United States Environmental Protection Agency

Office of Water
EPA 823-B-94-005a
August 1994

Water Quality Standards Handbook

Chapter 3: Water Quality Criteria

Water Quality Standards Handbook
CHAPTER 3: WATER QUALITY CRITERIA

(40 CFR 131.11)

CHAPTER 3 WATER QUALITY CRITERIA

The term "water quality criteria" has two different definitions under the Clean Water Act (CWA). Under section 304(a), EPA publishes water quality criteria that consist of scientific information regarding concentrations of specific chemicals or levels of parameters in water that protect aquatic life and human health (see section 3.1 of this Handbook). The States may use these contents as the basis for developing enforceable water quality standards. Water quality criteria are also elements of State water quality standards adopted under section 303(c) of the CWA (see sections 3.2 through 3.6 of this Handbook). States are required to adopt water quality criteria that will protect the designated use(s) of a water body. These criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use.

3.1 EPA Section 304(a) Guidance

EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were the "Green Book" (FWPCA, 1968) and the "Red Book" (USEPA, 1976). EPA also sponsored a contract effort that resulted in the "Blue Book" (NAS/NAE, 1973). These early efforts were premised on the use of literature reviews and the collective scientific judgment of Agency and advisory panels. However, when faced with the need to develop criteria for human health as well as aquatic life, the Agency determined that new procedures were necessary. Continued reliance solely on existing scientific literature was deemed inadequate because essential information was not available for many pollutants. EPA scientists developed formal methodologies for establishing scientifically defensible criteria. These were subjected to review by the Agency's Science Advisory Board of outside experts and the public. This effort culminated on November 28, 1980, when the Agency published criteria development guidelines for aquatic life and for human health, along with criteria for 64 toxic pollutants (USEPA, 1980a,b). Since that initial publication, the aquatic life methodology was amended (Appendix H), and additional criteria were proposed for public comment and finalized as Agency criteria guidance. EPA summarized the available criteria information in the "*Gold Book*" (USEPA, 1986a), which is updated from time to time. However, the individual criteria documents (see Appendix I), as updated, are the official guidance documents.

EPA's criteria documents provide a comprehensive toxicological evaluation of each chemical. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute criteria) and criteria continuous concentrations (chronic criteria) that the Agency recommends to protect aquatic life resources. The methodologies for these processes are described in Appendices H and J and outlined in sections 3.1.2 and 3.1.3 of this Handbook

3.1.1 State Use of EPA Criteria Documents

EPA's water quality criteria documents are available to assist States in:

- adopting water quality standards that include appropriate numeric water quality criteria;
- interpreting existing water quality standards that include narrative "no toxics in toxic amounts" criteria;
- making listing decisions under section 304(1) of the CWA;
- writing water quality-based NPDES permits and individual control strategies; and
- providing certification under section 401 of the CWA for any Federal permit or license (e.g., EPA-issued NPDES permits, CWA section 404 permits, or Federal Energy Regulatory Commission licenses).

In these situations, States have primary authority to determine the appropriate level to protect human health or welfare (in accordance with section 303(c)(2) of the CWA) for each water body. However, under the Clean Water Act, EPA must also review and approve State water quality standards; section 304(1) listing decisions and draft and final State-issued individual control strategies; and in States where EPA writes NPDES permits, EPA must develop appropriate water quality-based permit limitations. The States and EPA therefore have a strong interest in assuring that the decisions are legally defensible, are based on the best information available, and are subject to full and meaningful public comment and participation. It is very important that each decision be supported by an adequate record. Such a record is critical to meaningful comment, EPA's review of the State's decision, and any subsequent administrative or judicial review.

Any human health criterion for a toxicant is based on at least three interrelated considerations:

- cancer potency or systemic toxicity,
- exposure, and
- risk characterization.

States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments, when different from EPA's recommendation, must be clear and in the public record. If a State relies on EPA's section 304(a) criteria document (or other EPA documents), the State may reference and rely on the data in these documents and need not create duplicative or new material for inclusion in their records. However, where site-specific issues arise or the State decides to adopt an approach to any one of these three factors that differs from the approach in EPA's criteria document, the State must explain its reasons in a manner sufficient for a reviewer to determine that the approach chosen is based on sound scientific rationale (40 CFR 131.11(b)).

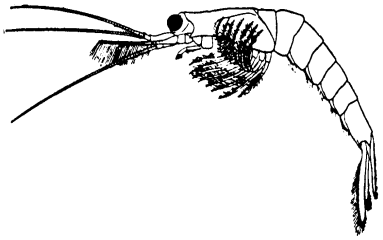
3.1.2 Criteria for Aquatic Life Protection

The development of national numerical water quality criteria for the protection of aquatic organisms is a complex process that uses information from many areas of aquatic toxicology. (See Appendix H for a detailed discussion of this process.) After a decision is made that a national criterion is needed

for a particular material, all available information concerning toxicity to, and bioaccumulation by, aquatic organisms is collected and reviewed for acceptability. If enough acceptable data for 48- to 96-hour toxicity tests on aquatic plants and animals are available, they are used to derive the acute criterion. If sufficient data on the ratio of acute to chronic toxicity concentrations are available, they are used to derive the chronic or long-term exposure criteria. If justified, one or both of the criteria may be related to other water quality characteristics, such as pH, temperature, or hardness. Separate criteria are developed for fresh and salt waters.

The Water Quality Standards Regulation allows States to develop numerical criteria or modify EPA's recommended criteria to account for site-specific or other scientifically defensible factors. Guidance on modifying national criteria is found in sections 3.6 and 3.7. When a criterion must be developed for a chemical for which a national criterion has not been established, the regulatory authority should refer to the EPA guidelines (Appendix H).

Magnitude for Aquatic Life Criteria



Water quality criteria for aquatic life contain two expressions of allowable magnitude: a criterion maximum concentration (CMC) to protect against acute (short-term) effects; and a criterion continuous concentration (CCC) to protect against chronic (long-term) effects. EPA derives acute criteria from 48- to 96-hour tests of lethality or immobilization. EPA derives chronic criteria from longer term (often greater than 28-day) tests that measure survival, growth, or reproduction. Where appropriate, the calculated criteria may be lowered to be protective of commercially or recreationally important species.

Duration for Aquatic Life Criteria

The quality of an ambient water typically varies in response to variations of effluent quality, stream flow, and other factors. Organisms in the receiving water are not experiencing constant, steady exposure but rather are experiencing fluctuating exposures, including periods of high concentrations, which may have adverse effects. Thus, EPA's criteria indicate a time period over which exposure is to be averaged, as well as an upper limit on the average concentration, thereby limiting the duration of exposure to elevated concentrations. For acute criteria, EPA recommends an averaging period of 1 hour. That is, to protect against acute effects, the 1-hour average exposure should not exceed the CMC. For chronic criteria, EPA recommends an averaging period of 4 days. That is, the 4-day average exposure should not exceed the CCC.

Frequency for Aquatic Life Criteria

To predict or ascertain the attainment of criteria, it is necessary to specify the allowable frequency for exceeding the criteria. This is because it is statistically impossible to project that criteria will never be exceeded. As ecological communities are naturally subjected to a series of stresses, the

allowable frequency of pollutant stress may be set at a value that does not significantly increase the frequency or severity of all stresses combined.

EPA recommends an average frequency for excursions of both acute and chronic criteria not to exceed once in 3 years. In all cases, the recommended frequency applies to actual ambient concentrations, and excludes the influence of measurement imprecision. EPA established its recommended frequency as part of its guidelines for deriving criteria (Appendix H). EPA selected the 3-year average frequency of criteria exceedence with the intent of providing for ecological recovery from a variety of severe stresses. This return interval is roughly equivalent to a 7Q10 design flow condition. Because of the nature of the ecological recovery studies available, the severity of criteria excursions could not be rigorously related to the resulting ecological impacts. Nevertheless, EPA derives its criteria intending that a single marginal criteria excursion (i.e., a slight excursion over a 1-hour period for acute or over a 4-day period for chronic) would require little or no time for recovery. If the frequency of marginal criteria excursions is not high, it can be shown that the frequency of severe stresses, requiring measurable recovery periods, would be extremely small. EPA thus expects the 3-year return interval to provide a very high degree of protection.

3.1.3 Criteria for Human Health Protection

This section reviews EPA's procedures used to develop assessments of human health effects in developing water quality criteria and reference ambient concentrations. A more complete human health effects discussion is included in the *Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Documents* (Appendix J). The procedures contained in this document are used in the development and updating of EPA water quality criteria and may be used in updating State criteria and in developing State criteria for those pollutants lacking EPA human health criteria. The procedures may also be applied as site-specific interpretations of narrative standards and as a basis for permit limits under 40 CFR 122.44 (d)(1)(vi).

Magnitude and Duration

Water quality criteria for human health contain only a single expression of allowable magnitude; a criterion concentration generally to protect against long-term (chronic) human health effects. Currently, national policy and prevailing opinion in the expert community establish that the duration for human health criteria for carcinogens should be derived assuming lifetime exposure, taken to be a 70-year time period. The duration of exposure assumed in deriving criteria for noncarcinogens is more complicated owing to a wide variety of endpoints: some developmental (and thus age-specific and perhaps gender-specific), some lifetime, and some, such as organoleptic effects, not duration-related at all. Thus, appropriate durations depend on the individual noncarcinogenic pollutants and the endpoints or adverse effects being considered.

Human Exposure Considerations

A complete human exposure evaluation for toxic pollutants of concern for bioaccumulation would encompass not only estimates of exposures due to fish consumption but also exposure from background concentrations and other exposure routes, The more important of these include recreational and occupational contact, dietary intake from other than fish, intake from air inhalation, and drinking water consumption. For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is the exposure default assumption, although the human health guidelines provide for considering other sources where data are available (see 45 F.R. 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only (57 F.R. 60862-3).

The consumption of contaminated fish tissue is of serious concern because the presence of even extremely low ambient concentrations of bioaccumulative pollutants (sublethal to aquatic life) in surface waters can result in residue concentrations in fish tissue that can pose a human health risk. Other exposure route information should be considered and incorporated in human exposure evaluations to the extent available.

Levels of actual human exposures from consuming contaminated fish vary depending upon a number of case-specific consumption factors. These factors include type of fish species consumed, type of fish tissue consumed, tissue lipid content, consumption rate and pattern, and food preparation practices. In addition, depending on the spatial variability in the fishery area, the behavior of the fish species, and the point of application of the criterion, the average exposure of fish may be only a small fraction of the expected exposure at the point of application of the criterion. If an effluent attracts fish, the average exposure might be greater than the expected exposure.

With shellfish, such as oysters, snails, and mussels, whole-body tissue consumption commonly occurs, whereas with fish, muscle tissue and roe are most commonly eaten. This difference in the types of tissues consumed has implications for the amount of available bioaccumulative contaminants likely to be ingested. Whole-body shellfish consumption presumably means ingestion of the entire burden of bioaccumulative contaminants. However, with most fish, selective cleaning and removal of internal organs, and sometimes body fat as well, from edible tissues, may result in removal of much of the lipid material in which bioaccumulative contaminants tend to concentrate.

Fish Consumption Values

EPA's human health criteria have assumed a human body weight of 70 kg and the consumption of 6.5 g of fish and shellfish per day. Based on data collected in 1973-74, the national per capita consumption of freshwater and estuarine fish was estimated to average 6.5 g/day. Per capita consumption of all seafood (including marine species) was estimated to average 14.3 g/day. The 95th percentile for consumption of all seafood by individuals over a period of 1 month was

estimated to be 42 g/day. The mean lipid content of fish and shellfish tissue consumed in this study was estimated to be 3.0 percent (USEPA, 1980c).

Currently, four levels of fish and shellfish consumption are provided in EPA guidance (USEPA, 1991a):

- 6.5 g/day to represent an estimate of average consumption of fish and shellfish from estuarine and freshwaters by the entire U.S. population. This consumption level is based on the average of both consumers and nonconsumers of.
- 20 g/day to represent an estimate of the average consumption of fish and shellfish from marine, estuarine, and freshwaters by the U.S. population. This average consumption level also includes both consumers and nonconsumers of.
- 165 g/day to represent consumption of fish and shellfish from marine, estuarine, and freshwaters by the 99.9th percentile of the U.S. population consuming the most fish or seafood.
- 180 g/day to represent a "reasonable worst case" based on the assumption that some individuals would consume fishand shellfish at a rate equal to the combined consumption of red meat, poultry, fish, and shellfish in the United States.

EPA is currently updating the national estuarine and freshwater fish and shellfish consumption default values and will provide a range of recommended national consumption values. This range will include:

- mean values appropriate to the population at large; and
- values appropriate for those individuals who consume a relatively large proportion of fish and shellfish in their diets (maximally exposed individuals).

Many States use EPA's 6.5 g/day consumption value. However, some States use the above-mentioned 20 g/day value and, for saltwaters, 37 g/day. In general, EPA recommends that the consumption values used in deriving criteria from the formulas in this chapter reflect the most current, relevant, and/or site-specific information available.

Bioaccumulation Considerations

The ratio of the contaminant concentrations in fish tissue versus that in water is termed either the bioconcentration factor (BCF) or the bioaccumulation factor (BAF). Bioconcentration is defined as involving contaminant uptake from water only (not from food). The bioaccumulation factor (BAF) is defined similarly to the BCF except that it includes contaminant uptake from both water and food. Under laboratory conditions, measurements of tissue/water partitioning are generally considered to involve uptake from water only. On the other hand, both processes are likely to apply in the field since the entire food chain is exposed.
The BAF/BCF ratio ranges from 1 to 100, with the highest ratios applying to organisms in higher trophic levels, and to chemicals with logarithm of the octanol-water partitioning coefficient (log P) close to 6.5.

Bioaccumulation considerations are integrated into the criteria equations by using food chain multipliers (FMs) in conjunction with the BCF. The bioaccumulation and bioconcentration factors for a chemical are related as follows:

BAF = FM x BCF

By incorporating the FM and BCF terms into the criteria equations, bioaccumulation can be addressed.

*These recommended FMs are conservative estimates; FMs for log P values greater than 6.5 may range from the values given to as low as 0.1 for contaminants with very low bioavailability.
In Table 3-1, FM values derived from the work of Thomann (1987, 1989) are listed according to log P value and trophic level of the organism. For chemicals with log P values greater than about 7, there is additional uncertainty regarding the degree of bioaccumulation, but generally, trophic level effects appear to decrease due to slow transport kinetics of these chemicals in fish, the growth rate of the fish, and the chemical's relatively low bioavailability. Trophic level 4 organisms are typically the most desirable species for sport fishing and, therefore, FMs for trophic level 4 should generally be used in the equations for calculating criteria. In those very rare situations where only lower trophic level organisms are found, e.g., possibly oyster beds, an FM for a lower trophic level might be considered.

Measured BAFs (especially for those chemicals with log P values above 6.5) reported in the literature should be used when available. To use experimentally measured BAFs in calculating the criterion, the (FM x BCF) term is replaced by the BAF in the equations in the following section. Relatively few BAFs have been measured accurately and reported, and their application to sites other than the specific ecosystem where they were developed is problematic and subject to uncertainty. The option is also available to develop BAFs experimentally, but this will be extremely resource intensive if done on a site-specific basis with all the necessary experimental and quality controls.

Table 3-1. Estimated Food Chain Multipliers (FMs)

Trophic Levels			
Log P	2	3	4
3.5	1.0	1.0	1.0
3.6	1.0	1.0	1.0
3.7	1.0	1.0	1.0
3.8	1.0	1.0	1.0
3.9	1.0	1.0	1.0
4.0	1.1	1.0	1.0
4.1	1.1	1.1	1.1
4.2	1.1	1.1	1.1
4.3	1.1	1.1	1.1
4.4	1.2	1.1	1.1
4.5	1.2	1.2	1.2
4.6	1.2	1.3	1.3
4.7	1.3	1.4	1.4
4.8	1.4	1.5	1.6
4.9	1.5	1.8	2.0
5.0	1.6	2.1	2.6
5.1	1.7	2.5	3.2
5.2	1.9	3.0	4.3
5.3	2.2	3.7	5.8
5.4	2.4	4.6	8.0
5.5	2.8	5.9	11
5.6	3.3	7.5	16
5.7	3.9	9.8	23
5.8	4.6	13	33
5.9	5.6	17	47
6.0	6.8	21	67
6.1	8.2	25	75
6.2	10	29	84
6.3	13	34	92
6.4	15	39	98
6.5	19	45	100
≥6.5	19.2*	45*	100*

Updating Human Health Criteria Using IRIS

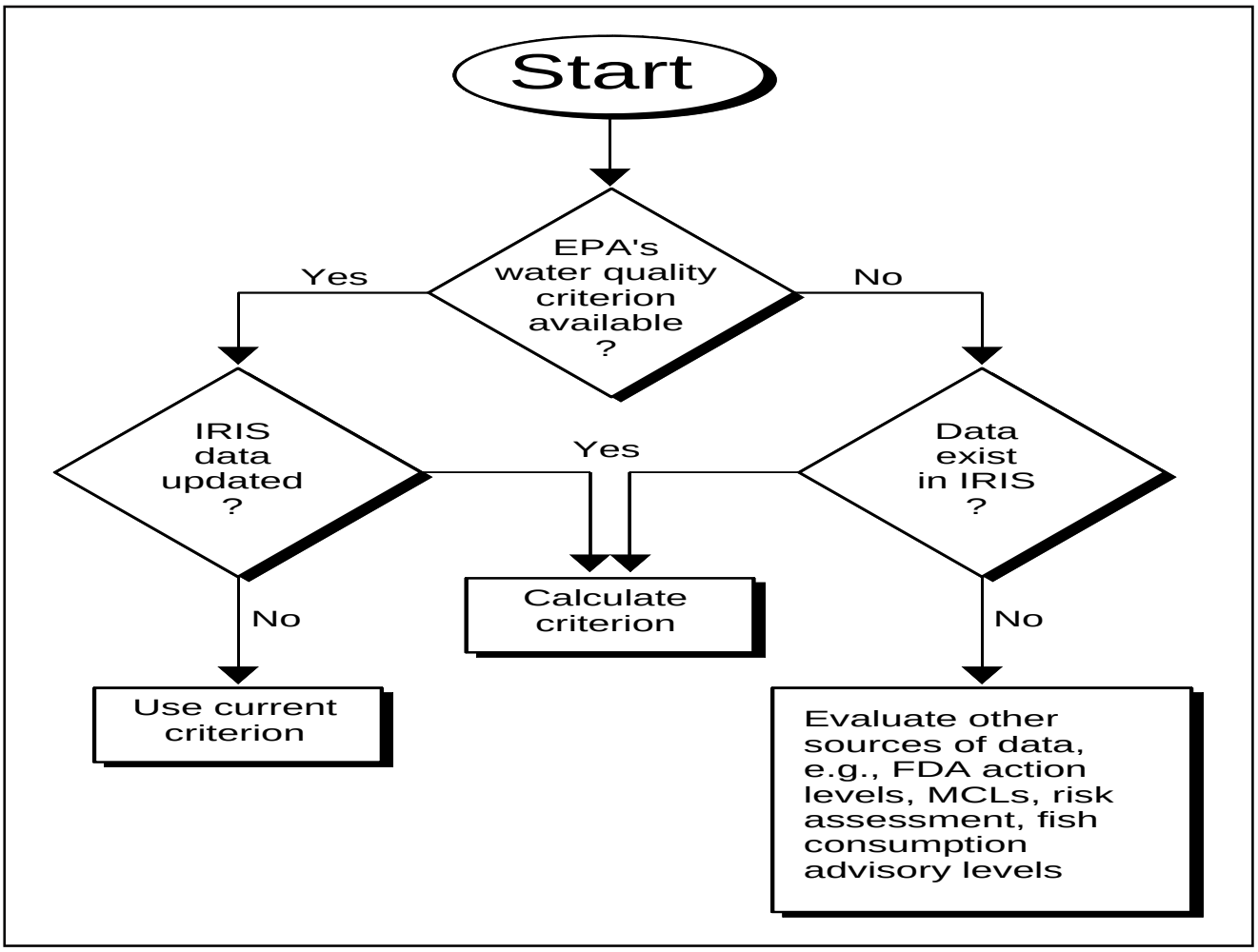
EPA recommends that States use the most current risk information in the process of updating human health criteria. The Integrated Risk Information System (IRIS) (Barns and Dourson, 1988; Appendix N) is an electronic data base of the USEPA that provides chemical-specific risk information on the relationship between chemical exposure and estimated human health effects. Risk assessment information contained in IRIS, except as specifically noted, has been reviewed and agreed upon by an interdisciplinary group of scientists representing various Program Offices within the Agency and represent an Agency-wide consensus. Risk assessment information and values are updated on a monthly basis and are approved for Agency-wide use. IRIS is intended to make risk assessment information readily available to those individuals who must perform risk assessments and also to increase consistency among risk assessment/risk management decisions.

IRIS contains two types of quantitative risks values: the oral Reference Dose (RfD) and the carcinogenic potency estimate or slope factor. The RfD (formerly known as the acceptable daily intake or ADI) is the human health hazard assessment for noncarcinogenic (target organ) effects. The carcinogenic potency estimate (formerly known as q_1^*) represents the upper bound cancer-causing potential resulting from lifetime exposure to a substance. The RfD or the oral carcinogenic potency estimate is used in the derivation of EPA human health criteria.

EPA periodically updates risk assessment information, including RfDs, cancer potency estimates, and related information on contaminant effects, and reports the current information on IRIS. Since IRIS contains the Agency's most recent quantitative risk assessment values, current IRIS values should be used by States in updating or developing new human health criteria. This means that the 1980 human health criteria should be updated with the latest IRIS values. The procedure for deriving an updated human health water quality criterion would require inserting the current Rfd or carcinogenic potency estimate on IRIS into the equations in Exhibit 3.1 or 3.2, as appropriate.

Figure 3-1 shows the procedure for determining an updated criterion using IRIS data. If a chemical has both carcinogenic and non-carcinogenic effects, i.e., both a cancer potency estimate and a RfD, both criteria should be calculated. The most stringent criterion applies

Figure 3-1. Procedure for determining an updated criterion using IRIS data.



Calculating Criteria for Non-carcinogens

The RfD is an estimate of the daily exposure to the human population that is likely to be without appreciable risk of causing deleterious effects during a lifetime. The RfD is expressed in units of mg toxicant per kg human body weight per day.

RfDs are derived from the "no-observed-adverse-effect level" (NOAEL) or the "lowest-observed-adverse-effect level" (LOAEL) identified from chronic or subchronic human epidemiology studies or animal exposure studies. (Note: "LOAEL" and "NOAEL" refer to animal and human toxicology and are therefore distinct from the aquatic toxicity terms "no-observed-effect concentration" (NOEC) and "lowest-observed-effect concentration" (LOEC).) Uncertainty factors are then applied to the NOAEL or LOAEL to account for uncertainties in the data associated with variability among individuals, extrapolation from nonhuman test species to humans, data on other than long-term exposures, and the use of a LOAEL (USEPA, 1988a). An additional uncertainty factor may be applied to account for significant weakness or gaps in the database.

The RfD is a threshold below which systemic toxic effects are unlikely to occur. While exposures above the RfD increase the probability of adverse effects, they do not produce a certainty of adverse effects. Similarly, while exposure at or below the RfD reduces the probability, it does not guarantee the absence of effects in all persons. The RfDs contained in IRIS are values that represent EPA's consensus (and have uncertainty spanning perhaps an order of magnitude). This means an RfD of 1.0 mg/kg/day could range from 0.3 to 3.0 mg/kg/day.

For noncarcinogenic effects, an updated criterion can be derived using the equation in Exhibit 3-1.

Exhibit 3-1. Equation for Deriving Human Health Criteria Based on Noncarcinogenic Effects

$$C\ (mg/l) = \frac{(RfD \times WT) - (DT + IN) \times WT}{WI + [FC \times L \times FM \times BCF]}$$

Where:

C=	updated water quality criterion (mg/l)
RfD =	oral reference dose (mg toxicant/kg human body weight/day)
WT =	weight of an average human adult (70 kg)
DT =	dietary exposure (other than fish) (mg toxicant/kg body human weight/day)
IN =	inhalation exposure (mg toxicant/kg body human weight/day)
WI =	average human adult water intake (2 l/day)
FC =	daily fish consumption (kg fish/day)
L =	ratio of lipid fraction of fish tissue consumed to 3%
FM =	food chain multiplier (from Table 3-1)
BCF =	bioconcentration factor (mg toxicant/kg fish divided by mg toxicant/L water) for fish with 3% lipid content

If the receiving water body is not used as a drinking water source, the factor WI can be deleted. Where dietary and/or inhalation exposure values are unknown, these factors may be deleted from the above calculation.

Calculating Criteria for Carcinogens

Any human health criterion for a carcinogen is based on at least three interrelated considerations: cancer potency, exposure, and risk characterization. When developing State criteria, States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments must be clear and in the public record.

Maximum protection of human health from the potential effects of exposure to carcinogens through the consumption of contaminated fish and/or other aquatic life would require a criterion of zero. The zero level is based upon the assumption of non-threshold effects (i.e., no safe level exists below which any increase in exposure does not result in an increased risk of cancer) for carcinogens. However, because a publicly acceptable policy for safety does not require the absence of all risk, a

numerical estimate of pollutant concentration (in µg/l) which corresponds to a given level of risk for a population of a specified size is selected instead. A cancer risk level is defined as the number of new cancers that may result in a population of specified size due to an increase in exposure (e.g., 10^{-6} risk level = 1 additional cancer in a population of 1 million). Cancer risk is calculated by multiplying the experimentally derived cancer potency estimate by the concentration of the chemical in the fish and the average daily human consumption of contaminated fish. The risk for a specified population (e.g., 1 million people or 10^{-6}) is then calculated by dividing the risk level by the specific cancer risk. EPA's ambient water quality criteria documents provide risk levels ranging from 10^{-5} to 10^{-7} as examples.

The cancer potency estimate, or slope factor (formerly known as the q_1^*), is derived using animal studies. High-dose exposures are extrapolated to low-dose concentrations and adjusted to a lifetime exposure period through the use of a linearized multistage model. The model calculates the upper 95 percent confidence limit of the slope of a straight line which the model postulates to occur at low doses. When based on human (epidemiological) data, the slope factor is based on the observed increase in cancer risk and is not extrapolated. For deriving criteria for carcinogens, the oral cancer potency estimates or slope factors from IRIS are used.

It is important to note that cancer potency factors may overestimate or underestimate the actual risk. Such potency estimates are subject to great uncertainty because of two primary factors:

- adequacy of the cancer data base (i.e., human vs. animal data); and
- limited information regarding the mechanism of cancer causation.

Risk levels of 10^{-5}, 10^{-6}, and 10^{-7} are often used by States as minimal risk levels in interpreting their standards. EPA considers risks to be additive, i.e., the risk from individual chemicals is not necessarily the overall risk from exposure to water. For example, an individual risk level of 10^{-6} may yield a higher overall risk level if multiple carcinogenic chemicals are present.

For carcinogenic effects, the criterion can be determined by using the equation in Exhibit 3-2.

Exhibit 3-2. Equation for Deriving Human Health Criteria Based on Carcinogenic Effects

$$C\ (mg/l) = \frac{(RL \times WT)}{q_l^* [WI + FC \times L \times (FM \times BCF)]}$$

Where:

C =	updated water quality criterion (mg/l)
RL =	risk level (10^{-x}) where x is usually in the range of 4 to 6
WT =	weight of an average human adult (70 kg)
q_1^* =	carcinogenic potency factor (kg day/mg)
WI =	average human adult water intake (2 l/day)
FC =	daily fish consumption (kg fish/day)

$$C\ (mg/l) = \frac{(RL \times WT)}{q_l^* [WI + FC \times L \times (FM \times BCF)]}$$

L = ratio of lipid fraction of fish tissue consumed to 3% assumed by EPA
FM = food chain multiplier (from Table 3-1)
BCF = bioconcentration factor (mg toxicant/kg fish divided by mg toxicant/L water) for fish with 3% lipid content

If the receiving water body is not designated as a drinking water source, the factor WI can be deleted.

Deriving Quantitative Risk Assessments in the Absence of IRIS Values

The RfDs or cancer potency estimates comprise the existing dose-response factors for developing criteria. When IRIS data are unavailable, quantitative risk level information may be developed according to a State's own procedures. Some States have established their own procedures whereby dose-response factors can be developed based upon extrapolation of acute and/or chronic animal data to concentrations of exposure protective of fish consumption by humans.
here owing to the complexity of the subject.

3.2 Section 304(a) Criteria to State Designated Uses

The section 304(a)(1) criteria published by EPA from time to time can be used to support the designated uses found in State standards. The following sections briefly discuss the relationship between certain criteria and individual use classifications. Additional information on this subject also can be found in the "Green Book" (FWPCA, 1968); the "Blue Book" (NAS/NAE, 1973); the "Red Book" USEPA, 1976); the EPA *Water Quality Criteria Documents* (see Appendix I); the"Gold Book" (USEPA, 1986a); and future EPA section 304(a)(1) water quality criteria publications.

Where a water body is designated for more than one use, criteria necessary to protect the most sensitive use must be applied. The following four sections discuss the major types of use categories.

3.2.1 Recreation

Recreational uses of water include activities such as swimming, wading, boating, and fishing. Often insufficient data exist on the human health effects of physical and chemical pollutants, including most toxics, to make a determination of criteria for recreational uses. However, as a general guideline, recreational waters that contain chemicals in concentrations toxic or otherwise harmful to man if ingested, or irritating to the skin or mucous membranes of the human body upon brief immersion, should be avoided. The section 304(a)(1) human health effects criteria based on direct human drinking water intake and fish consumption might provide useful guidance in these circumstances. Also, section 304(a)(1) criteria based on human health effects may be used to

support this designated use where fishing is included in the State definition of "recreation." In this latter situation, only the portion of the criterion based on fish consumption should be used. Section 304(a)(1) criteria to protect recreational uses are also available for certain physical, microbiological, and narrative "free from" aesthetic criteria.

Research regarding bacteriological indicators has resulted in EPA recommending that States use *Escherichia coli* or enterococci as indicators of recreational water quality (USEPA, 1986b) rather than fecal coliform because of the better correlation with gastroenteritis in swimmers.

The "Green Book" and "Blue Book" provide additional information on protecting recreational uses such as pH criteria to prevent eye irritation and microbiological criteria based on aesthetic considerations.

3.2.2 Aquatic Life

The section 304(a)(1) criteria for aquatic life should be used directly to support this designated use. If subcategories of this use are adopted (e.g., to differentiate between coldwater and warmwater fisheries), then appropriate criteria should be set to reflect the varying needs of such subcategories.

3.2.3 Agricultural and Industrial Uses

The "Green Book" (FWPCA, 1968) and "Blue Book" (NAS/NAE, 1973) provide some information on protecting agricultural and industrial uses. Section 304(a)(1) criteria for protecting these uses have not been specifically developed for numerous parameters pertaining to these uses, including most toxics.

Where criteria have not been specifically developed for these uses, the criteria developed for human health and aquatic life are usually sufficiently stringent to protect these uses. States may also establish criteria specifically designed to protect these uses.

3.2.4 Public Water Supply

The drinking water exposure component of the section 304(a)(1) criteria based on human health effects can apply directly to this use classification. The criteria also may be appropriately modified depending upon whether the specific water supply system falls within the auspices of the Safe Drinking Water Act's (SDWA) regulatory control and the type and level of treatment imposed upon the supply before delivery to the consumer. The SDWA controls the presence of contaminants in finished ("at-the-tap") drinking water.

A brief description of relevant sections of the SDWA is necessary to explain how the Act will work in conjunction with section 304(a)(1) criteria in protecting human health from the effects of toxics due to consumption of water. Pursuant to section 1412 of the SDWA, EPA has promulgated "National Primary Drinking Water Standards" for certain radionuclide, microbiological, organic, and inorganic

substances. These standards establish maximum contaminant levels (MCLs), which specify the maximum permissible level of a contaminant in water that may be delivered to a user of a public water system now defined as serving a minimum of 25 people. MCLs are established based on consideration of a range of factors including not only the health effects of the contaminants but also treatment capability, monitoring availability, and costs. Under section 1401(1)(D)(i) of the SDWA, EPA is also allowed to establish the minimum quality criteria for water that may be taken into a public water supply system.

Section 304(a)(1) criteria provide estimates of pollutant concentrations protective of human health, but do not consider treatment technology, costs, and other feasibility factors. The section 304(a)(1) criteria also include fish bioaccumulation and consumption factors in addition to direct human drinking water intake. These numbers were not developed to serve as "at-the-tap" drinking water standards, and they have no regulatory significance under the SDWA. Drinking water standards are established based on considerations, including technological and economic feasibility, not relevant to section 304(a)(1) criteria. Section 304(a)(1) criteria are more analogous to the maximum contaminant level goals (MCLGs) (previously known as RMCLs) under section 1412(b)(1)(B) of the SDWA in which, based upon a report from the National Academy of Sciences, the Administrator should set target levels for contaminants in drinking water at which "no known or anticipated adverse effects occur and which allow an adequate margin of safety." MCLGs do not take treatment, cost, and other feasibility factors into consideration. Section 304(a)(1) criteria are, in concept, related to the health-based goals specified in the MCLGs.

MCLs of the SDWA, where they exist, control toxic chemicals in finished drinking water. However, because of variations in treatment, ambient water criteria may be used by the States as a supplement to SDWA regulations. When setting water quality criteria for public water supplies, States have the option of applying MCLs, section 304(a)(1) human health effects criteria, modified section 304(a)(1) criteria, or controls more stringent than these three to protect against the effects of contaminants by ingestion from drinking water.

For treated drinking water supplies serving 25 people or greater, States must control contaminants down to levels at least as stringent as MCLs (where they exist for the pollutants of concern) in the finished drinking water. However, States also have the options to control toxics in the ambient water by choosing section 304(a)(1) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment process reduces the level of pollutants, or a more stringent contaminant level than the former three options.

3.3 State Criteria Requirements

Section 131.11(a)(1) of the Regulation requires States to adopt water quality criteria to protect the designated use(s). The State criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use(s). For waters with multiple use designations, the criteria must support the most sensitive use.

In section 131.11, States are encouraged to adopt both numeric and narrative criteria. Aquatic life criteria should protect against both short-term (acute) and long-term (chronic) effects. Numeric criteria are particularly important where the cause of toxicity is known or for protection against pollutants with potential human health impacts or bioaccumulation potential. Numeric water quality criteria may also be the best way to address nonpoint source pollution problems. Narrative criteria can be the basis for limiting toxicity in waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity but where there are no numeric criteria in the State standards. Narrative criteria also can be used where toxicity cannot be traced to a particular pollutant.

Section 131.11(a)(2) requires States to develop implementation procedures which explain how the State will ensure that narrative toxics criteria are met.

To more fully protect aquatic habitats, it is EPA's policy that States fully integrate chemical-specific, whole-effluent, and biological assessment approaches in State water quality programs (see Appendix R). Specifically, each of these three methods can provide a valid assessment of non-attainment of designated aquatic life uses but can rarely demonstrate use attainment separately. Therefore, EPA supports a policy of independent application of these three water quality assessment approaches. Independent application means that the validity of the results of any one of the approaches does not depend on confirmation by one or both of the other methods. This policy is based on the unique attributes, limitations, and program applications of each of the three approaches. Each method alone can provide valid and independently sufficient evidence of non-attainment of water quality standards, irrespective of any evidence, or lack thereof, derived from the other two approaches. The failure of one method to confirm impacts identified by another method does not negate the results of the initial assessment.

It is also EPA's policy that States should designate aquatic life uses that appropriately address biological integrity and adopt biological criteria necessary to protect those uses (see section 3.5.3 and Appendices C, K, and R).

3.4 Criteria for Toxicants

Applicable requirements for State adoption of water quality criteria for toxicants vary depending upon the toxicant. The reason for this is that the 1983 Water Quality Standards Regulation (Appendix A) and the Water Quality Act of 1987 which amended the Clean Water Act (Public Law 100-4) include more specific requirements for the particular toxicants listed pursuant to CWA section 307(a). For regulatory purposes, EPA has translated the 65 compounds and families of compounds listed pursuant to section 307(a) into 126 more specific substances, which EPA refers to as "priority toxic pollutants." The 126 priority toxic pollutants are listed in the WQS regulation and in Appendix P of this Handbook. Because of the more specific requirements for priority toxic pollutants, it is convenient to organize the requirements applicable to State adoption of criteria for toxicants into three categories:

- requirements applicable to priority toxic pollutants that have been the subject of CWA section 304(a)(1) criteria guidance (see section 3.4.1);
- requirements applicable to priority toxic pollutants that have not been the subject of CWA section 304(a)(1) criteria guidance (see section 3.4.1); and
- requirements applicable to all other toxicants (e.g., non-conventional pollutants like ammonia and chlorine) (see section 3.4.2).

3.4.1 Priority Toxic Pollutant Criteria

The criteria requirements applicable to priority toxic pollutants (i.e., the first two categories above) are specified in CWA section 303(c)(2)(B). Section 303(c)(2)(B), as added by the Water Quality Act of 1987, provides that:

Whenever a State reviews water quality standards pursuant to paragraph (1) of this subsection, or revises or adopts new standards pursuant to this paragraph, such State shall adopt criteria for all toxic pollutants listed pursuant to section 307(a)(1) of this Act for which criteria have been published under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses. Such criteria shall be specific numerical criteria for such toxic pollutants. Where such numerical criteria are not available, whenever a State reviews water quality standards pursuant to paragraph (1), or revises or adopts new standards pursuant to this paragraph, such State shall adopt criteria based on biological monitoring or assessment methods consistent with information published pursuant to section 304(a)(8). Nothing in this section shall be construed to limit or delay the use of effluent limitations or other permit conditions based on or involving biological monitoring or assessment methods or previously adopted numerical criteria.

EPA, in devising guidance for section 303(c)(2)(B), attempted to provide States with the maximum flexibility that complied with the express statutory language but also with the overriding congressional objective: prompt adoption and implementation of numeric toxics criteria. EPA believed that flexibility was important so that each State could comply with section 303(c)(2)(B) and to the extent possible, accommodate its existing water quality standards regulatory approach.

General Requirements

To carry out the requirements of section 303(c)(2)(B), whenever a State revises its water quality standards, it must review all available information and data to first determine whether the discharge or the presence of a toxic pollutant is interfering with or is likely to interfere with the attainment of the designated uses of any water body segment.

If the data indicate that it is reasonable to expect the toxic pollutant to interfere with the use, or it actually is interfering with the use, then the State must adopt a numeric limit for the specific pollutant. If a State is unsure whether a toxic pollutant is interfering with, or is likely to interfere

with, the designated use and therefore is unsure that control of the pollutant is necessary to support the designated use, the State should undertake to develop sufficient information upon which to make such a determination. Presence of facilities that manufacture or use the section 307(a) toxic pollutants or other information indicating that such pollutants are discharged or will be discharged strongly suggests that such pollutants could be interfering with attaining designated uses. If a State expects the pollutant not to interfere with the designated use, then section 303(1)(2)(B) does not require a numeric standard for that pollutant.

Section 303(c)(2)(B) addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act, which are codified at 40 CFR 131.36(b). The section 307(a) list contains 65 compounds and families of compounds, which potentially include thousands of specific compounds. The Agency has interpreted that list to include 126 "priority" toxic pollutants for regulatory purposes. Reference in this guidance to toxic pollutants or section 307(a) toxic pollutants refers to the 126 priority toxic pollutants unless otherwise noted. Both the list of priority toxic pollutants and recommended criteria levels are subject to change.

The national criteria recommendations published by EPA under section 304(a) (see section 3.1, above) of the Act include values for both acute and chronic aquatic life protection; only chronic criteria recommendations have been established to protect human health. To comply with the statute, a State needs to adopt aquatic life and human health criteria where necessary to support the appropriate designated uses. Criteria for the protection of human health are needed for water bodies designated for public water supply. When fish ingestion is considered an important activity, then the human health-related water quality criteria recommendation developed under section 304(a) of the CWA should be used; that is, the portion of the criteria recommendation based on fish consumption. For those pollutants designated as carcinogens, the recommendation for a human health criterion is generally more stringent than the aquatic life criterion for the same pollutant. In contrast, the aquatic life criteria recommendations for noncarcinogens are generally more stringent than the human health recommendations. When a State adopts a human health criterion for a carcinogen, the State needs to select a risk level. EPA has estimated risk levels of 10^{-5}, 10^{-6}, and 10^{-7} in its criteria documents under one set of exposure assumptions. However, the State is not limited to choosing among the risk levels published in the section 304(a) criteria documents, nor is the State limited to the base case exposure assumptions; it must choose the risk level for its conditions and explain its rationale.

EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations. However, if a State selects a criterion that represents an upper bound risk level less protective than 1 in 100,000 (e.g., 10^{-5}), the State needs to have substantial support in the record for this level. This support focuses on two distinct issues. First, the record must include documentation that the decision maker considered the public interest of the State in selecting the risk level, including documentation of public participation in the decision making process as required by the Water Quality Standards Regulation at 40 CFR 131.20(b). Second, the record must include an analysis showing that the risk level selected, when combined with other risk assessment variables, is a balanced and reasonable estimate of actual risk

posed, based on the best and most representative information available. The importance of the estimated actual risk increases as the degree of conservatism in the selected risk level diminishes. EPA carefully evaluates all assumptions used by a State if the State chose to alter any one of the standard EPA assumption values (57 F.R. 60864, December 22, 1993).

EPA does not intend to propose changes to the current requirements regarding the bases on which a State can adopt numeric criteria (40 CFR 131.11(b)(1)). Under EPA's regulation, in addition to basing numeric criteria on EPA's section 304(a) criteria documents, States may also base numeric criteria on site-specific determinations or other scientifically defensible methods.

EPA expects each State to comply with the new statutory requirements in any section 303(c) water quality standards review initiated after enactment of the Water Quality Act of 1987. The structure of section 303(c) is to require States to review their water quality standards at least once each 3 year period. Section 303(c)(2)(B) instructs States to include reviews for toxics criteria whenever they initiate a triennial review. Therefore, even if a State has complied with section 303(c)(2)(B), the State must review its standards each triennium to ensure that section 303(c)(2)(B) requirements continue to be met, considering that EPA may have published additional section 304(a) criteria documents and that the State will have new information on existing water quality and on pollution sources.

It should be noted that nothing in the Act or in the Water Quality Standards Regulation restricts the right of a State to adopt numeric criteria for any pollutant not listed pursuant to section 307(a)(1), and that such criteria may be expressed as concentration limits for an individual pollutant or for a toxicity parameter itself as measured by whole-effluent toxicity testing. However, neither numeric toxic criteria nor whole-effluent toxicity should be used as a surrogate for, or to supersede the other.

State Options

States may meet the requirements of CWA section 303(c)(2)(B) by choosing one of three scientifically and technically sound options (or some combination thereof):

1. Adopt statewide numeric criteria in State water quality standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present;
2. Adopt specific numeric criteria in State water quality standards for section 307(a) toxic pollutants as necessary to support designated uses where such pollutants are discharged or are present in the affected waters and could reasonably be expected to interfere with designated uses;
3. Adopt a "translator procedure" to be applied to a narrative water quality standard provision that prohibits toxicity in receiving waters. Such a procedure is to be used by the State in calculating derived numeric criteria, which shall be used for all purposes under section 303(c) of the CWA. At a minimum, such criteria need to be developed for section 307(a) toxic pollutants, as necessary to support designated

uses, where these pollutants are discharged or present in the affected waters and could reasonably be expected to interfere with designated uses.

Option 1 is consistent with State authority to establish water quality standards. Option 2 most directly reflects the CWA requirements and is the option recommended by EPA. Option 3, while meeting the requirements of the CWA, is best suited to supplement numeric criteria from option 1 or 2. The three options are discussed in more detail below.

OPTION 1:
Adopt statewide numeric criteria in State water quality standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present.

Pro:

- simple, straightforward implementation
- ensures that States will satisfy statute
- makes maximum uses of EPA recommendations
- gets specific numbers into State water quality standards fast, at first

Con:

- some priority toxic pollutants may not be discharged in State
- may cause unnecessary monitoring by States
- might result in "paper standards"

Option 1 is within a State's legal authority under the CWA to adopt broad water quality standards. This option is the most comprehensive approach to satisfy the statutory requirements because it would include all of the priority toxic pollutants for which EPA has prepared section 304(a) criteria guidance for either or both aquatic life protection and human health protection. In addition to a simple adoption of EPA's section 304(a) guidance as standards, a State must select a risk level for those toxic pollutants which are carcinogens (i.e., that cause or may cause cancer in humans).

Many States find this option attractive because it ensures comprehensive coverage of the priority toxic pollutants with scientifically defensible criteria without the need to conduct a resource-intensive evaluation of the particular segments and pollutants requiring criteria. This option also would not be more costly to dischargers than other options because permit limits would be based only on the regulation of the particular toxic pollutants in their discharges and not on the total listing in the water quality standards. Thus, actual permit limits should be the same under any of the options.

The State may also exercise its authority to use one or more of the techniques for adjusting water quality standards:

- establish or revise designated stream uses based on use attainability analyses (see section 2.9);
- develop site-specific criteria; or
- allow short-term variances (see section 5.3) when appropriate.

All three of these techniques may apply to standards developed under any of the three options discussed in this guidance. It is likely that States electing to use option 1 will rely more on variances because the other two options are implemented with more site-specific data being available. It should be noted, however, that permits issued pursuant to such water quality variances still must comply with any applicable antidegradation and antibacksliding requirements.

OPTION 2:

Adopt specific numeric criteria in State water quality standards for section 307(a) toxic pollutants as necessary to support designated uses where such pollutants are discharged or are present in the affected waters and could reasonably be expected to interfere with designated uses.

Pro:

- directly reflects statutory requirement
- standards based on demonstrated need to control problem pollutants
- State can use EPA's section 304(a) national criteria recommendations or other scientifically acceptable alternative, including site-specific criteria
- State can consider current or potential toxic pollutant problems
- State can go beyond section 307(a) toxics list, as desired

Con:

- may be difficult and time consuming to determine if, and which, pollutants are interfering with the designated use
- adoption of standards can require lengthy debates on correct criteria limit to be included in standards
- successful State toxic control programs based on narrative criteria may be halted or slowed as the State applies its limited resources to developing numeric standards
- difficult to update criteria once adopted as part of standards
- to be absolutely technically defensible, may need site-specific criteria in many situations, leading to a large workload for regulatory agency

EPA recommends that a State use this option to meet the statutory requirement. It directly reflects all the Act's requirements and is flexible, resulting in adoption of numeric water quality standards as needed. To assure that the State is capable of dealing with new problems as they arise, EPA also recommends that States adopt a translator procedure the same as, or similar to, that described in

option 3, but applicable to all chemicals causing toxicity and not just priority pollutants as is the case for option 3.

Beginning in 1988, EPA provided States with candidate lists of priority toxic pollutants and water bodies in support of CWA section 304(l) implementation. These lists were developed because States were required to evaluate existing and readily available water-related data to comply with section 304(l), 40 CFR 130.10(d). A similar "strawman" analysis of priority pollutants potentially requiring adoption of numeric criteria under section 303(c)(2)(B) was furnished to most States in September or October of 1990 for their use in ongoing and subsequent triennial reviews. The primary differences between the "strawman" analysis and the section 304(l) candidate lists were that the "strawman" analysis (1) organized the results by chemical rather than by water body, (2) included data for certain STORET monitoring stations that were not used in constructing the candidate lists, (3) included data from the Toxics Release Inventory database, and (4) did not include a number of data sources used in preparing the candidate lists (e.g., those, such as fish kill information, that did not provide chemical-specific information).

EPA intends for States, at a minimum, to use the information gathered in support of section 304(l) requirements as a starting point for identifying (1) water segments that will need new and/or revised water quality standards for section 307(a) toxic pollutants, and (2) which priority toxic pollutants require adoption of numeric criteria. In the longer term, EPA expects similar determinations to occur during each triennial review of water quality standards as required by section 303(c).

In identifying the need for numeric criteria, EPA is encouraging States to use information and data such as:

- presence or potential construction of facilities that manufacture or use priority toxic pollutants;
- ambient water monitoring data, including those for sediment and aquatic life (e.g., fish tissue data);
- NPDES permit applications and permittee self-monitoring reports;
- effluent guideline development documents, many of which contain section 307(a)(1) priority pollutant scans;
- pesticide and herbicide application information and other records of pesticide or herbicide inventories;
- public water supply source monitoring data noting pollutants with Maximum Contaminant Levels (MCLs); and
- any other relevant information on toxic pollutants collected by Federal, State, interstate agencies, academic groups, or scientific organizations.

States are also expected to take into account newer information as it became available, such as information in annual reports from the Toxic Chemical Release Inventory requirements of the Emergency Planning and Community Right-To-Know Act of 1986 (Title III, Public Law 99-499).

Where the State's review indicates a reasonable expectation of a problem from the discharge or presence of toxic pollutants, the State should identify the pollutant(s) and the relevant segment(s). In making these determinations, States should use their own EPA-approved criteria or existing EPA water quality criteria for purposes of segment identification. After the review, the State may use other means to establish the final criterion as it revises its standards.

As with option 1, a State using option 2 must follow all its legal and administrative requirements for adoption of water quality standards. Since the resulting numeric criteria are part of a State's water quality standards, they are required to be submitted by the State to EPA for review and either approval or disapproval.

EPA believes this option offers the State optimum flexibility. For section 307(a) toxic pollutants adversely affecting designated uses, numeric criteria are available for permitting purposes. For other situations, the State has the option of defining site-specific criteria.

OPTION 3:

Adopt a procedure to be applied to the narrative water quality standard provision that prohibits toxicity in receiving waters. Such a procedure would be used by a State in calculating derived numeric criteria to be used for all purposes of water quality criteria under section 303(c) of the CWA. At a minimum such criteria need to be derived for section 307(a) toxic pollutants where the discharge or presence of such pollutants in the affected waters could reasonably be expected to interfere with designated uses, as necessary to support such designated uses.

Pro:

- allows a State flexibility to control priority toxic pollutants
- reduces time and cost required to adopt specific numeric criteria as water quality standards regulations
- allows immediate use of latest scientific information available at the time a State needs to develop derived numeric criteria
- revisions and additions to derived numeric criteria can be made without need to revise State law
- State can deal more easily with a situation where it did not establish water quality standards for the section 307(a) toxic pollutants during the most recent triennial review
- State can address problems from non-section 307(a) toxic pollutants

Con:

- EPA is currently on notice that a derived numeric criterion may invite legal challenge

- once the necessary procedures are adopted to enhance legal defensibility (e.g., appropriate scientific methods and public participation and review), actual savings in time and costs may be less than expected
- public participation in development of derived numeric criteria may be limited when such criteria are not addressed in a hearing on water quality standards

EPA believes that adoption of a narrative standard along with a translator mechanism as part of a State's water quality standard satisfies the substantive requirements of the statute. These criteria are subject to all the State's legal and administrative requirements for adoption of standards plus review and either approval or disapproval by EPA, and result in the development of derived numeric criteria for specific section 307(a) toxic pollutants. They are also subject to an opportunity for public participation. Nevertheless, EPA believes the most appropriate use of option 3 is as a supplement to either option 1 or 2. Thus, a State would have formally adopted numeric criteria for toxic pollutants that occur frequently; that have general applicability statewide for inclusion in NPDES permits, total maximum daily loads, and waste load allocations; and that also would have a sound and predictable method to develop additional numeric criteria as needed. This combination of options provides a complete regulatory scheme.

Although the approach in option 3 is similar to that currently allowed in the Water Quality Standards Regulation (40 CFR 131.11(a)(2)), this guidance discusses several administrative and scientific requirements that EPA believes are necessary to comply with section 303(c)(2)(B).

1. The Option 3 Procedure Must Be Used To Calculate Derived Numeric Water Quality Criteria

States must adopt a specific procedure to be applied to a narrative water quality criterion. To satisfy section 303(c)(2)(B), this procedure shall be used by the State in calculating derived numeric criteria, which shall be used for all purposes under section 303(c) of the CWA. Such criteria need to be developed for section 307(a) toxic pollutants as necessary to support designated uses, where these pollutants are discharged or are present in the affected waters and could reasonably be expected to interfere with the designated uses.

To assure protection from short-term exposures, the State procedure should ensure development of derived numeric water quality criteria based on valid acute aquatic toxicity tests that are lethal to half the affected organisms (LC50) for the species representative of or similar to those found in the State. In addition, the State procedure should ensure development of derived numeric water quality criteria for protection from chronic exposure by using an appropriate safety factor applicable to this acute limit. If there are saltwater components to the State's aquatic resources, the State should establish appropriate derived numeric criteria for saltwater in addition to those for freshwater.

The State's documentation of the tests should include a detailed discussion of its quality control and quality assurance procedures. The State should also include a description (or reference existing technical agreements with EPA) of the procedure it will use to calculate derived acute and chronic

numeric criteria from the test data, and how these derived criteria will be used as the basis for deriving appropriate TMDLs, WLAs, and NPDES permit limits.

As discussed above, the procedure for calculating derived numeric criteria needs to protect aquatic life from both acute and chronic exposure to specific chemicals. Chronic aquatic life criteria are to be met at the edge of the mixing zone. The acute criteria are to be met (1) at the end-of-pipe if mixing is not rapid and complete and a high rate diffuser is not present; or (2) after mixing if mixing is rapid and complete or a high rate diffuser is present. (See EPA's *Technical Support Document for Water Quality-based Toxics Control*, USEPA 1991a.)

EPA has not established a national policy specifying the point of application in the receiving water to be used with human health criteria. However, EPA has approved State standards that apply human health criteria for fish consumption at the mixing zone boundary and/or apply the criteria for drinking water consumption, at a minimum, at the point of use. EPA has also proposed more stringent requirements for the application of human health criteria for highly bioaccumulative pollutants in the *Water Quality guidance for the Great Lakes System* (50 F.R. 20931, 21035, April 16, 1993) including elimination of mixing zones.

In addition, the State should also include an indication of potential bioconcentration or bioaccumulation by providing for:

- laboratory tests that measure the steady-state bioconcentration rate achieved by a susceptible organism; and/or
- field data in which ambient concentrations and tissue loads are measured to give an appropriate factor.

In developing a procedure to be used in calculating derived numeric criteria for the protection of aquatic life, the State should consider the potential impact that bioconcentration has on aquatic and terrestrial food chains.

The State should also use the derived bioconcentration factor and food chain multiplier to calculate chronically protective numeric criteria for humans that consume aquatic organisms. In calculating this derived numeric criterion, the State should indicate data requirements to be met when dealing with either threshold (toxic) or non-threshold (carcinogenic) compounds. The State should describe the species and the minimum number of tests, which may generally be met by a single mammalian chronic test if it is of good quality and if the weight of evidence indicates that the results are reasonable. The State should provide the method to calculate a derived numeric criterion from the appropriate test result.

Both the threshold and non-threshold criteria for protecting human health should contain exposure assumptions, and the State procedure should be used to calculate derived numeric criteria that address the consumption of water, consumption of fish, and combined consumption of both water and fish. The State should provide the assumptions regarding the amount of fish and the quantity of water consumed per person per day, as well as the rationale used to select the assumptions. It needs to include the number of tests, the species necessary to establish a dose-response relationship, and the procedure to be used to calculate the derived numeric criteria. For non-threshold contaminants, the State should specify the model used to extrapolate to low dose and the risk level. It should also address incidental exposure from other water sources (e.g., swimming). When calculating derived numeric criteria for multiple exposure to pollutants, the State should consider additive effects, especially for carcinogenic substances, and should factor in the contribution to the daily intake of toxicants from other sources (e.g., food, air) when data are available.

2. The State Must Demonstrate That the Procedure Results in Derived Numeric Criteria Are Protective

The State needs to demonstrate that its procedures for developing criteria, including translator methods, yield fully protective criteria for human health and for aquatic life. EPA's review process will proceed according to EPA's regulation of 40 CFR 131.11, which requires that criteria be based on sound scientific rationale and be protective of all designated uses. EPA will use the expertise and experience it has gained in developing section 304(a) criteria for toxic pollutants by application of its own translator method (USEPA, 1980b; USEPA, 1985b).

Once EPA has approved the State's procedure, the Agency's review of derived numeric criteria, for example, for pollutants other than section 307(a) toxic pollutants resulting from the State's procedure, will focus on the adequacy of the data base rather than the calculation method. EPA also encourages States to apply such a procedure to calculate derived numeric criteria to be used as the basis for deriving permit limitations for nonconventional pollutants that also cause toxicity.

3. The State Must Provide Full Opportunity for Public Participation in Adoption of the Procedure

The Water Quality Standards Regulation requires States to hold public hearings to review and revise water quality standards in accordance with provisions of State law and EPA's Public Participation Regulation (40 CFR 25). Where a State plans to adopt a procedure to be applied to the narrative

criterion, it must provide full opportunity for public participation in the development and adoption of the procedure as part of the State's water quality standards.

While it is not necessary for the State to adopt each derived numeric criterion into its water quality standards and submit it to EPA for review and approval, EPA is very concerned that all affected parties have adequate opportunity to participate in the development of a derived numeric criterion even though it is not being adopted directly as a water quality standard.

A State can satisfy the need to provide an opportunity for public participation in the development of derived numeric criteria in several ways, including:

- a specific hearing on the derived numeric criterion;
- the opportunity for a public hearing on an NPDES permits as long as public notice is given that a criterion for a toxic pollutant as part of the permit issuance is being contemplated; or
- a hearing coincidental with any other hearing as long as it is made clear that development of a specific criterion is also being undertaken.

For example, as States develop their lists and individual control strategies (ICSs) under section 304(1), they may seek full public participation. NPDES regulations also specify public participation requirements related to State permit issuance. Finally, States have public participation requirements associated with Water Quality Management Plan updates. States may take advantage of any of these public participation requirements to fulfill the requirement for public review of any resulting derived numeric criteria. In such cases, the State must give prior notice that development of such criteria is under consideration.

4. The Procedure Must Be Formally Adopted and Mandatory

Where a State elects to supplement its narrative criterion with an accompanying implementing procedure, it must formally adopt such a procedure as a part of its water quality standards. The procedure must be used by the State to calculate derived numeric criteria that will be used as the basis for all standards' purposes, including the following: developing TMDLs, WLAs, and limits in NPDES permits; determining whether water use designations are being met; and identifying potential nonpoint source pollution problems.

5. The Procedure Must Be Approved by EPA as Part of the State's Water Quality Standards Regulation

To be consistent with the requirements of the Act, the State's procedure to be applied to the narrative criterion must be submitted to EPA for review and approval, and will become a part of the State's water quality standards. (See 40 CFR 131.21 for further discussion.) This requirement may be satisfied by a reference in the standards to the procedure, which may be contained in another

document, which has legal effect and is binding on the State, and all the requirements for public review, State implementation, and EPA review and approval are satisfied.

Criteria Based on Biological Monitoring

For priority toxic pollutants for which EPA has not issued section 304(a)(1) criteria guidance, CWA section 303(c)(2)(B) requires States to adopt criteria based on biological monitoring or assessment methods. The phrase "biological monitoring or assessment methods" includes:

- whole-effluent toxicity control methods;
- biological criteria methods; or
- other methods based on biological monitoring or assessment.

The phrase "biological monitoring or assessment methods" in its broadest sense also includes criteria developed through translator procedures. This broad interpretation of that phrase is consistent with EPA's policy of applying chemical-specific, biological, and whole-effluent toxicity methods independently in an integrated toxics control program. It is also consistent with the intent of Congress to expand State standards programs beyond chemical-specific approaches.

States should also consider developing protocols to derive and adopt numeric criteria for priority toxic pollutants (or other pollutants) where EPA has not issued section 304(a) criteria guidance. The State should consider available laboratory toxicity test data that may be sufficient to support derivation of chemical-specific criteria. Existing data need not be as comprehensive as that required to meet EPA's 1985 guidelines in order for a State to use its own protocols to derive criteria. EPA has described such protocols in the proposed *Water Quality Guidance for the Great Lakes System* (58 F.R. 20892, at 21016, April 16, 1993.) This is particularly important where other components of a State's narrative criterion implementation procedure (e.g., WET controls or biological criteria) may not ensure full protection of designated uses. For some pollutants, a combination of chemical-specific and other approaches is necessary (e.g., pollutants where bioaccumulation in fish tissue or water consumption by humans is a primary concern).

Biologically based monitoring or assessment methods serve as the basis for control where no specific numeric criteria exist or where calculation or application of pollutant-by-pollutant criteria appears infeasible. Also, these methods may serve as a supplemental measurement of attainment of water quality standards in addition to numeric and narrative criteria. The requirement for both numeric criteria and biologically based methods demonstrates that section 303(c)(2)(B) contemplates that States develop a comprehensive toxics control program regardless of the status of EPA's section 304(a) criteria.

The whole-effluent toxicity (WET) testing procedure is the principal biological monitoring guidance developed by EPA to date. The purpose of the WET procedure is to control point source dischargers of toxic pollutants. The procedure is particularly useful for monitoring and controlling the toxicity of complex effluents that may not be well controlled through chemical-specific numeric criteria. As

such, biologically based effluent testing procedures are a necessary component of a State's toxics control program under section 303(c)(2)(B) and a principal means for implementing a State's narrative "free from toxics" standard.

Guidance documents EPA considers to serve the purpose of section 304(a)(8) include the *Technical Support Document for Water Quality-based Toxics Control* (USEPA, 1991a; *Guidelines for Deriving National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (Appendix H); *Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents* (Appendix J); *Methods for Measuring Acute Toxicity of Effluents to Freshwater and Marine Organisms* (USEPA, 1991d); *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms* (USEPA, 1991e); and *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms* (USEPA, 1991f).

3.4.2 Criteria for Nonconventional Pollutants

Criteria requirements applicable to toxicants that are not priority toxic pollutants (e.g., ammonia and chlorine), are specified in the 1983 Water Quality Standards Regulation (see 40 CFR 131.11). Under these requirements, States must adopt criteria based on sound scientific rationale that cover sufficient parameters to protect designated uses. Both numeric and narrative criteria (discussed in sections 3.5.1 and 3.5.2, below) may be applied to meet these requirements.

3.5 Forms of Criteria

States are required to adopt water quality criteria, based on sound scientific rationale, that contain sufficient parameters or constituents to protect the designated use. EPA believes that an effective State water quality standards program should include both parameter-specific (e.g., ambient numeric criteria) and narrative approaches.

3.5.1 Numeric Criteria

Numeric criteria are required where necessary to protect designated uses. Numeric criteria to protect aquatic life should be developed to address both short-term (acute) and long-term (chronic) effects. Saltwater species, as well as freshwater species, must be adequately protected. Adoption of numeric criteria is particularly important for toxicants known to be impairing surface waters and for toxicants with potential human health impacts (e.g., those with high bioaccumulation potential). Human health should be protected from exposure resulting from consumption of water and fish or other aquatic life (e.g., mussels, crayfish). Numeric water quality criteria also are useful in addressing nonpoint source pollution problems.

In evaluating whether chemical-specific numeric criteria for toxicants that are <u>not</u> priority toxic pollutants are required, States should consider whether other approaches (such as whole-effluent toxicity criteria or biological controls) will ensure full protection of designated uses. As mentioned

above, a combination of independent approaches may be required in some cases to support the designated uses and comply with the requirements of the Water Quality Standards Regulation (e.g., pollutants where bioaccumulation in fish tissue or water consumption by humans is a primary concern).

3.5.2 Narrative Criteria

To supplement numeric criteria for toxicants, all States have also adopted narrative criteria for toxicants. Such narrative criteria are statements that describe the desired water quality goal, such as the following:

All waters, including those within mixing zone, shall be free from substances attributable to wastewater discharge or other pollutant sources that:

1. Settle to form objectionable deposits;
2. Float as debris, scum, oil, or other matter forming nuisances;
3. Produce objectionable color, odor, taste, or turbidity;
4. Cause injury to or are toxic to, or produce adverse physiological responses in humans, animals, or plants; or
5. Produce undesirable or nuisance aquatic life (54 F.R.28627, July 6, 1989).

EPA considers that the narrative criteria apply to all designated uses at all flows and are necessary to meet the statutory requirements of section 303(c)(2)(A) of the CWA.

Narrative toxic criteria (No. 4, above) can be the basis for establishing chemical-specific limits for waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity and the State has not adopted chemical-specific numeric criteria. Narrative toxic criteria are cited as a basis for establishing whole-effluent toxicity controls in EPA permitting regulations at 40 CFR 122.44(d)(1)(v).

To ensure that narrative criteria for toxicants are attained, the Water Quality Standards Regulation requires States to develop implementation procedures (see 40 CFR 131.11(a)(2)). Such implementation procedures.

Exhibit 3-3. Components of a State Implementation Procedure for Narrative Toxics Criteria

State implementation procedures for narrative toxics criteria should describe the following:

- Specific, scientifically defensible methods by which the State will implement its narrative toxics standard for all toxicants, including:
    - methods for chemical-specific criteria, including methods for applying chemical-specific criteria in permits, developing or modifying chemical-specific criteria via a "translator procedure" (defined and discussed below),

and calculating site-specific criteria based on local water chemistry or biology);
    - methods for developing and implementing whole-effluent toxicity criteria and/or controls; and
    - methods for developing and implementing biological criteria.

- How these methods will be integrated in the State's toxics control program (i.e., how the State will proceed when the specified methods produce conflicting or inconsistent results).
- Application criteria and information needed to apply numerical criteria, for example:
    - methods the State will use to identify those pollutants to be regulated in a specific discharge;
    - an incremental cancer risk level for carcinogens;
    - methods for identifying compliance thresholds in permits where calculated limits are below detection;
    - methods for selecting appropriate hardness, pH, and temperature variables for criteria expressed as functions;
    - methods or policies controlling the size and in-zone quality of mixing zones
    - design flows to be used in translating chemical-specific numeric criteria for aquatic life and human health into permit limits; and
    - other methods and information needed to apply standards on a case-by-case basis.

(Exhibit 3-3) should address all mechanisms to be used by the State to ensure that narrative criteria are attained. Because implementation of chemical-specific numeric criteria is a key component of State toxics control programs, narrative criteria implementation procedures must describe or reference the State's procedures to implement such chemical-specific numeric criteria (e.g., procedures for establishing chemical-specific permit limits under the NPDES permitting program). Implementation procedures must also address State programs to control whole-effluent toxicity (WET) and may address programs to implement biological criteria, where such programs have been developed by the State. Implementation procedures therefore serve as umbrella documents that describe how the State's various toxics control programs are integrated to ensure adequate protection for aquatic life and human health and attainment of the narrative toxics criterion. In essence, the procedure should apply the "independent application" principle, which provides for independent evaluations of attainment of a designated use based on chemical-specific, whole-effluent toxicity, and biological criteria methods (see section 3.5.3 and Appendices C, K, and R).

EPA encourages, and may ultimately require, State implementation procedures to provide for implementation of biological criteria. However, the regulatory basis for requiring whole-effluent toxicity (WET) controls is clear. EPA regulations at 40 CFR 122.44(d)(1)(v) require NPDES permits to contain WET limits where a permittee has been shown to cause, have the reasonable potential to cause, or contribute to an in-stream excursion of a narrative criterion. Implementation of chemical-specific controls is also required by EPA regulations at 40 CFR 122.44(d)(1). State implementation procedures should, at a minimum, specify or reference methods to be used in implementing

chemical-specific and whole-effluent toxicity-based controls, explain how these methods are integrated, and specify needed application criteria.

In addition to EPA's regulation at 40 CFR 131, EPA has regulations at 40 CFR 122.44 that cover the National Surface Water Toxics Control Program. These regulations are intrinsically linked to the requirements to achieve water quality standards, and specifically address the control of pollutants both with and without numeric criteria. For example, section 122.44(d)(1)(vi) provides the permitting authority with several options for establishing effluent limits when a State does not have a chemical-specific numeric criterion for a pollutant present in an effluent at a concentration that causes or contributes to a violation of the State's narrative criteria.

3.5.3 Biological Criteria

The Clean Water Act of 1972 directs EPA to develop programs that will evaluate, restore, and maintain the chemical, physical, and biological integrity of the Nation's waters. In response to this directive, States and EPA have implemented chemically based water quality programs that address significant water pollution problems. However, over the past 20 years, it has become apparent that these programs alone cannot identify and address all surface water pollution problems. To help create a more comprehensive program, EPA is setting a priority for the development of biological criteria as part of State water quality standards. This effort will help States and EPA (1) achieve the biological integrity objective of the CWA set forth in section 101, and (2) comply with the statutory requirements under sections 303 and 304 of the Act (see Appendices C and K).

Regulatory Bases for Biocriteria

The primary statutory basis for EPA's policy that States should develop biocriteria is found in sections 101(a) and 303(c)(2)(B) of the Clean Water Act. Section 101(a) of the CWA gives the general goal of biological criteria. It establishes as the objective of the Act the restoration and maintenance of the chemical, physical, and biological integrity of the Nation's waters. To meet this objective, water quality criteria should address biological integrity. Section 101(a) includes the interim water quality goal for the protection and propagation of fish, shellfish, and wildlife.

Section 304(a) of the Act provides the legal basis for the development of informational criteria, including biological criteria. Specific directives for the development of regulatory biocriteria can be found in section 303(c), which requires EPA to develop criteria based on biological assessment methods when numerical criteria are not established.

Section 304(a) directs EPA to develop and publish water quality criteria and information on methods for measuring water quality and establishing water quality criteria for toxic pollutants on bases other than pollutant-by-pollutant, including biological monitoring and assessment methods that assess:

- the effects of pollutants on aquatic community components (". . . plankton, fish, shellfish, wildlife, plant life . . .") and community attributes (". . . biological community diversity, productivity, and stability . . .") in any body of water; and
- factors necessary " . . . to restore and maintain the chemical, physical, and biological integrity of all navigable waters . . ." for " . . . the protection of shellfish, fish, and wildlife for classes and categories of receiving waters …"

Once biocriteria are formally adopted into State standards, biocriteria and aquatic life use designations serve as direct, legal endpoints for determining aquatic life use attainment/non-attainment. CWA section 303(c)(2)(B) provides that when numeric criteria are not available, States shall adopt criteria for toxics based on biological monitoring or assessment methods; biocriteria can be used to meet this requirement.

Development and Implementation of Biocriteria

Biocriteria are numerical values or narrative expressions that describe the expected reference biological integrity of aquatic communities inhabiting waters of a designated aquatic life use. In the most desirable scenario, these would be waters that are either in pristine condition or minimally impaired. However, in some areas these conditions no longer exist and may not be attainable. In these situations, the reference biological communities represent the best attainable conditions. In either case, the reference conditions then become the basis for developing biocriteria for major surface water types (streams, rivers, lakes, wetlands, estuaries, or marine waters).

Biological criteria support designated aquatic life use classifications for application in State standards (see chapter 2). Each State develops its own designated use classification system based on the generic uses cited in the Act (e.g., protection and propagation of fish, shellfish, and wildlife). Designated uses are intentionally general. However, States may develop subcategories within use designations to refine and clarify the use class. Clarification of the use class is particularly helpful when a variety of surface waters with distinct characteristics fit within the same use class, or do not fit well into any category.

For example, subcategories of aquatic life uses may be on the basis of attainable habitat (e.g., coldwater versus warmwater stream systems as represented by distinctive trout or bass fish communities, respectively). Special uses may also be designated to protect particularly unique, sensitive, or valuable aquatic species, communities, or habitats.

Resident biota integrate multiple impacts over time and can detect impairment from known and unknown causes. Biological criteria can be used to verify improvement in water quality in response to regulatory and other improvement efforts and to detect new or continuing degradation of waters. Biological criteria also provide a framework for developing improved best management practices and management measures for nonpoint source impacts. Numeric biological criteria can provide effective monitoring criteria for more definitive evaluation of the health of an aquatic ecosystem.

The assessment of the biological integrity of a water body should include measures of the structure and function of the aquatic community within a specified habitat. Expert knowledge of the system is required for the selection of appropriate biological components and measurement indices. The development and implementation of biological criteria requires:

- selection of surface waters to use in developing reference conditions for each designated use;
- measurement of the structure and function of aquatic communities in reference surface waters to establish biological criteria;
- measurement of the physical habitat and other environmental characteristics of the water resource; and
- establishment of a protocol to compare the biological criteria to biota in comparable test waters to determine whether impairment has occurred.

These elements serve as an interactive network that is particularly important during early development of biological criteria where rapid accumulation of information is effective for refining both designated uses and developing biological criteria values and the supporting biological monitoring and assessment techniques.

3.5.4 Sediment Criteria

While ambient water quality criteria are playing an important role in assuring a healthy aquatic environment, they alone have not been sufficient to ensure appropriate levels of environmental protection. Sediment contamination, which can involve deposition of toxicants over long periods of time, is responsible for water quality impacts in some areas.

EPA has authority to pursue the development of sediment criteria in streams, lakes and other waters of the United States under sections 104 and 304(a)(1) and (2) of the CWA as follows:

- section 104(n)(1) authorizes the Administrator to establish national programs that study the effects of pollution, including sedimentation, in estuaries on aquatic life;
- section 304(a)(1) directs the Administrator to develop and publish criteria for water quality, including information on the factors affecting rates of organic and inorganic sedimentation for varying types of receiving waters;
- section 304(a)(2) directs the Administrator to develop and publish information on, among other issues, "the factors necessary for the protection and propagation of shellfish, fish, and wildlife for classes and categories of receiving waters. . . ."

To the extent that sediment criteria could be developed that address the concerns of the section 404(b)(1) Guidelines for discharges of dredged or fill material under the CWA or the Marine Protection, Research, and Sanctuaries Act, they could also be incorporated into those regulations.

EPA's current sediment criteria development effort, as described below, focuses on criteria for the protection of aquatic life. EPA anticipates potential future expansion of this effort to include sediment criteria for the protection of human health.

Chemical Approach to Sediment Criteria Development

Over the past several years, sediment criteria development activities have centered on evaluating and developing the Equilibrium Partitioning Approach for generating sediment criteria. The Equilibrium Partitioning Approach focuses on predicting the chemical interaction between sediments and contaminants. Developing an understanding of the principal factors that influence the sediment/contaminant interactions will allow predictions to be made regarding the level of contaminant concentration that benthic and other organisms may be exposed to. Chronic water quality criteria, or possibly other toxicological endpoints, can then be used to predict potential biological effects. In addition to the development of sediment criteria, EPA is also working to develop a standardized sediment toxicity test that could be used with or independently of sediment criteria to assess chronic effects in fresh and marine waters.

Equilibrium Partitioning (EqP) Sediment Quality Criteria (SQC) are the U.S. Environmental Protection Agency's best recommendation of the concentration of a substance in sediment that will not unacceptably affect benthic organisms or their uses.

Methodologies for deriving effects-based SQC vary for different classes of compounds. For non-ionic organic chemicals, the methodology requires normalization to organic carbon. A methodology for deriving effects-based sediment criteria for metal contaminants is under development and is expected to require normalization to acid volatile sulfide. EqP SQC values can be derived for varying degrees of uncertainty and levels of protection, thus permitting use for ecosystem protection and remedial programs.

Application of Sediment Criteria

SQC would provide a basis for making more informed decisions on the environmental impacts of contaminated sediments. Existing sediment assessment methodologies are limited in their ability to identify chemicals of concern, responsible parties, degree of contamination, and zones of impact. To make the most informed decisions, EPA believes that a comprehensive approach using SQC and biological test methods is preferred.

Sediment criteria will be particularly valuable in site-monitoring applications where sediment contaminant concentrations are gradually approaching a criterion over time or as a preventive tool to ensure that point and nonpoint sources of contamination are controlled and that uncontaminated sediments remain uncontaminated. Also comparison of field measurements to sediment criteria will be a reliable method for providing early warning of a potential problem. An early warning would provide an opportunity to take corrective action before adverse impacts occur. For the reasons

mentioned above, it has been identified that SQC are essential to resolving key contaminated sediment and source control issues in the Great Lakes.

Specific Applications

Specific applications of sediment criteria are under development. The primary use of EqP-based sediment criteria will be to assess risks associated with contaminants in sediments. The various offices and programs concerned with contaminated sediment have different regulatory mandates and, thus, have different needs and areas for potential application of sediment criteria. Because each regulatory need is different, EqP-based sediment quality criteria designed specifically to meet the needs of one office or program may have to be implemented in different ways to meet the needs of another office or program.

One mode of application of EqP-based numerical sediment quality criteria would be in a tiered approach. In such an application, when contaminants in sediments exceed the sediment quality criteria the sediments would be considered as causing unacceptable impacts. Further testing may or may not be required depending on site-specific conditions and the degree in which a criterion has been violated. (In locations where contamination significantly exceeds a criterion, no additional testing would be required. Where sediment contaminant levels are close to a criterion, additional testing might be necessary.) Contaminants in a sediment at concentrations less than the sediment criterion would not be of concern. However, in some cases the sediment could not be considered safe because it might contain other contaminants above safe levels for which no sediment criteria exist. In addition, the synergistic, antagonistic, or additive effects of several contaminants in the sediments may be of concern.

Additional testing in other tiers of an evaluation approach, such astoxicity tests, could be required to determine if the sediment is safe. It is likely that such testing would incorporate site-specific considerations. Examples of specific applications of sediment criteria after they are developed include the following:

- Establish permit limits for point sources to ensure that uncontaminated sediments remain uncontaminated or sediments already contaminated have an opportunity to cleanse themselves. Of course, this would occur only after criteria and the means to tie point sources to sediment contamination are developed.
- Establish target levels for nonpoint sources of sediment contamination.
- For remediation activities, SQC would be valuable in identifying:
    - need for remediation,
    - spatial extent of remediation area,
    - benefits derived from remediation activities,
    - responsible parties,
    - impacts of depositing contaminated sediments in water environments, and
    - success of remediation activities.

In tiered testing sediment evaluation processes, sediment criteria and biological testing procedures work very well together.

Sediment Criteria Status

Science Advisory Board Review

The Science Advisory Board has completed a second review of the EqP approach to deriving sediment quality criteria for non-ionic contaminants. The November 1992 report (USEPA, 1992c) endorses the EqP approach to deriving criteria as ". . . sufficiently valid to be used in the regulatory process if the uncertainty associated with the method is considered, described, and incorporated," and that "EPA should establish criteria on the basis of present knowledge within the bounds of uncertainty"

The Science Advisory Board also identified the need for ". . . a better understanding of the uncertainty around the assumptions inherent in the approach, including assumptions of equilibrium, bioavailability, and kinetics, all critical to the application of the EqP."

Sediment Criteria Documents and Application Guidance

EPA efforts at producing sediment criteria documents are being directed first toward phenanthrene, fluoranthene, dieldrin, acenaphthene, and endrin. Efforts are also being directed towards producing a guidance document on the derivation and interpretation of sediment quality criteria. The criteria documents were announced in the *Federal Register* in January 1994; the public comment period ended June 1994. Final documents and implementation guidance should be available in early 1996.

Methodology for Developing Sediment Criteria for Metal Contaminants

EPA is proceeding to develop a methodology for calculating sediment criteria for benthic toxicity to metal contaminants, with key work focused on identifying and understanding the role of acid volatile sulfides (AVS), and other binding factors, in controlling the bioavailability of metal contaminants. A variety of field and laboratory verification studies are under way to add additional support to the methodology. Standard AVS sampling and analytical procedures are under development. Presentation of the metals methodology to the SAB for review is anticipated for Fall 1994.

Biological Approach to Sediment Criteria Development

Under the Contaminated Sediment Management Strategy, EPA programs have committed to using consistent biological methods to determine if sediments are contaminated. In the water program, these biological methods will be used as a complement to the sediment-chemical criteria under development. The biological methods consist of both toxicity and bioaccumulation tests. Freshwater and saltwater benthic species, selected to represent the sensitive range of species' responses to toxicity, are used in toxicity tests to measure sediment toxicity. Insensitive freshwater and saltwater benthic species that form the base of the food chain are used in toxicity tests to

measure the bioaccumulation potential of sediment. In FY 1994, acute toxicity tests and bioaccumulation tests selected by all the Agency programs should be standardized and available for use. Training for States and EPA Regions on these methods is expected to begin in FY1995.

In the next few years, research will be conducted to develop standardized chronic toxicity tests for sediment as well as toxicity identification evaluation (TIE) methods. The TIE approach will be used to identify the specific chemicals in a sediment causing acute or chronic toxicity in the test organisms. Under the Contaminated Sediment Management Strategy, EPA's programs have also agreed to incorporate these chronic toxicity and TIE methods into their sediment testing when they are available.

3.5.5 Wildlife Criteria

Terrestrial and avian species are useful as sentinels for the health of the ecosystem as a whole. In many cases, damage to wildlife indicates that the ecosystem itself is damaged. Many wildlife species that are heavily dependent on the aquatic food web reflect the health of aquatic systems. In the case of toxic chemicals, terminal predators such as otter, mink, gulls, terns, eagles, ospreys, and turtles are useful as integrative indicators of the status or health of the ecosystem.

Statutory and Regulatory Authority

Section 101(a)(2) of the CWA sets, as an interim goal of,

> …wherever attainable…water quality which provides for the protection and propagation of fish, shellfish, and wildlife…(emphasis added).

Section 304(a)(1) of the Act also requires EPA to:

> …develop and publish… criteria for water quality accurately reflecting…the kind and extent of all identifiable effects on health and welfare including…wildlife.

The Water Quality Standards Regulation reflect the statutory goals and requirements by requiring States to adopt, where attainable, the CWA section 101(a)(2) goal uses of protection and propagation of fish, shellfish, and wildlife (40 CFR 131.10), and to adopt water quality criteria sufficient to protect the designated use (40 CFR 131.11).

Wildlife Protection in Current Aquatic Criteria

Current water quality criteria methodology is designed to protect fish, benthic invertebrates, and zooplankton; however, there is a provision in the current aquatic life criteria guidelines (Appendix H) that is intended to protect wildlife that consume aquatic organisms from the bioaccumulative potential of a compound. The final residue value can be based on either the FDA Action Level or a wildlife feeding study. However, if maximum permissible tissue concentration is not available from a

wildlife feeding study, a final residue value cannot be derived and the criteria quantification procedure continues without further consideration of wildlife impacts. Historically, wildlife have been considered only after detrimental effects on wildlife populations have been observed in the environment (this occurred with relationship to DDT, selenium, and PCBs).

Wildlife Criteria Development

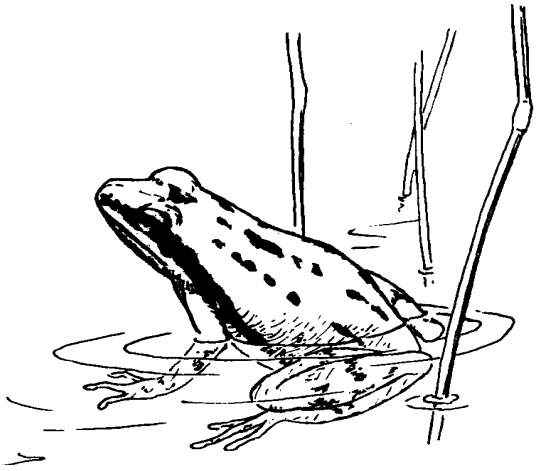
EPA's national wildlife criteria effort began following release of a 1987 Government Accounting Office study entitled *Wildlife Management – National Refuge Contamination Is Difficult To Confirm and Clean Up* (GAO, 1987). After waterfowl deformities observed at Kesterson Wildlife Refuge were linked to selenium contamination in the water, Congress requested this study and recommended that "the Administrator of EPA, in close coordination with the Secretary of the Interior, develop water quality criteria for protecting wildlife and their refuge habitat."

In November of 1988, EPA's Environmental Research Laboratory in Corvallis sponsored a workshop entitled *Water Quality Criteria To Protect Wildlife Resources*, (USEPA, 1989g) which was co-chaired by EPA and the Fish and Wildlife Service (FWS). The workshop brought together 26 professionals from a variety of institutions, including EPA, FWS, State governments, academia, and consultants who had expertise in wildlife toxicity, aquatic toxicity, ecology, environmental risk assessment, and conservation. Efforts at the workshop focused on evaluating the need for, and developing a strategy for production of wildlife criteria. Two recommendations came out of that workshop:

1. The process by which ambient water quality criteria are established should be modified to consider effects on wildlife; and
2. chemicals should be prioritized based on their potential to adversely impact wildlife species.

Based on the workshop recommendations, screening level wildlife criteria (SLWC) were calculated for priority pollutants and chemicals of concern submitted by the FWS to gauge the extent of the problem by:

1. evaluating whether existing water quality criteria for aquatic life are protective of wildlife, and
2. prioritizing chemicals for their potential to adversely impact wildlife species.



There were 82 chemicals for which EPA had the necessary toxicity information as well as ambient water quality criteria, advisories, or lowest-observed-adverse-effect levels (LOAELs) to compare with the SLWC values.

As would be expected, the majority of chemicals had SLWC larger than existing water quality criteria, advisories, or LOAELs for aquatic life. However, the screen identified classes of compounds for which current ambient water quality criteria may not be adequately protective of wildlife: chlorinated alkanes, benzenes, phenols, metals, DDT, and dioxins. Many of these compounds are produced in very large amounts and have a variety of uses (e.g., solvents, flame retardants, organic syntheses of fungicides and herbicides, and manufacture of plastics and textiles. The manufacture and use of these materials produce waste byproduct). Also, 5 of the 21 are among the top 25 pollutants identified at Superfund sites in 1985 (3 metals, 2 organics).

Following this initial effort, EPA held a national meeting in April 1992 to constructively discuss and evaluate proposed methodologies for deriving wildlife criteria to build consensus among the scientific community as to the most defensible scientifically approach(es) to be pursued by EPA in developing useful and effective wildlife criteria.

The conclusions of this national meeting were as follows:

- wildlife criteria should have a tissue-residue component when appropriate;
- peer-review of wildlife criteria and data sets should be used in their derivation
- wildlife criteria should incorporate methods to establish site-specific wildlife criteria;
- additional amphibian and reptile toxicity data are needed;
- further development of inter-species toxicological sensitivity factors are needed; and
- criteria methods should measure biomarkers in conjunction with other studies.

On April 16, 1993, EPA proposed wildlife criteria in the *Water Quality Guidance for the Great Lakes System* (58 F.R. 20802). The proposed wildlife criteria are based on the current EPA noncancer human health criteria approach. In this proposal, in addition to requesting comments on the proposed Great Lakes criteria and methods, EPA also requested comments on possible modifications of the proposed Great Lakes approach for consideration in the development of national wildlife criteria.

3.5.6 Numeric Criteria for Wetlands

Extension of the EPA national 304(a) numeric aquatic life criteria to wetlands is recommended as part of a program to develop standards and criteria for wetlands. Appendices D and E provide an overview of the need for standards and criteria for wetlands. The 304(a) numeric aquatic life criteria are designed to be protective of aquatic life for surface waters and are generally applicable to most wetland types. Appendix E provides a possible approach, based on the site-specific guidelines, for detecting wetland types that might not be protected by direct application of national 304(a) criteria. The evaluation can be simple and inexpensive for those wetland types for which sufficient water chemistry and species assemblage data are available, but will be less useful for wetland types for which these data are not readily available. In Appendix E, the site-specific approach is described and recommended for wetlands for which modification of the 304(a) numeric criteria are considered necessary. The results of this type of evaluation, combined with information on local or regional

environmental threats, can be used to prioritize wetland types (and individual criteria) for further site-specific evaluations and/or additional data collection. Close coordination among regulatory agencies, wetland scientists, and criteria experts will be required.

3.6 Policy on Aquatic Life Criteria for Metals

It is the policy of the Office of Water 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 than does total recoverable metal. This conclusion regarding metals bioavailability is supported by a majority of the scientific community within and outside EPA. 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.

Until the scientific uncertainties are better resolved, a range of different risk management decisions can be justified by a State. EPA recommends that State water quality standards be based on dissolved metal--a conversion factor must be used in order to express the EPA criteria articulated as total recoverable as dissolved. (See the paragraph below for technical details on developing dissolved criteria.) EPA will also approve a State risk management decision to adopt standards based on total recoverable metal, if those standards are otherwise approvable as a matter of law. (*Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria* USEPA, 1993f)

3.6.1 Background

The implementation of metals criteria is complex due to the site-specific nature of metals toxicity. This issue covers a number of areas including the expression of aquatic life criteria; total maximum daily loads (TMDLs), permits, effluent monitoring, and compliance; and ambient monitoring. The following Sections, based on the policy memorandum referenced above, provide additional guidance in each of these areas. Included in this Handbook as Appendix J are three guidance documents issued along with the Office of Water policy memorandum with additional technical details. They are: *Guidance Document on Expression of Aquatic Life Criteria as Dissolved Criteria* (Attachment #2), *Guidance Document on Dynamic Modeling and Translators* (Attachment #3), and *Guidance Document on Monitoring* (Attachment #4). These will be supplemented as additional information becomes available.

Since metals toxicity is significantly affected by site-specific factors, it presents a number of programmatic challenges. Factors that must be considered in the management of metals in the aquatic environment include: toxicity specific to effluent chemistry; toxicity specific to ambient water chemistry; different patterns of toxicity for different metals; evolution of the state of the science of metals toxicity, fate, and transport; resource limitations for monitoring, analysis, implementation, and research functions; concerns regarding some of the analytical data currently on record due to possible sampling and analytical contamination; and lack of standardized protocols for clean and ultraclean metals analysis. The States have the key role in the risk management process of

balancing these factors in the management of water programs. The site-specific nature of this issue could be perceived as requiring a permit-by-permit approach to implementation. However, EPA believes that this guidance can be effectively implemented on a broader level, across any waters with roughly the same physical and chemical characteristics, and recommends that States work with the EPA with that perspective in mind.

3.6.2 Expression of Aquatic Life Criteria

Dissolved vs. Total Recoverable Metal

A major issue is whether, and how, to use dissolved metal concentrations ("dissolved metal") or total recoverable metal concentrations ("total recoverable metal") in setting State water quality standards. In the past, States have used both approaches when applying the same EPA Section 304(a) criteria guidance. Some older criteria documents may have facilitated these different approaches to interpretation of the criteria because the documents were somewhat equivocal with regards to analytical methods. The May 1992 interim guidance continued the policy that either approach was acceptable.

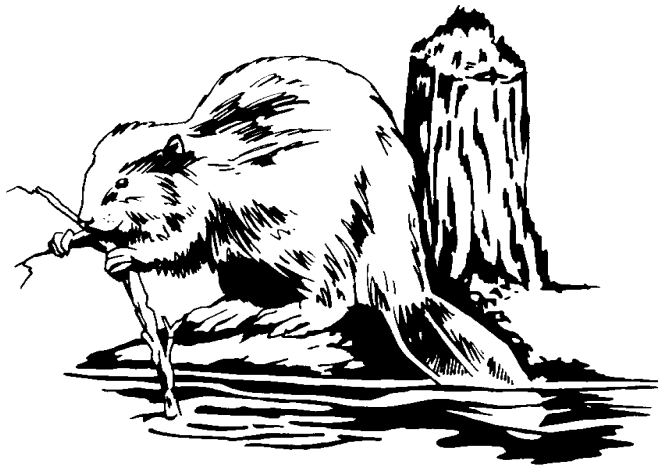
The position that the dissolved metals approach is more accurate has been questioned because it neglects the possible toxicity of particulate metal. It is true that some studies have indicated that particulate metals appear to contribute to the toxicity of metals, perhaps because of factors such as desorption of metals at the gill surface, but these same studies indicate the toxicity of particulate metal is substantially less than that of dissolved metal.

Furthermore, any error incurred from excluding the contribution of particulate metal will generally be compensated by other factors which make criteria conservative. For example, metals in toxicity tests are added as simple salts to relatively clean water. Due to the likely presence of a significant concentration of metals binding agents in many discharges and ambient waters, metals in toxicity tests would generally be expected to be more bioavailable than metals in discharges or in ambient waters.

If total recoverable metal is used for the purpose of specifying water quality standards, the lower bioavailability of particulate metal and lower bioavailability of sorbed metals as they are discharged may result in an overly conservative water quality standard. The use of dissolved metal in water quality standards gives a more accurate result in the water column. However, total recoverable measurements in ambient water have value, in that exceedences of criteria on a total recoverable basis are an indication that metal loadings could be a stress to the ecosystem, particularly in locations other than the water column (*e.g.*, in the sediments).

The reasons for the potential consideration of total recoverable measurements include risk management considerations not covered by evaluation of water column toxicity alone. The ambient water quality criteria are neither designed nor intended to protect sediments, or to prevent effects in the food webs containing sediment dwelling organisms. A risk manager, however, 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 conservative approach could include the use of total recoverable metal in water quality standards. However, since consideration of sediment impacts is not incorporated into the criteria methodology, the degree of conservatism inherent in the total recoverable approach is unknown. The uncertainty of metal impacts in sediments stem from the lack of sediment criteria and an imprecise understanding of the fate and transport of metals. EPA will continue to pursue research and other activities to close these knowledge gaps.



Dissolved Criteria

In the toxicity tests used to develop EPA metals criteria for aquatic life, some fraction of the metal is dissolved while some fraction is bound to particulate matter. The present criteria were developed using total recoverable metal measurements or measures expected to give equivalent results in toxicity tests, and are articulated as total recoverable. Therefore, in order to express the EPA criteria as dissolved, a total recoverable to dissolved conversion factor must be used. Attachment #2 in Appendix J provides guidance for calculating EPA dissolved criteria from the published total recoverable criteria. The data expressed as percentage metal dissolved are presented as recommended values and ranges. However, the choice within ranges is a State risk management decision. EPA has recently supplemented the data for copper and is proceeding to further supplement the data for copper and other metals. As testing is completed, EPA will make this information available and this is expected to reduce the magnitude of the ranges for some of the conversion factors provided. EPA also strongly encourages the application of dissolved criteria across a watershed or waterbody, as technically sound and the best use of resources.

Site-Specific Criteria Modifications

While the above methods will correct some site-specific factors affecting metals toxicity, further refinements are possible. EPA has issued guidance for three site-specific criteria development methodologies: recalculation procedure, water-effect ratio (WER) procedure (called the indicator species procedure in previous guidance) and resident species procedure. (See Section 3.7 of this Chapter.)

In the National Toxics Rule (57 FR 60848, December 22, 1992), EPA recommended the WER as an optional method for site-specific criteria development for certain metals. EPA committed in the NTR preamble to provide additional guidance on determining the WERs. The *Interim Guidance on the Determination and Use of Water-Effect Ratios for Metals* was issued by EPA on February 22, 1994 and is intended to fulfill that commitment. This interim guidance supersedes all guidance

concerning water-effect ratios and the recalculation procedure previously issued by EPA. This guidance is included as Appendix L to this Handbook.

In order to meet current needs, but allow for changes suggested by protocol users, EPA issued the guidance as "interim." EPA will accept WERs developed using this guidance, as well as by using other scientifically defensible protocols.

3.6.3 Total Maximum Daily Loads (TMDLs) and National Pollutant Discharge Elimination System (NPDES) Permits

Dynamic Water Quality Modeling

Although not specifically part of the reassessment of water quality criteria for metals, dynamic or probabilistic models are another useful tool for implementing water quality criteria, especially for those criteria protecting aquatic life. These models provide another way to incorporate site-specific data. The *Technical Support Document for Water Quality-based Toxics Control* (TSD) (USEPA, 1991a) describes dynamic, as well as static (steady-state) models. Dynamic models make the best use of the specified magnitude, duration, and frequency of water quality criteria and, therefore, provide a more accurate representation of the probability that a water quality standard exceedence will occur. In contrast, steady-state models frequently apply a number of simplifying, worst case assumptions which makes them less complex but also less accurate than dynamic models.

Dynamic models have received increased attention over the last few years as a result of the widespread belief that steady-state modeling is over-conservative due to environmentally conservative dilution assumptions. This belief has led to the misconception that dynamic models will always lead to less stringent regulatory controls (e.g., NPDES effluent limits) than steady-state models, which is not true in every application of dynamic models. EPA considers dynamic models to be a more accurate approach to implementing water quality criteria and continues to recommend their use. Dynamic modeling does require a commitment of resources to develop appropriate data. (See Appendix J, Attachment #3 and the USEPA, 1991a for details on the use of dynamic models.)

Dissolved-Total Metal Translators

Expressing ambient water quality criteria for metals as the dissolved form of a metal poses a need to be able to translate from dissolved metal to total recoverable metal for TMDLs and NPDES permits. TMDLs for metals must be able to calculate: (1) dissolved metal in order to ascertain attainment of water quality standards, and (2) total recoverable metal in order to achieve mass balance necessary for permitting purposes.

EPA's NPDES regulations require that limits of metals in permits be stated as total recoverable in most cases (see 40 CFR §122.45(c)) except when an effluent guideline specifies the limitation in another form of the metal, the approved analytical methods measure only dissolved metal, or the permit writer expresses a metals limit in another form (e.g., dissolved, valent specific, or total) when

required to carry out provisions of the Clean Water Act. This is because the chemical conditions in ambient waters frequently differ substantially from those in the effluent, and there is no assurance that effluent particulate metal would not dissolve after discharge. The NPDES rule does not require that State water quality standards be expressed as total recoverable; rather, the rule requires permit writers to translate between different metal forms in the calculation of the permit limit so that a total recoverable limit can be established. Both the TMDL and NPDES uses of water quality criteria require the ability to translate between dissolved metal and total recoverable metal. Appendix J, Attachment #3 provides guidance on this translation.

3.6.4 Guidance on Monitoring

Use of Clean Sampling and Analytical Techniques

In assessing waterbodies to determine the potential for toxicity problems due to metals, the quality of the data used is an important issue. Metals data are used to determine attainment status for water quality standards, discern trends in water quality, estimate background loads for TMDLs, calibrate fate and transport models, estimate effluent concentrations (including effluent variability), assess permit compliance, and conduct research. The quality of trace level metal data, especially below 1 ppb, may be compromised due to contamination of samples during collection, preparation, storage, and analysis. Depending on the level of metal present, the use of "clean" and "ultraclean" techniques for sampling and analysis may be critical to accurate data for implementation of aquatic life criteria for metals.

The significance of the sampling and analysis contamination problem increases as the ambient and effluent metal concentration decreases and, therefore, problems are more likely in ambient measurements. "Clean" techniques refer to those requirements (or practices for sample collection and handling) necessary to produce reliable analytical data in the part per billion (ppb) range. "Ultraclean" techniques refer to those requirements or practices necessary to produce reliable analytical data in the part per trillion (ppt) range. Because typical concentrations of metals in surface waters and effluents vary from one metal to another, the effect of contamination on the quality of metals monitoring data varies appreciably.

EPA plans to develop protocols on the use of clean and ultra-clean techniques and is coordinating with the United States Geological Survey (USGS) on this project, because USGS has been doing work on these techniques for some time, especially the sampling procedures. Draft protocols for clean techniques were presented at the Norfolk, VA analytical methods conference in the Spring of 1994 and final protocols are expected to be available in early 1995. The development of comparable protocols for ultra-clean techniques is underway and are expected to be available in late 1995. In developing these protocols, we will consider the costs of these techniques and will give guidance as to the situations where their use is necessary. Appendix L, pp. 98-108 provide some general guidance on the use of clean analytical techniques. We recommend that this guidance be used by States and Regions as an interim step, while the clean and ultra-clean protocols are being developed.

Use of Historical Data

The concerns about metals sampling and analysis discussed above raise corresponding concerns about the validity of historical data. Data on effluent and ambient metal concentrations are collected by a variety of organizations including Federal agencies (e.g., EPA, USGS), State pollution control agencies and health departments, local government agencies, municipalities, industrial dischargers, researchers, and others. The data are collected for a variety of purposes as discussed above.

Concern about the reliability of the sample collection and analysis procedures is greatest where they have been used to monitor very low level metal concentrations. Specifically, studies have shown data sets with contamination problems during sample collection and laboratory analysis, that have resulted in inaccurate measurements. For example, in developing a TMDL for New York Harbor, some historical ambient data showed extensive metals problems in the harbor, while other historical ambient data showed only limited metals problems. Careful resampling and analysis in 1992/1993 showed the latter view was correct. The key to producing accurate data is appropriate quality assurance (QA) and quality control (QC) procedures. EPA believes that most historical data for metals, collected and analyzed with appropriate QA and QC at levels of 1 ppb or higher, are reliable. The data used in development of EPA criteria are also considered reliable, both because they meet the above test and because the toxicity test solutions are created by adding known amounts of metals.

With respect to effluent monitoring reported by an NPDES permittee, the permittee is responsible for collecting and reporting quality data on a Discharge Monitoring Report (DMR). Permitting authorities should continue to consider the information reported to be true, accurate, and complete as certified by the permittee. Where the permittee becomes aware of new information specific to the effluent discharge that questions the quality of previously submitted DMR data, the permittee must promptly submit that information to the permitting authority. The permitting authority will consider all information submitted by the permittee in determining appropriate enforcement responses to monitoring/reporting and effluent violations. (See Appendix J, Attachment #4 for additional details.)

3.7 Site-Specific Aquatic Life Criteria

The purpose of this section is to provide guidance for the development of site-specific water quality criteria which reflect local environmental conditions. Site-specific criteria are allowed by regulation and are subject to EPA review and approval. The Federal water quality standards regulation at section 131.11(b)(1)(ii) provides States with the opportunity to adopt water quality criteria that are "...modified to reflect site-specific conditions." Site-specific criteria, as with all water quality criteria, must be based on a sound scientific rationale in order to protect the designated use. Existing guidance and practice are that EPA will approve site-specific criteria developed using appropriate procedures.

A site-specific criterion is intended to come closer than the national criterion to providing the intended level of protection to the aquatic life at the site, usually by taking into account the biological and/or chemical conditions (i.e., the species composition and/or water quality characteristics) at the site. The fact that the U.S. EPA has made these procedures available should not be interpreted as implying that the agency advocates that states derive site-specific criteria before setting state standards. Also, derivation of a site-specific criterion does not change the intended level of protection of the aquatic life at the site.

3.7.1 History of Site-Specific Criteria Guidance

National water quality criteria for aquatic life may be under- or over-protective if:

1. the species at the site are more or less sensitive than those included in the national criteria data set (*e.g.*, the national criteria data set contains data for trout, salmon, penaeid shrimp, and other aquatic species that have been shown to be especially sensitive to some materials), or
2. physical and/or chemical characteristics of the site alter the biological availability and/or toxicity of the chemical (*e.g.*, alkalinity, hardness, pH, suspended solids and salinity influence the concentration(s) of the toxic form(s) of some heavy metals, ammonia and other chemicals).

Therefore, it is appropriate that site-specific procedures address each of these conditions separately as well as the combination of the two. In the early 1980's, EPA recognized that laboratory-derived water quality criteria might not accurately reflect site-specific conditions and, in response, created three procedures to derive site-specific criteria. This Handbook contains the details of these procedures, referenced below.

1. The Recalculation Procedure is intended to take into account relevant differences between the sensitivities of the aquatic organisms in the national dataset and the sensitivities of organisms that occur at the site (see Appendix L, pp. 90-97).
2. The Water-Effect Ratio Procedure (called the Indicator Species Procedure in USEPA, 1983a; 1984f) provided for the use of a water-effect ratio (WER) that is intended to take into account relevant differences between the toxicities of the chemical in laboratory dilution water and in site water (see Appendix L).
3. The Resident Species Procedure intended to take into account both kinds of differences simultaneously (see Section 3.7.6).

These procedures were first published in the 1983 *Water Quality Standards Handbook* (USEPA, 1983a) and expanded upon in the *Guidelines for Deriving Numerical Aquatic Site-Specific Water Quality Criteria by Modifying National Criteria* (USEPA, 1984f). Interest has increased in recent years as states have devoted more attention to chemical-specific water quality criteria for aquatic life. In addition, interest in water-effect ratios increased when they were integrated into some of the aquatic

life criteria for metals that were promulgated for several states in the National Toxics Rule (57 FR 60848, December 22, 1992). The *Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals* (USEPA, 1993f) (see Section 3.6 of this Handbook) provided further guidance on site-specific criteria for metals by recommending the use of dissolved metals for setting and measuring compliance with water quality standards.

The early guidance concerning WERs (USEPA, 1983a; 1984f) contained few details and needed revision, especially to take into account newer guidance concerning metals. To meet this need, EPA issued *Interim Guidance on the Determination and Use of Water-Effect Ratios for Metals* in 1994 (Appendix L). Metals are specifically addressed in Appendix L because of the National Toxics Rule and because of current interest in aquatic life criteria for metals; although most of this guidance also applies to other pollutants, some obviously applies only to metals. Appendix L supersedes all guidance concerning water-effect ratios and the Indicator Species Procedure given in Chapter 4 of the *Water Quality Standards Handbook* (USEPA, 1983a) and in *Guidelines for Deriving Numerical Aquatic Site-Specific Water Quality Criteria by Modifying National Criteria* (USEPA, 1984f). Appendix L (p. 90-98) also supersedes the guidance in these earlier documents for the Recalculation Procedure for performing site-specific criteria modifications. The Resident Species Procedure remains essentially unchanged since 1983 (except for changes in the averaging periods to conform to the 1985 aquatic life criteria guidelines (USEPA, 1985b) and is presented in Section 3.7.6, below.

The previous guidance concerning site-specific procedures did not allow the Recalculation Procedure and the WER procedure to be used together in the derivation of a site-specific aquatic life criterion; the only way to take into account both species composition and water quality characteristics in the determination of a site-specific criterion was to use the Resident Species Procedure. A specific change contained Appendix L is that, except in jurisdictions that are subject to the National Toxics Rule, the Recalculation Procedure and the WER Procedure may now be used together provided that the recalculation procedure is performed first. Both the Recalculation Procedure and the WER Procedure are based directly on the guidelines for deriving national aquatic life criteria (USEPA 1985) and, when the two are used together, use of the Recalculation Procedure must be performed first because the Recalculation Procedure has specific implications concerning the determination of the WER.

3.7.2 Preparing to Calculate Site-Specific Criteria

Adopting site-specific criteria in water quality standards is a State option--not a requirement. Moreover, EPA is not advocating that States use site-specific criteria development procedures for

setting all aquatic life criteria as opposed to using the National Section 304(a) criteria recommendations. Site-specific criteria are not needed in all situations. When a State considers the possibility of developing site-specific criteria, it is essential to involve the appropriate EPA Regional office at the start of the project.

This early planning is also essential if it appears that data generation and testing may be conducted by a party other than the State or EPA. The State and EPA need to apply the procedures judiciously and must consider the complexity of the problem and the extent of knowledge available concerning the fate and effect of the pollutant under consideration. If site-specific criteria are developed without early EPA involvement in the planning and design of the task, the State may expect EPA to take additional time to closely scrutinize the results before granting any approval to the formally adopted standards.

The following sequence of decisions need to be made before any of the procedures are initiated:

- verify that site-specific criteria are actually needed (*e.g.*, that the use of clean sampling and/or analytical techniques, especially for metals, do not result in attainment of standards.)
- Define the site boundaries.
- Determine from the national criterion document and other sources if physical and/or chemical characteristics are known to affect the biological availability and/or toxicity of a material of interest.
- If data in the national criterion document and/or from other sources indicate that the range of sensitivity of the selected resident species to the material of interest is different from the range for the species in the national criterion document, and variation in physical and/or chemical characteristics of the site water is not expected to be a factor, use the *Recalculation Procedure* (Section 3.7.4).
- If data in the national criterion document and/or from other sources indicate that physical and/or chemical characteristics of the site water may affect the biological availability and/or toxicity of the material of interest, and the selected resident species range of sensitivity is <u>similar</u> to that for the species in the national criterion document, use the *Water-Effect Ratio Procedure* (Section 3.7.5).
- If data in the national criterion document and/or from other sources indicated that physical and/or chemical characteristics of the site water may affect the biological availability and/or toxicity of the material of interest, and the selected resident species range of sensitivity is <u>different</u> from that for the species in the national criterion document, and if both these differences are to be taken into account, use the *Recalculation Procedure in conjunction with the Water-Effect Ratio Procedure* or use the *Resident Species Procedure* (Section 3.7.6).

3.7.3 Definition of a Site

Since the rationales for site-specific criteria are usually based on potential differences in species sensitivity, physical and chemical characteristics of the water, or a combination of the two, the concept of site must be consistent with this rationale.

In the general context of site-specific criteria, a "site" may be a state, region, watershed, waterbody, or segment of a waterbody. The site-specific criterion is to be derived to provide adequate protection for the entire site, however the site is defined.

If water quality effects on toxicity are not a consideration, the site can be as large as a generally consistent biogeographic zone permits. For example, large portions of the Chesapeake Bay, Lake Michigan, or the Ohio River may be considered as one site if their respective aquatic communities do not vary substantially. However, when a site-specific criterion is derived using the Recalculation Procedure, all species that "occur at the site" need to be taken into account when deciding what species, if any, are to be deleted from the dataset. Unique populations or less sensitive uses within sites may justify a designation as a distinct site.

If the species of a site are toxicologically comparable to those in the national criteria data set for a material of interest, and physical and/or chemical water characteristics are the only factors supporting modification of the national criteria, then the site can be defined on the basis of expected changes in the material's biological availability and/or toxicity due to physical and chemical variability of the site water. However, when a site-specific criterion is derived using a WER, the WER is to be adequately protective of the entire site. If, for example, a site-specific criterion is being derived for an estuary, WERs could be determined using samples of the surface water obtained from various sampling stations, which, to avoid confusion, should not be called "sites". If all the WERs were sufficiently similar, one site-specific criterion could be derived to apply to the whole estuary. If the WERs were sufficiently different, either the lowest WER could be used to derive a site-specific criterion for the whole estuary, or the data might indicate that the estuary should be divided into two or more sites, each with its own criterion.

3.7.4 The Recalculation Procedure

The Recalculation Procedure is intended to cause a site-specific criterion to appropriately differ from a national aquatic life criterion if justified by demonstrated pertinent toxicological differences between the aquatic species that occur at the site and those that were used in the derivation of the national criterion. There are at least three reasons why such differences might exist between the two sets of species.

- First, the national dataset contains aquatic species that are sensitive to many pollutants, but these and comparably sensitive species might not occur at the site.
- Second, a species that is critical at the site might be sensitive to the pollutant and require a lower criterion. (A critical species is a species that is commercially or recreationally important at the site, a species that exists at the site and is listed as threatened or endangered under section 4 of the Endangered Species Act, or a

species for which there is evidence that the loss of the species from the site is likely to cause an unacceptable impact on a commercially or recreationally important species, a threatened or endangered species, the abundances of a variety of other species, or the structure or function of the community.)

- Third, the species that occur at the site might represent a narrower mix of species than those in the national dataset due to a limited range of natural environmental conditions.

The procedure presented in Appendix L, pp. 90-98 is structured so that corrections and additions can be made to the national dataset without the deletion process being used to take into account taxa that do not occur at the site; in effect, this procedure makes it possible to update the national aquatic life criterion. All corrections and additions that have been approved by EPA are required, whereas use of the deletion process is optional. The deletion process may not be used to remove species from the criterion calculation that are not currently present at a site due to degraded conditions.

The Recalculation Procedure is more likely to result in lowering a criterion if the net result of addition and deletion is to decrease the number of genera in the dataset, whereas the procedure is more likely to result in raising a criterion if the net result of addition and deletion is to increase the number of genera in the dataset.

For the lipid soluble chemicals whose national Final Residue Values are based on Food and Drug Administration (FDA) action levels, adjustments in those values based on the percent lipid content of resident aquatic species is appropriate for the derivation of site-specific Final Residue Values. For lipid-soluble materials, the national Final Residue Value is based on an average 11 percent lipid content for edible portions for the freshwater chinook salmon and lake trout and an average of 10 percent lipids for the edible portion for saltwater Atlantic herring. Resident species of concern may have higher (e.g., Lake Superior siscowet, a race of lake trout) or lower (e.g., many sport fish) percent lipid content than used for the national Final Residue Value.

For some lipid-soluble materials such as polychlorinated biphenyls (PCB) and DDT, the national Final Residue Value is based on wildlife consumers of fish and aquatic invertebrate species rather than an FDA action level because the former provides a more stringent residue level. See the National Guidelines (USEPA, 1985b) for details.

For the lipid-soluble materials whose national Final Residue Values are based on wildlife effects, the limiting wildlife species (mink for PCB and brown pelican for DDT) are considered acceptable surrogates for resident avian and mammalian species (e.g., herons, gulls, terns, otter, etc.) Conservatism is appropriate for those two chemicals, and no less restrictive modification of the national Final Residue Value is appropriate. The site-specific Final Residue Value would be the same as the national value.

3.7.5 The Water-Effect Ratio (WER) Procedure

The guidance on the Water-Effect Ratio Procedure presented in Appendix L is intended to produce WERs that may be used to derive site-specific aquatic life criteria from most national and state aquatic life criteria that were derived from laboratory toxicity data.

As indicated in Appendix L, the determination of a water-effect ratio may require substantial resources. A discharger should consider cost-effective, preliminary measures described in this Appendix L (e.g., use of "clean" sampling and chemical analytical techniques especially for metals, or in non-NTR States, a recalculated criterion) to determine if an indicator species site-specific criterion is really needed. In many instances, use of these other measures may eliminate the need for deriving water-effect ratios. The methods described in the 1994 interim guidance (Appendix L) should be sufficient to develop site-specific criteria that resolve concerns of dischargers when there appears to be no instream toxicity but, where (a) a discharge appears to exceed existing or proposed water quality-based permit limits, or (b) an instream concentration appears to exceed an existing or proposed water quality criterion.

WERs obtained using the methods described in Appendix L should only be used to adjust aquatic life criteria that were derived using laboratory toxicity tests. WERs determined using the methods described herein cannot be used to adjust the residue-based mercury Criterion Continuous Concentration (CCC) or the field-based selenium freshwater criterion.

Except in jurisdictions that are subject to the NTR, the WERs may also be used with site-specific aquatic life criteria that are derived using the Recalculation Procedure described in Appendix L (p.90).

Water-Effect Ratios in the Derivation of Site-Specific Criteria

A central question concerning WERs is whether their use by a State results in a site-specific criterion subject to EPA review and approval under Section 303(c) of the Clean Water Act?

Derivation of a water-effect ratio by a State is a site-specific criterion adjustment subject to EPA review and approval/disapproval under Section 303(c). There are two options by which this review can be accomplished.

Option 1:

A State may derive and submit each individual water-effect ratio determination to EPA for review and approval. This would be accomplished through the normal review and revision process used by a State.

Option 2:

A State can amend its water quality standards to provide a formal procedure which includes derivation of water-effect ratios, appropriate definition of sites, and enforceable monitoring provisions to assure that designated uses are protected. Both this procedure and the resulting criteria would be subject to full public participation requirements. EPA would review and approve/disapprove this protocol as a revised standard as part of the State's triennial review/revision. After adoption of the procedure, public review of a site-specific criterion could be accomplished in conjunction with the public review required for permit issuance. For public information, EPA recommends that once a year the State publish a list of site-specific criteria.

An exception to this policy applies to the waters of the jurisdictions included in the National Toxics Rule. The EPA review is not required for the jurisdictions included in the National Toxics Rule where EPA established the procedure for the State for application to the criteria promulgated. The National Toxics Rule was a formal rulemaking process (with notice and comment) in which EPA pre-authorized the use of a correctly applied water-effect ratio. That same process has not yet taken place in States not included in the National Toxics Rule.

However, the National Toxics Rule does not affect State authority to establish scientifically defensible procedures to determine Federally authorized WERs, to certify those WERs in NPDES permit proceedings, or to deny their application based on the State's risk management analysis.

As described in Section 131.36(b)(iii) of the water quality standards regulation (the official regulatory reference to the National Toxics Rule), the water-effect ratio is a site-specific calculation. As indicated on page 60866 of the preamble to the National Toxics Rule, the rule was constructed as a rebuttable presumption. The water-effect ratio is assigned a value of 1.0 until a different water-effect ratio is derived from suitable tests representative of conditions in the affected waterbody. It is the responsibility of the State to determine whether to rebut the assumed value of 1.0 in the National Toxics Rule and apply another value of the water-effect ratio in order to establish a site-specific criterion. The site-specific criterion is then used to develop appropriate NPDES permit limits. The rule thus provides a State with the flexibility to derive an appropriate site-specific criterion for specific waterbodies.

As a point of emphasis, although a water-effect ratio affects permit limits for individual dischargers, it is the State in all cases that determines if derivation of a site-specific criterion based on the water-effect ratio is allowed and it is the State that ensures that the calculations and data analysis are done completely and correctly.

3.7.6 The Resident Species Procedure

The resident Species Procedure for the derivation of a site-specific criterion accounts for differences in resident species sensitivity and differences in biological availability and/or toxicity of a material due to variability in physical and chemical characteristics of a site water. Derivation of the site-

specific criterion maximum concentration (CMC) and site-specific criterion continuous concentration (CCC) are accomplished after the complete acute toxicity minimum data set requirements have been met by conducting tests with resident species in site water. Chronic tests may also be necessary. This procedure is designed to compensate concurrently for any real differences between the sensitivity range of species represented in the national data set and for site water which may markedly affect the biological availability and/or toxicity of the material of interest.

Certain families of organisms have been specified in the National Guidelines acute toxicity minimum data set (e.g., Salmonidae in fresh water and Penaeidae or Mysidae in salt water); if this or any other requirement cannot be met because the family or other group (e.g., insect or benthic crustacean) in fresh water is not represented by resident species, select a substitute(s) from a sensitive family represented by one or more resident species and meet the 8 family minimum data set requirement. If all the families at the site have been tested and the minimum data set requirements have not been met, use the most sensitive resident family mean acute value as the site-specific Final Acute Value.

To derive the criterion maximum concentration divide the site-specific Final Acute Value by two. The site-specific Final Chronic Value can be obtained as described in the Appendix L. The lower of the site-specific Final Chronic Value (as described in the recalculation procedure - Appendix L, p. 90) and the recalculated site-specific Final Residue Value becomes the site-specific criterion continuous concentration unless plant or other data (including data obtained from the site-specific tests) indicates a lower value is appropriate. If a problem is identified, judgment should be used in establishing the site-specific criterion.

The frequency of testing (e.g., the need for seasonal testing) will be related to the variability of the physical and chemical characteristics of site water as it is expected to affect the biological availability and/or toxicity of the material of interest. As the variability increases, the frequency of testing will increase. Many of the limitations discussed for the previous two procedures would also apply to this procedure.

Endnotes

1. Proceedings in production.
   Contact: Ecological Risk Assessment Branch (4304)
   U.S. Environmental Protection Agency
   401 M Street, S.W.
   Washington, DC 20460
   Telephone (202) 260-1940