatic life, based upon any existing Tier I criteria. Where there is no Tier I criterion nor sufficient data to calculate a Tier I criterion, the permitting authority shall calculate a Tier II value for such pollutant for the protection of human health, and aquatic life and the preliminary WLAs shall be based upon such values. Where there is insufficient data to calculate a Tier II value, the permitting authority shall apply the procedure set forth in section C of this procedure to determine

whether data must be generated to calculate a Tier II value.

2. The following provisions in procedure 3 of appendix F shall be used as the basis for determining preliminary WLAs in accordance with section 1 of this procedure: procedure 3.B.9, Background Concentrations of Pollutants; procedure 3.C, Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs), procedures 3.C.1, and 3.C.3 through 3.C.6; procedure 3.D, Deriving TMDLs for Discharges to Lakes (when the receiving water is an open water of the Great Lakes (OWGL), an inland lake or other water of the Great Lakes System with no appreciable flow relative to its volume); procedure 3.E, Deriving TMDLs, WLAs and Preliminary WLAs, and load allocations (LAs) for Discharges to Great Lakes System Tributaries (when the receiving water is a tributary or connecting channel of the Great Lakes that exhibits appreciable flow relative to its volume); and procedure 3.F, Mixing Zone Demonstration Requirements.

3. The permitting authority shall develop PELs consistent with the preliminary WLAs developed pursuant to sections A.1 and A.2 of this procedure, and in accordance with existing State or Tribal procedures for converting WLAs into WQBELs. At a minimum:

a. The PELs based upon criteria and values for the protection of human health and wildlife shall be expressed as monthly limitations;

b. The PELs based upon criteria and values for the protection of aquatic life from chronic effects shall be expressed as either monthly limitations or weekly limitations; and

c. The PELs based upon the criteria and values for the protection of aquatic life from acute effects shall be expressed as daily limitations.

B. *Determining Reasonable Potential Using Effluent Pollutant Concentration Data.*

If representative, facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to the waters of the Great Lakes System, the permitting authority shall apply the following procedures:

1. The permitting authority shall specify the PEQ as the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration; or the maximum observed effluent concentration, whichever is greater. In calculating the PEQ, the permitting authority shall identify the number of effluent samples and the coefficient of variation of the effluent data, obtain the appropriate multiplying factor from Table 1 of procedure 6 of appendix F, and multiply the maximum effluent concentration by that factor. The coefficient of variation of the effluent data shall be calculated as the ratio of the standard deviation of the effluent data divided by the arithmetic average of the effluent data, except that where there are fewer than ten effluent concentration data points the coefficient of variation shall be specified as 0.6. If the PEQ exceeds any of the PELs developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in a NPDES permit for such pollutant.

2. In lieu of following the procedures under section B.1 of this procedure, the permitting authority may apply procedures consistent with the following:

a. The permitting authority shall specify the PEQ as the 95th percentile of the distribution of the projected population of daily values of the facility-specific effluent monitoring data projected using a scientifically defensible statistical method that accounts for and captures the long-term daily variability of the effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on the criteria and values for the protection of aquatic life from acute effects developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant;

b. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of monthly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the monthly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values for the protection of aquatic life from chronic effects, human health or wildlife developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant; and

c. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of weekly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the weekly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values to protect aquatic life from chronic effects developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant.

C. *Developing Necessary Data to Calculate Tier II Values Where Such Data Does Not Currently Exist.*

1. Except as provided in sections C.2, C.4, or D of this procedure, for each pollutant listed in Table 6 of part 132 that a permittee reports as known or believed to be present in its effluent, and for which pollutant data sufficient to calculate Tier II values for noncancer human health, acute aquatic life and chronic aquatic life do not exist, the permitting authority shall take the following actions:

a. The permitting authority shall use all available, relevant information, including Quantitative Structure Activity Relationship information and other relevant toxicity information, to estimate ambient screening values for such pollutant which will protect humans from health effects other than cancer, and aquatic life from acute and chronic effects.

b. Using the procedures specified in sections A.1 and A.2 of this procedure, the permitting authority shall develop preliminary WLAs for the discharge of the pollutant from the point source to protect human health, acute aquatic life, and chronic aquatic life, based upon the estimated ambient screening values.

c. The permitting authority shall develop PELs in accordance with section A.3 of this procedure, which are consistent with the preliminary WLAs developed in accordance with section C.1.b of this procedure.

d. The permitting authority shall compare the PEQ developed according to the procedures set forth in section B of this procedure to the PELs developed in accordance with section C.1.c of this procedure. If the PEQ exceeds any of the PELs, the permitting authority shall generate or require the permittee to generate the data necessary to derive Tier II values for noncancer human health, acute aquatic life and chronic aquatic life.

e. The data generated in accordance with section C.1.d of this procedure shall be used in calculating Tier II values as required under section A.1 of this procedure. The calculated Tier II value shall be used in calculating the preliminary WLA and PEL under section A of this procedure, for purposes of determining whether a WQBEL must be included in the permit. If the permitting authority finds that the PEQ exceeds the calculated PEL, a WQBEL for the pollutant or a permit limit on an indicator parameter consistent with 40 CFR 122.44(d)(1)(vi)(C) must be included in the permit.

2. With the exception of bioaccumulative chemicals of concern (BCCs), a permitting authority is not required to apply the procedures set forth in section C.1 of this procedure or include WQBELs to protect aquatic life for any pollutant listed in Table 6 of part 132 discharged by an existing point source into the Great Lakes System, if:

a. There is insufficient data to calculate a Tier I criterion or Tier II value for aquatic life for such pollutant;

b. The permittee has demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water; and

c. The permittee has demonstrated in accordance with procedure 6 of this appendix that the whole effluent does not exhibit acute or chronic toxicity.

3. Nothing in sections C.1 or C.2 of this procedure shall preclude or deny the right of a permitting authority to:

a. Determine, in the absence of the data necessary to derive a Tier II value, that the discharge of the pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above a narrative criterion for water quality; and

b. Incorporate a WQBEL for the pollutant into an NPDES permit.

4. If the permitting authority develops a WQBEL consistent with section C.3 of this procedure, and the permitting authority demonstrates that the WQBEL developed under section C.3 of this procedure is at least as stringent as a WQBEL that would have been based upon the Tier II value or values for that pollutant, the permitting authority shall not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value or values for that pollutant.

D. *Consideration of Intake Pollutants in Determining Reasonable Potential.*

1. *General.*

a. Any procedures adopted by a State or Tribe for considering intake pollutants in water quality-based permitting shall be consistent with this section and section E.

b. The determinations under this section and section E shall be made on a pollutant-by-pollutant, outfall-by-outfall, basis.

c. This section and section E apply only in the absence of a TMDL applicable to the discharge prepared by the State or Tribe and approved by EPA, or prepared by EPA pursuant to 40 CFR 130.7(d), or in the absence of an assessment and remediation plan submitted and approved in accordance with procedure 3.A. of appendix F. This section and section E do not alter the permitting authority's obligation under 40 CFR 122.44(d)(vii)(B) to develop effluent limitations consistent with the assumptions and requirements of any available WLA for the discharge, which is part of a TMDL prepared by the State or Tribe and approved by EPA pursuant to 40 CFR 130.7, or prepared by EPA pursuant to 40 CFR 130.7(d).

2. *Definition of Same Body of Water.*

a. This definition applies to this section and section E of this procedure.

b. An intake pollutant is considered to be from the same body of water as the discharge

if the permitting authority finds that the intake pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee. This finding may be deemed established if:

i. The background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water;

ii. There is a direct hydrological connection between the intake and discharge points; and

iii. Water quality characteristics (e.g., temperature, Ph, hardness) are similar in the intake and receiving waters.

c. The permitting authority may also consider other site-specific factors relevant to the transport and fate of the pollutant to make the finding in a particular case that a pollutant would or would not have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee.

d. An intake pollutant from groundwater may be considered to be from the same body of water if the permitting authority determines that the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee, except that such a pollutant is not from the same body of water if the groundwater contains the pollutant partially or entirely due to human activity, such as industrial, commercial, or municipal operations, disposed actions, or treatment processes.

e. An intake pollutant is the amount of a pollutant that is present in waters of the United States (including groundwater as provided in section D.2.d of this procedure) at the time it is withdrawn from such waters by the discharger or other facility (e.g., public water supply) supplying the discharger with intake water.

3. *Reasonable Potential Determination.*

a. The permitting authority may use the procedure described in this section of procedure 5 in lieu of procedures 5.A through C provided the conditions specified below are met.

b. The permitting authority may determine that there is no reasonable potential for the discharge of an identified intake pollutant or pollutant parameter to cause or contribute to an excursion above a narrative or numeric water quality criterion within an applicable water quality standard where a discharger demonstrates to the satisfaction of the permitting authority (based upon information provided in the permit application or other information deemed necessary by the permitting authority) that:

i. The facility withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made;

ii. The facility does not contribute any additional mass of the identified intake pollutant to its wastewater;

iii. The facility does not alter the identified intake pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left instream;

iv. The facility does not increase the identified intake pollutant concentration, as defined by the permitting authority, at the edge of the mixing zone, or at the point of discharge if a mixing zone is not allowed, as compared to the pollutant concentration in the intake water, unless the increased concentration does not cause or contribute to an excursion above an applicable water quality standard; and

v. The timing and location of the discharge would not cause adverse water quality impacts to occur that would not occur if the identified intake pollutant were left instream.

c. Upon a finding under section D.3.b of this procedure that a pollutant in the discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority is not required to include a WQBEL for the identified intake pollutant in the facility's permit, provided:

i. The NPDES permit fact sheet or statement of basis includes a specific determination that there is no reasonable potential for the discharge of an identified intake pollutant to cause or contribute to an excursion above an applicable narrative or numeric water quality criterion and references appropriate supporting documentation included in the administrative record;

ii. The permit requires all influent, effluent, and ambient monitoring necessary to demonstrate that the conditions in section D.3.b of this procedure are maintained during the permit term; and

iii. The permit contains a reopener clause authorizing modification or revocation and reissuance of the permit if new information indicates changes in the conditions in section D.3.b of this procedure.

d. Absent a finding under section D.3.b of this procedure that a pollutant in the discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority shall use the procedures under sections 5.A through C of this procedure to determine whether a discharge causes, has the reasonable potential to cause, or contribute to an excursion above an applicable narrative or numeric water quality criterion.

E. *Consideration of Intake Pollutants in Establishing WQBELs.*

1. *General.* This section applies only when the concentration of the pollutant of concern upstream of the discharge (as determined using the provisions in procedure 3.B.9 of appendix F) exceeds the most stringent applicable water quality criterion for that pollutant.

2. The requirements of sections D.1–D.2 of this procedure shall also apply to this section.

3. *Intake Pollutants from the Same Body of Water.*

a. In cases where a facility meets the conditions in sections D.3.b.i and D.3.b.iii through D.3.b.v of this procedure, the permitting authority may establish effluent limitations allowing the facility to discharge a mass and concentration of the pollutant that are no greater than the mass and concentration of the pollutant identified in the facility's intake water (''no net addition limitations''). The permit shall specify how compliance with mass and concentration limitations shall be assessed. No permit may authorize ''no net addition limitations'' which are effective after March 23, 2007. After that date, WQBELs shall be established in accordance with procedure 5.F.2 of appendix F.

b. Where proper operation and maintenance of a facility's treatment system results in removal of a pollutant, the permitting authority may establish limitations that reflect the lower mass and/or concentration of the pollutant achieved by such treatment, taking into account the feasibility of establishing such limits.

c. For pollutants contained in intake water provided by a water system, the concentration of the intake pollutant shall be determined at the point where the raw water supply is removed from the same body of water, except that it shall be the point where the water enters the water supplier's distribution system where the water treatment system removes any of the identified pollutants from the raw water supply. Mass shall be determined by multiplying the concentration of the pollutant determined in accordance with this paragraph by the volume of the facility's intake flow received from the water system.

4. *Intake Pollutants from a Different Body of Water.* Where the pollutant in a facility's discharge originates from a water of the United States that is not the same body of water as the receiving water (as determined in accordance with section D.2 of this procedure), WQBELs shall be established based upon the most stringent applicable water quality criterion for that pollutant.

5. *Multiple Sources of Intake Pollutants.* Where a facility discharges intake pollutants that originate in part from the same body of water, and in part from a different body of water, the permitting authority may apply the procedures of sections E.3 and E.4 of this procedure to derive an effluent limitation reflecting the flow-weighted average of each source of the pollutant, provided that adequate monitoring to determine compliance can be established and is included in the permit.

F. *Other Applicable Conditions.*

1. In addition to the above procedures, effluent limitations shall be established to comply with all other applicable State, Tribal and Federal laws and regulations, including technology-based requirements and antidegradation policies.

2. Once the permitting authority has determined in accordance with this procedure that a WQBEL must be included in an NPDES permit, the permitting authority shall:

a. Rely upon the WLA established for the point source either as part of any TMDL prepared under procedure 3 of this appendix and approved by EPA pursuant to 40 CFR 130.7, or as part of an assessment and remediation plan developed and approved in accordance with procedure 3.A of this appendix, or, in the absence of such TMDL or plan, calculate WLAs for the protection of acute and chronic aquatic life, wildlife and human health consistent with the provisions referenced in section A.1 of this procedure for developing preliminary wasteload allocations, and

b. Develop effluent limitations consistent with these WLAs in accordance with existing State or Tribal procedures for converting WLAs into WQBELs.

3. When determining whether WQBELs are necessary, information from chemical-specific, whole effluent toxicity and biological assessments shall be considered independently.

4. If the geometric mean of a pollutant in fish tissue samples collected from a waterbody exceeds the tissue basis of a Tier I criterion or Tier II value, after consideration of the variability of the pollutant's bioconcentration and bioaccumulation in fish, each facility that discharges detectable levels of such pollutant to that water has the reasonable potential to cause or contribute to an excursion above a Tier I criteria or a Tier II value and the permitting authority shall establish a WQBEL for such pollutant in the NPDES permit for such facility.

PROCEDURE 6: WHOLE EFFLUENT TOXICITY REQUIREMENTS

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 6 of appendix F of part 132.

The following definitions apply to this part:

Acute toxic unit (TU_a). $100/LC_{50}$ where the LC_{50} is expressed as a percent effluent in the test medium of an acute whole effluent toxicity (WET) test that is statistically or graphically estimated to be lethal to 50 percent of the test organisms.

Chronic toxic unit (TU_c). 100/NOEC or 100/IC_{25}, where the NOEC and IC_{25} are expressed as a percent effluent in the test medium.

Inhibition concentration 25 (IC_{25}). the toxicant concentration that would cause a 25 percent reduction in a non-quantal biological measurement for the test population. For example, the IC_{25} is the concentration of toxicant that would cause a 25 percent reduction in mean young per female or in growth for the test population.

No observed effect concentration (NOEC). The highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

A. *Whole Effluent Toxicity Requirements.* The Great Lakes States and Tribes shall adopt whole effluent toxicity provisions consistent with the following:

1. A numeric acute WET criterion of 0.3 acute toxic units (TU_a) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that 0.3 TU_a measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from acute effects of WET. At the discretion of the permitting authority, the foregoing requirement shall not apply in an acute mixing zone that is sized in accordance with EPA-approved State and Tribal methods.

2. A numeric chronic WET criterion of one chronic toxicity unit (TU_c) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that one TU_c measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from the chronic effects of WET. At the discretion of the permitting authority, the foregoing requirements shall not apply within a chronic mixing zone consistent with: (a) procedures 3.D.1 and 3.D.4, for discharges to the open of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volume, or (b) procedure 3.E.5 for discharges to tributaries and connecting channels of the Great Lakes System.

B. *WET Test Methods.* All WET tests performed to implement or ascertain compliance with this procedure shall be performed in accordance with methods established in 40 CFR part 136.

C. *Permit Conditions.*

1. Where a permitting authority determines pursuant to section D of this procedure that the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority:

a. Shall (except as provided in section C.1.e of this procedure) establish a water quality-based effluent limitation (WQBEL) or WQBELs for WET consistent with section C.1.b of this procedure;

b. Shall calculate WQBELs pursuant to section C.1.a. of this procedure to ensure attainment of the State's or Tribe's chronic WET criteria under receiving water flow conditions described in procedures 3.E.1.a (or where applicable, with procedure 3.E.1.e) for Great Lakes System tributaries and connecting channels, and with mixing zones no larger than allowed pursuant to section A.2. of this procedure. Shall calculate WQBELs to ensure attainment of the State's or Tribe's acute WET criteria under receiving water flow conditions described in procedure 3.E.1.b (or where applicable, with procedure 3.E.1.e) for Great Lakes System tributaries and connecting channels, with an allowance for mixing zones no greater than specified pursuant to section A.1 of this procedure.

c. May specify in the NPDES permit the conditions under which a permittee would be required to perform a toxicity reduction evaluation.

d. May allow with respect to any WQBEL established pursuant to section C.1.a of this procedure an appropriate schedule of compliance consistent with procedure 9 of appendix F; and

e. May decide on a case-by-case basis that a WQBEL for WET is not necessary if the State's or Tribe's water quality standards do not contain a numeric criterion for WET, and the permitting authority demonstrates in accordance with 40 CFR 122.44(d)(1)(v) that chemical-specific effluent limits are sufficient to ensure compliance with applicable criteria.

2. Where a permitting authority lacks sufficient information to determine pursuant to section D of this procedure whether the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, then the permitting authority should consider including in the NPDES permit appropriate conditions to require generation of additional data and to control toxicity if found, such as:

a. WET testing requirements to generate the data needed to adequately characterize the toxicity of the effluent to aquatic life;

b. Language requiring a permit reopener clause to establish WET limits if any toxicity testing data required pursuant to section C.2.a of this procedure indicate that the WET of an effluent is or may be discharged at levels that will cause, have the reasonable

potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.

3. Where sufficient data are available for a permitting authority to determine pursuant to section D of this procedure that the WET of an effluent neither is nor may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority may include conditions and limitations described in section C.2 of this procedure at its discretion.

D. *Reasonable Potential Determinations.* The permitting authority shall take into account the factors described in 40 CFR 122.44(d)(1)(ii) and, where representative facility-specific WET effluent data are available, apply the following requirements in determining whether the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.

1. The permitting authority shall characterize the toxicity of the discharge by:

a. Either averaging or using the maximum of acute toxicity values collected within the same day for each species to represent one daily value. The maximum of all daily values for the most sensitive species tested is used for reasonable potential determinations;

b. Either averaging or using the maximum of chronic toxicity values collected within the same calendar month for each species to represent one monthly value. The maximum of such values, for the most sensitive species tested, is used for reasonable potential determinations:

c. Estimating the toxicity values for the missing endpoint using a default acute-chronic ratio (ACR) of 10, when data exist for either acute WET or chronic WET, but not for both endpoints.

2. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric acute WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

$(TU_a$ effluent) (B) (effluent flow/(Qad+effluent flow))>AC

Where TU_a effluent is the maximum measured acute toxicity of 100 percent effluent determined pursuant to section D.1.a. of this procedure, B is the multiplying factor taken from Table F6–1 of this procedure to convert the highest measured effluent toxicity value to the estimated 95th percentile toxicity value for the discharge, effluent flow is the same effluent flow used to calculate the preliminary wasteload allocations (WLAs) for individual pollutants to meet the acute criteria and values for those pollutants, AC is the numeric acute WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.1 of this procedure and expressed in TU_a, and Qad is the amount of the receiving water available for dilution calculated using: (i) the specified design flow(s) for tributaries and connecting channels in section C.1.b of this procedure, or where appropriate procedure 3.E.1.e of appendix F, and using EPA-approved State and Tribal procedures for establishing acute mixing zones in tributaries and connecting channels, or (ii) the EPA-approved State and Tribal procedures for establishing acute mixing zones in OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6–1 of this procedure shall be based on a coefficient of variation (CV) or 0.6. Where there are 10 or more individual WET tests, the multiplying factor taken from Table F6–1 shall be based on a CV calculated as the standard deviation of the acute toxicity values found in the WET tests divided by the arithmetic mean of those toxicity values.

3. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric chronic WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

$(TU_c$ effluent) (B) (effluent flow/Qad+effluent flow))>CC

Where TU_c effluent is the maximum measured chronic toxicity value of 100 percent effluent determined in accordance with section D.1.b. of this procedure, B is the multiplying factor taken from Table F6–1 of this procedure, effluent flow is the same effluent flow used to calculate the preliminary WLAs for individual pollutants to meet the chronic criteria and values for those pollutants, CC is the numeric chronic WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.2 of this procedure and expressed in TU_c, and Qad is the amount of the receiving water available for dilution calculated using: (i) the design flow(s) for tributaries and connecting channels specified in procedure 3.E.1.a of appendix F, and where appropriate procedure 3.E.1.e of appendix F, and in accordance with the provisions of procedure 3.E.5 for chronic mixing zones, or (ii) procedures 3.D.1 and 3.D.4 for discharges to the OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6–1 of this procedure shall be based on a CV of 0.6. Where there are 10 more individual WET tests, the multiplying factor taken from

Table F6–1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests divided by the arithmetic mean of the WET tests.

TABLE F6–1.—REASONABLE POTENTIAL MULTIPLYING FACTORS: 95% CONFIDENCE LEVEL AND 95% PROBABILITY BASIS

Number of Samples	Coefficient of variation																			
	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1
3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0
30	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
40	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3
50	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
60	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
70	1.0	1.0	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
80	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8
90	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
100	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7

PROCEDURE 7: LOADING LIMITS

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

Whenever a water quality-based effluent limitation (WQBEL) is developed, the WQBEL shall be expressed as both a concentration value and a corresponding mass loading rate.

A. Both mass and concentration limits shall be based on the same permit averaging periods such as daily, weekly, or monthly averages, or in other appropriate permit averaging periods.

B. The mass loading rates shall be calculated using effluent flow rates that are consistent with those used in establishing the WQBELs expressed in concentration.

PROCEDURE 8: WATER QUALITY-BASED EFFLUENT LIMITATIONS BELOW THE QUANTIFICATION LEVEL

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

When a water quality-based effluent limitation (WQBEL) for a pollutant is calculated to be less than the quantification level:

A. *Permit Limits.* The permitting authority shall designate as the limit in the NPDES permit the WQBEL exactly as calculated.

B. *Analytical Method and Quantification Level.*

1. The permitting authority shall specify in the permit the most sensitive, applicable, analytical method, specified in or approved under 40 CFR part 136, or other appropriate method if one is not available under 40 CFR part 136, to be used to monitor for the presence and amount in an effluent of the pollutant for which the WQBEL is established; and shall specify in accordance with section B.2 of this procedure, the quantification level that can be achieved by use of the specified analytical method.

2. The quantification level shall be the minimum level (ML) specified in or approved under 40 CFR part 136 for the method for that pollutant. If no such ML exists, or if the method is not specified or approved under 40 CFR part 136, the quantification level shall be the lowest quantifiable level practicable. The permitting authority may specify a higher quantification level if the permittee demonstrates that a higher quantification level is appropriate because of effluent-specific matrix interference.

3. The permit shall state that, for the purpose of compliance assessment, the analytical method specified in the permit shall be used to monitor the amount of pollutant in an effluent down to the quantification level, provided that the analyst has complied with the specified quality assurance/quality control procedures in the relevant method.

4. The permitting authority shall use applicable State and Tribal procedures to average and account for monitoring data. The permitting authority may specify in the permit the value to be used to interpret sample values below the quantification level.

C. *Special Conditions.* The permit shall contain a reopener clause authorizing modification or revocation and reissuance of the permit if new information generated as a result of special conditions included in the permit indicates that presence of the pollutant in the discharge at levels above the WQBEL. Special conditions that may be included in the permit include, but are not limited to, fish tissue sampling, whole effluent toxicity (WET) tests, limits and/or monitoring requirements on internal waste streams, and monitoring for surrogate parameters. Data generated as a result of special conditions can be used to reopen the permit to establish more stringent effluent limits or conditions, if necessary.

D. *Pollutant Minimization Program.* The permitting authority shall include a condition in the permit requiring the permittee to develop and conduct a pollutant minimization program for each pollutant with a WQBEL below the quantification level.The goal of the pollutant minimization program shall be to maintain the effluent at or below the WQBEL. In addition, States and Tribes may consider cost-effectiveness when evaluating the requirements of a PMP. The pollutant minimization program shall include, but is not limited to, the following:

1. An annual review and semi-annual monitoring of potential sources of the pollutant, which may include fish tissue monitoring and other bio-uptake sampling;

2. Quarterly monitoring for the pollutant in the influent to the wastewater treatment system;

3. Submittal of a control strategy designed to proceed toward the goal of maintaining the effluent below the WQBEL;

4. Implementation of appropriate, cost-effective control measures consistent with the control strategy; and

5. An annual status report that shall be sent to the permitting authority including:

a. All minimization program monitoring results for the previous year;

b. A list of potential sources of the pollutant; and

c. A summary of all action undertaken pursuant to the control strategy.

6. Any information generated as a result of procedure 8.D can be used to support a request for subsequent permit modifications, including revisions to (e.g., more or less frequent monitoring), or removal of the requirements of procedure 8.D, consistent with 40 CFR 122.44, 122.62 and 122.63.

PROCEDURE 9: COMPLIANCE SCHEDULES

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 9 of appendix F of part 132.

A. *Limitations for New Great Lakes Dischargers.* When a permit issued on or after March 23, 1997 to a new Great Lakes discharger (defined in Part 132.2) contains a water quality-based effluent limitation (WQBEL), the permittee shall comply with such a limitation upon the commencement of the discharge.

B. *Limitations for Existing Great Lakes Dischargers.*

1. Any existing permit that is reissued or modified on or after March 23, 1997 to contain a new or more restrictive WQBEL may allow a reasonable period of time, up to five years from the date of permit issuance or modification, for the permittee to comply with that limit, provided that the Tier I criterion or whole effluent toxicity (WET) criterion was adopted (or, in the case of a narrative criterion, Tier II value, or Tier I criterion derived pursuant to the methodology in appendix A of part 132, was newly derived) after July 1, 1977.

2. When the compliance schedule established under paragraph 1 goes beyond the term of the permit, an interim permit limit effective upon the expiration date shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect the final limit and its compliance date.

3. If a permit establishes a schedule of compliance under paragraph 1 which exceeds one year from the date of permit issuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The time between such interim dates may not exceed one year. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages for completion, the permit shall require, at a minimum, specified dates for annual submission of progress reports on the status of any interim requirements.

C. *Delayed Effectiveness of Tier II Limitations for Existing Great Lakes Discharges.*

1. Whenever a limit (calculated in accordance with Procedure 3) based upon a Tier II value is included in a reissued or modified permit for an existing Great Lakes discharger, the permit may provide a reasonable period of time, up to two years, in which to provide additional studies necessary to develop a Tier I criterion or to modify the Tier II value. In such cases, the permit shall require compliance with the Tier II limitation

within a reasonable period of time, no later than five years after permit issuance or modification, and contain a reopener clause.

2. The reopener clause shall authorize permit modifications if specified studies have been completed by the permittee or provided by a third-party during the time allowed to conduct the specified studies, and the permittee or a third-party demonstrates, through such studies, that a revised limit is appropriate. Such a revised limit shall be incorporated through a permit modification and a reasonable time period, up to five years, shall be allowed for compliance. If incorporated prior to the compliance date of the original Tier II limitation, any such revised limit shall not be considered less-stringent for purposes of the anti-backsliding provisions of section 402(o) of the Clean Water Act.

3. If the specified studies have been completed and do not demonstrate that a revised limit is appropriate, the permitting authority may provide a reasonable additional period of time, not to exceed five years with which to achieve compliance with the original effluent limitation.

4. Where a permit is modified to include new or more stringent limitations, on a date within five years of the permit expiration date, such compliance schedules may extend beyond the term of a permit consistent with section B.2 of this procedure.

5. If future studies (other than those conducted under paragraphs 1, 2, or 3 above) result in a Tier II value being changed to a less stringent Tier II value or Tier I criterion, after the effective date of a Tier II-based limit, the existing Tier II-based limit may be revised to be less stringent if:

(a) It complies with sections 402(o) (2) and (3) of the CWA; or,

(b) In non-attainment waters, where the existing Tier II limit was based on procedure 3, the cumulative effect of revised effluent limitation based on procedure 3 of this appendix will assure compliance with water quality standards; or,

(c) In attained waters, the revised effluent limitation complies with the State or Tribes' antidegradation policy and procedures.

[60 FR 15387, Mar. 23, 1995, as amended at 63 FR 20110, Apr. 23, 1998]

PART 133—SECONDARY TREATMENT REGULATION

Sec.

133.100 Purpose.
133.101 Definitions.
133.102 Secondary treatment.
133.103 Special considerations.
133.104 Sampling and test procedures.
133.105 Treatment equivalent to secondary treatment.

AUTHORITY: Secs. 301(b)(1)(B), 304(d)(1), 304(d)(4), 308, and 501 of the Federal Water Pollution Control Act as amended by the Federal Water Pollution Control Act Amendments of 1972, the Clean Water Act of 1977, and the Municipal Wastewater Treatment Construction Grant Amendments of 1981; 33 U.S.C. 1311(b)(1)(B), 1314(d) (1) and (4), 1318, and 1361; 86 Stat. 816, Pub. L. 92–500; 91 Stat. 1567, Pub. L. 95–217; 95 Stat. 1623, Pub. L. 97–117.

SOURCE: 49 FR 37006, Sept. 20, 1984, unless otherwise noted.

§ 133.100 Purpose.

This part provides information on the level of effluent quality attainable through the application of secondary or equivalent treatment.

§ 133.101 Definitions.

Terms used in this part are defined as follows:

(a) *7-day average.* The arithmetic mean of pollutant parameter values for samples collected in a period of 7 consecutive days.

(b) *30-day average.* The arithmetic mean of pollutant parameter values of samples collected in a period of 30 consecutive days.

(c) *Act.* The Clean Water Act (33 U.S.C. 1251 *et seq.*, as amended).

(d) *BOD.* The five day measure of the pollutant parameter biochemical oxygen demand (BOD).

(e) *$CBOD_5$.* The five day measure of the pollutant parameter carbonaceous biochemical oxygen demand ($CBOD_5$).

(f) *Effluent concentrations consistently achievable through proper operation and maintenance.* (1) For a given pollutant parameter, the 95th percentile value for the 30-day average effluent quality achieved by a treatment works in a period of at least two years, excluding values attributable to upsets, bypasses, operational errors, or other unusual conditions, and (2) a 7-day average value equal to 1.5 times the value derived under paragraph (f)(1) of this section.

(g) *Facilities eligible for treatment equivalent to secondary treatment.* Treatment works shall be eligible for consideration for effluent limitations described for treatment equivalent to secondary treatment (§ 133.105), if:

(1) The BOD_5 and SS effluent concentrations consistently achievable