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Tuesday
December 22, 1992

Federal Register

Part II

Environmental Protection Agency

40 CFR Part 131
Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4680-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance

AGENCY: Environmental Protection Agency.

ACTION: Correction notice; final rule.

SUMMARY: EPA is correcting typographical errors in the final rule for water quality standards for priority toxic pollutants which appeared in the Federal Register on December 22, 1992, 57 FR 60848.

FOR FURTHER INFORMATION CONTACT: David K. Sabock, Chief, Water Quality Standards Branch (WH-585), Office of Water, Environmental Protection Agency, 401-M Street, SW, Washington, DC 20460. Telephone number is 202-260-1318.

SUPPLEMENTARY INFORMATION: EPA promulgated a final rule to establish numeric water quality criteria for priority toxic pollutants applicable to State water quality standards under section 303(c) of the Clean Water Act on December 22, 1992 (57 FR 60848). These criteria became the enforceable criteria for all purposes under the Clean Water Act for the 12 States and 2 territories listed in the rule on February 5, 1993.

Description of Errors and Corrections

On Page 60911, EPA has been advised that the legibility of the matrix on some of the printed notices is such that it is not clear that Arsenic is identified as number 2 on the table and Silver is number 11. In addition, pollutant number 12 is Thallium.

On page 60917, middle column, line 49, the phrase "* * * the lethal concentration of * * *" is incorrect. It should read "* * * the concentration lethal to * * *."

On page 60919, in the middle column dealing with paragraph (6) Florida, in subparagraph (ii), the applicable criteria for Class II and Class III (marine) were inadvertently omitted from the text. The applicable criteria for both Class II and Class III (marine) should read: "This classification is assigned the criteria in: Column D2-#16."

On page 60920, dealing with paragraph (10) California, in subparagraph (ii), the applicable criteria for "Waters of the Sacramento-San Joaquin Delta" should also include pollutant #67 in Column D1; this pollutant was inadvertently omitted from the list.

On page 60921 dealing with paragraph (10) California, in subparagraph (ii), the fifth paragraph beginning "All enclosed bays and estuaries" under the heading "Water and Use Classification", the words "that do not include an MUN designation" were omitted from the first line. The correct wording is: "All enclosed bays and estuaries that are waters of the United States *that do not include an MUN designation* and that the State has. . ."

On page 60922, dealing with paragraph (12) Alaska, in subparagraph (ii), the applicable criteria assigned to use classification (1)(A)(ii) is incorrectly printed as Column D1. The correct reference should be to Column D2.

Dated: May 25, 1993.

Tudor Davies,

Acting Assistant Administrator for Water.

[FR Doc. 93-12845 Filed 5-28-93; 8:45 am]

BILLING CODE 6560-50-M

Corrections

Federal Register
Vol. 58, No. 121
Friday, June 25, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4660-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; State's Compliance

Correction

In rule document 93-12845 beginning on page 31177 in the issue of Tuesday, June 1, 1993, make the following correction:

On page 31178, in the first column, in the fifth full paragraph, in the fourth line, "(1)(A)(ii)" should read "(1)(A)(iii)".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY-930-4210-06; WYW 128871]

Proposed Withdrawal and Opportunity for Public Meeting; Wyoming

Correction

In notice document 93-13009, appearing on page 31538 in the issue of Thursday, June 3, 1993 in land description T.41 N., R. 117 W., "34 and 25" should read "34 and 35".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4658-1]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; State's Compliance

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is amending a rule issued on December 22, 1992, to withdraw a portion of that rule as it applies to the State of Washington. The aquatic life criteria for arsenic and selenium adopted by Washington and approved by EPA make the Federally promulgated criteria for these pollutants unnecessary.

EFFECTIVE DATE: This amendment is effective July 6, 1993.

ADDRESSES: The administrative record for the consideration of Washington's revised standards is available for public inspection from the Environmental Protection Agency, Region X Office, Water Division, 1200 Sixth Avenue, Seattle, WA, 98101, during normal business hours of 8 a.m. until 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: David K. Sabock, Chief, Water Quality Standards Branch (WH-585), Office of Water, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The telephone number is 202-260-1315.

SUPPLEMENTARY INFORMATION: A final rule to establish numeric water quality criteria for those States and Territories that failed to comply fully with section 303(c)(2)(B) of the Clean Water Act was published in the Federal Register on December 22, 1992 (57 FR 60848). Federal criteria were promulgated for 12 States and 2 Territories, and these criteria became the legally enforceable water quality standards in the named States and Territories for all purposes and programs under the Clean Water Act on February 5, 1993.

As indicated in the preamble to the final rule, EPA would amend the rule to withdraw criteria from the rule when a State adopted and EPA approved criteria that met the requirements of the Clean Water Act (see 57 FR 60860). On November 25, 1992, the State of Washington adopted revisions to the State's surface water quality standards, Chapter 173-201A of the Washington Administrative Code, regarding aquatic life criteria for arsenic and selenium. The State adopted criteria identical to those promulgated by EPA for both fresh and marine waters. These criteria were approved by EPA on March 25, 1993.

EPA's promulgated criteria for arsenic and selenium are now duplicative of EPA-approved State criteria and are no longer needed to meet the requirements of the Act. It is EPA's policy to withdraw promulgated water quality standards when the State adopts new or revised standards which meet the requirements of the Act (57 FR 60848). Accordingly, EPA is amending its rule promulgated December 22, 1992, to withdraw the criteria for arsenic and selenium for the protection of aquatic life for Washington. Other criteria promulgated by EPA for Washington remain in force.

Washington complied with the public participation requirements in its adoption of State standards. Additionally, because Washington adopted, and EPA approved, water quality criteria for arsenic and selenium for the protection of fresh and marine aquatic life identical to those being withdrawn in today's rule, EPA has determined that additional public participation in this action is unnecessary and constitutes good cause for issuing this final rule without notice and comment. For the same reasons, the Agency has determined that good cause exists to waive the requirement for a 30-day period before the amendment becomes effective and therefore the amendments will be immediately effective.

This action imposes no new regulatory requirements but merely withdraws a Federal regulation. Therefore, this rule imposes no costs and does not require a regulatory impact analysis under Executive Order 12291. The Agency has determined that this action will have no significant impact on a substantial number of small entities. The rule also does not impose any requirements subject to the Paperwork Reduction Act.

List of Subjects in 40 CFR Part 131

Water pollution control, Water quality standards, Toxic pollutants.

Dated: June 8, 1993.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble title 40, Chapter I, part 131 of the Code of Federal Regulations is amended as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

§ 131.36 [Amended]

2. Section 131.36(d)(14)(ii) is amended in "Fish and Shellfish: Fish" use classification, under the listing of applicable criteria, by removing the entries "Column B1 and B(2)—#2, 10" and "Column C1—#2, 10" in their entirety and by removing "#2" and "#10" from the entry for Column C2.

[FR Doc. 93-15862 Filed 7-2-93; 8:45 am]

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federal register

Tuesday
December 22, 1992

Part II

Environmental Protection Agency

40 CFR Part 131

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4543-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This rule promulgates for 14 States, the chemical-specific, numeric criteria for priority toxic pollutants necessary to bring all States into compliance with the requirements of section 303(c)(2)(B) of the Clean Water Act (CWA). States determined by EPA to fully comply with section 303(c)(2)(B) requirements are not affected by this rule.

The rule addresses two situations. For a few States, EPA is promulgating a limited number of criteria which were previously identified as necessary in disapproval letters to such States, and which the State has failed to address. For other States, Federal criteria are necessary for all priority toxic pollutants for which EPA has issued section 304(a) water quality criteria guidance and that are not the subject of approved State criteria.

When these standards take effect, they will be the legally enforceable standards in the named States for all purposes and programs under the Clean Water Act, including planning, monitoring, NPDES permitting, enforcement and compliance.

EPA is also withdrawing today the human health criteria published in the 1980 Ambient Water Quality Criteria documents for: Beryllium, Cadmium, Chromium, Lead, Methyl Chloride, Selenium, Silver, and 1,1,1 Trichloroethane. A summary of the criteria recommendation and the notice of availability of each criteria document were published at 45 FR 79318, November 28, 1980.

EFFECTIVE DATE: This rule shall be effective February 5, 1993.

ADDRESSES: The public may inspect the administrative record for this rulemaking, including documentation supporting the aquatic life and human health criteria, and all public comments received on the proposed rule at the Environmental Protection Agency, Standards and Applied Science Division, Office of Science and Technology, room 919 East Tower, Waterside Mall, 401 M Street, SW., Washington, DC 20460 (Telephone: 202-260-1315) on weekdays during the Agency's normal business hours of 8 a.m. to 4:30 p.m. A reasonable fee will be charged for photocopies. Inquiries can be made by calling 202-260-1315.

FOR FURTHER INFORMATION CONTACT: David K. Sabock or R. Kent Ballentine, Telephone 202-260-1315.

SUPPLEMENTARY INFORMATION:

This preamble is organized according to the following outline:

A. Introduction and Overview
1. Introduction
2. Overview
B. Statutory and Regulatory Background
1. Pre-Water Quality Act Amendments of 1987 (Pub. L. 100-4)
2. The Water Quality Act Amendments of 1987 (Pub. L. 100-4)
a. Description of the New Requirements
b. EPA's Initial Implementing Actions for sections 303(c) and 304(l)
3. EPA's Program Guidance for section 303(c)(2)(B)
C. State Actions Pursuant to section 303(c)(2)(B)
D. Determining State Compliance with section 303(c)(2)(B)
1. EPA's Review of State Water Quality Standards for Toxics
2. Determining Current Compliance Status
E. Rationale and Approach For Developing the Final Rule
1. Legal Basis
2. Approach for Developing the Final Rule
3. Approach for States that Fully Comply Subsequent to Issuance of this Final Rule
F. Derivation of Criteria
1. Section 304(a) Criteria Process
2. Aquatic Life Criteria
3. Criteria for Human Health
4. Section 304(a) Human Health Criteria Excluded
5. Cancer Risk Level
6. Applying EPA's Nationally Derived Criteria to State Waters
7. Application of Metals Criteria
G. Description of the Final Rule and Changes from Proposal
1. Changes from Proposal
2. Scope
3. EPA Criteria for Priority Toxic Pollutants
4. Applicability
H. (Reserved)
I. Response to Public Comments
1. Legal Authority
2. Science
3. Economics
4. Implementation
5. Timing and Process
6. State Issues
J. Executive Order 12291
K. Regulatory Flexibility Act
L. Paperwork Reduction Act

A. Introduction and Overview

1. Introduction

This section of the Preamble introduces the topics which are addressed subsequently and provides a brief overview of EPA's basis and rationale for promulgating Federal criteria for priority toxic pollutants. Section B of this Preamble presents a description of the evolution of the Federal Government's efforts to control toxic pollutants beginning with a discussion of the authorities in the Federal Water Pollution Control Act Amendments of 1972. Also described in some detail is the development of the water quality standards review and revision process which provides for establishing both narrative goals and enforceable numeric requirements for controlling toxic pollutants. This discussion includes the changes enacted in the 1987 Clean Water Act Amendments which are the basis for this rule. Section C summarizes State efforts since 1987 to comply with the requirements of section 303(c)(2)(B). Section D describes EPA's procedure for determining whether a State has fully complied with section 303(c)(2)(B). Section E sets out the rationale and approach for developing the final rule, including a discussion of EPA's legal basis. Section F describes the development of the criteria included in this rule. Section G summarizes the provisions of the final rule. (Section H is reserved.) Section I contains the response to major public comments received on the proposal. Sections J, K, and L address the requirements of Executive Order 12291, the Regulatory Flexibility Act, and the Paperwork Reduction Act, respectively. Section M provides a list of subjects covered in this rule.

A public hearing on the proposed rule was held on December 19, 1991, in Washington, DC. A total of 26 non-EPA people registered at the hearing. The public comment period closed on December 19, 1991. EPA received a total of 153 written comments on the proposed rule.

2. Overview

This rule, which establishes Federal criteria for certain priority toxic pollutants in a number of States, is important for several environmental, programmatic and legal reasons.

First, control of toxic pollutants in surface waters is an important priority to achieve the Clean Water Act's goals and objectives. The most recent National Water Quality Inventory indicates that one-third of monitored river miles, lake acres, and coastal waters have elevated levels of toxics. Forty-seven States and Territories have reported elevated levels of toxic pollutants in fish tissues. States have issued a total of 586 fishing advisories and 135 bans, attributed mostly to industrial discharges and land disposal.

The absence of State water quality standards for toxic pollutants undermines State and EPA toxic control efforts to address these problems. Without clearly established water quality goals, the effectiveness of many of EPA's water programs is jeopardized. Permitting, enforcement, coastal water quality improvement, fish tissue quality protection, certain nonpoint source controls, drinking water quality protection, and ecological protection all depend to a significant extent on complete and adequate water quality standards. Numeric criteria for toxics are essential to the process of controlling toxics because they allow States and EPA to evaluate the adequacy of existing and potential control measures to protect aquatic ecosystems and human health. Formally adopted standards are the legal basis for including water quality-based effluent limitations in NPDES permits to control toxic pollutant discharges. The critical importance of controlling toxic pollutants has been recognized by Congress and is reflected, in part, by the addition of section 303(c)(2)(B) to the Act. Congressional impatience with the pace of State toxics control programs is well documented in the legislative history of the 1987 CWA amendments. In order to protect human health, aquatic ecosystems, and successfully implement toxics controls, EPA believes that all actions which are available to the Agency must be taken to ensure that all necessary numeric criteria for priority toxic pollutants are established in a timely manner.

Second, as States and EPA continue the transition from an era of primarily technology-based controls to an era in which technology-based controls are integrated with water quality-based controls, it is important that EPA ensures timely compliance with CWA requirements. An active Federal role is essential to assist States in getting in place complete toxics criteria as part of their pollution control programs. While most States recognize the need for enforceable water quality standards for toxic pollutants, their recent adoption efforts have often been stymied by a variety of factors including limited resources, competing environmental priorities, and difficult scientific, policy and legal challenges. Most water quality criteria for toxic pollutants have been available since 1980. Section 303 of the CWA requires States to review, revise, and adopt updated water quality standards every three years as part of a continuing triennial review process. The water quality standards regulation has required State adoption of numeric criteria for toxic pollutants since 1983 (see 40 CFR 131.11). Despite the availability of scientific guidance documents and clear statutory and regulatory requirements, a preliminary assessment of the water quality standards for all States in February of 1990 showed that only six States had established fully acceptable criteria for toxic pollutants. This rate of toxics criteria adoption is contrary to the CWA requirements and is a reflection of the difficulties faced by States. In such circumstances, it is EPA's responsibility to exercise its CWA authorities to move forward the toxic control program in concert with the statutory scheme.

EPA's action will also help restore equity among the States. The CWA is designed to ensure all waters are sufficiently clean to protect public health and the environment. The CWA allows some flexibility and differences among States in their adopted and approved water quality standards, but it was not designed to reward inaction and inability to meet statutory requirements.

Although most States have made important progress toward satisfying CWA requirements, some have still failed to fully comply with section 303(c)(2)(B). The CWA authorizes EPA to promulgate standards where necessary to meet the requirements of the Act. Where States have not satisfied the CWA requirement to adopt water quality standards for toxic pollutants, which was reemphasized by Congress in 1987, it is imperative that EPA take action.

EPA's ability to oversee State standards-setting activities and to correct deficiencies in State water quality standards is critical to the effective implementation of section 303(c)(2)(B). This rule is a necessary and important component of EPA's implementation of section 303(c)(2)(B) as well as EPA's overall efforts to control toxic pollutants in surface waters.

On February 26, 1992, EPA's Deputy Administrator issued "Guidance on Risk Characterization for Risk Managers and Risk Assessors" which addresses a problem that affects public perception regarding the reliability of EPA's scientific assessments and related regulatory decisions. The guidance noted that "when risk information is presented to the * * * public, the results have been boiled down to a point estimate of risk * * * which do not fully convey the range of information considered and used in developing the assessment." The guidance lays out principles and implementation procedures to address risk assessments in future EPA presentations, reports and decision packages. The guidance specifically notes, "*However, we do not* expect risk assessment documents that are close to completion to be rewritten."

The proposal for this final rule was published in November, 1991, three months prior to the risk assessment guidance being issued. Since the Agency was striving to meet a mid-February statutory deadline for final publication, when the risk guidance was issued the rulemaking package was essentially complete. The specifics of the aquatic life and human health guidelines are discussed in the preamble and in the response to public comments. The actual methodology and criteria documents describe in detail the risk assessment process involved in deriving a water quality criteria and the water quality standards contained in this rule and the resulting risk characterization. The water quality criteria methodology and individual criteria documents are part of the record for this rule. Therefore, while all the specifics of the new risk characterization guidance were not followed in this preamble, the spirit of the guidance is reflected.

Moreover, EPA has initiated a review and update of these criteria methodologies. These updates will be conducted in conformance with the risk characterization guidance and include public involvement and review.

B. Statutory and Regulatory Background

1. Pre-Water Quality Act Amendments of 1987 (Pub. L. 100-4)

Section 303(c) of the 1972 Federal Water Pollution Control Act Amendments (FWPCA) (33 U.S.C. 1313(c)) established the statutory basis for the current water quality standards program. It completed the transition from the previously established program of water quality standards for interstate waters to one requiring standards for all surface waters of the United States.

Although the major innovation of the 1972 FWPCA was technology-based controls, Congress maintained the concept of water quality standards both as a mechanism to establish goals for the Nation's waters and as a regulatory requirement when standardized technology controls for point source discharges and/or nonpoint source controls were inadequate. In recent years, these so-called water quality-based controls have received new emphasis by Congress and EPA in the continuing quest to enhance and maintain water quality to protect the public health and welfare.

Briefly stated, the key elements of section 303(c) are:

(a) A water quality standard is defined as the designated beneficial uses of a water segment and the water quality criteria necessary to support those uses;

(b) The minimum beneficial uses to be considered by States in establishing water quality standards are specified as public water supplies, propagation of fish and wildlife, recreation, agricultural uses, industrial uses and navigation;

(c) A requirement that State standards must protect public health or welfare, enhance the quality of water and serve the purposes of the Clean Water Act;

(d) A requirement that States must review their standards at least once each three year period using a process that includes public participation;

(e) The process for EPA review of State standards which may ultimately result in the promulgation of a superseding Federal rule in cases where a State's standards are not consistent with the applicable requirements of the CWA, or in situations where the Agency determines Federal standards are necessary to meet the requirements of the Act.

Another major innovation in the 1972 FWPCA was the establishment of the National Pollutant Discharge Elimination System (NPDES) which requires point source discharges to obtain a permit before legally discharging to the waters of the United States. In addition to the permit limits established on the basis of technology (e.g. effluent limitations guidelines), the Act requires discharges to meet instream water quality standards. (See section 301(b)(1)(C), 33 U.S.C. 1311(b)(1)(C)).

The water quality standards serve a dual function under the Clean Water Act regulatory scheme. Standards establish narrative and numeric definitions and quantification of the Act's goals and policies (see section 101, 33 U.S.C. 1251) which provide a basis for identifying impaired waters. Water quality standards also establish regulatory requirements which are translated into specific discharge requirements. In order to fulfill this critical function, adopted State criteria must contain sufficient parametric coverage to protect both human health and aquatic life.

In its initial efforts to control toxic pollutants, the FWPCA, pursuant to section 307, required EPA to designate a list of toxic pollutants and to establish toxic pollutant effluent standards based on a formal rulemaking record. Such rulemaking required formal hearings, including cross-examination of witnesses. EPA struggled with this unwieldy process and ultimately promulgated effluent standards for six toxic pollutants, pollutant families or mixtures. (See 40 CFR part 129.) Congress amended section 307 in the 1977 Clean Water Act Amendments by endorsing the Agency's alternative procedure of regulating toxic pollutants by use of effluent limitations guidelines, by amending the procedure for establishing toxic pollutant effluent standards to provide for more flexibility in the hearing process for establishing a record, and by directing the Agency to include sixty-five specific pollutants or classes of pollutants on the toxic pollutant list. EPA published the required list on January 31, 1978 (43 FR 4109). This toxic pollutant list was the basis on which EPA's efforts on criteria development for toxics was focused.

During planning efforts to develop effluent limitations guidelines and water quality criteria, the list of sixty-five toxic pollutants was judged too broad as some of the pollutants were, in fact, general families or classes of organic compounds consisting of many individual chemicals. EPA selected key chemicals of concern within the 65 families of pollutants and identified a more specific list of 129 priority toxic pollutants. Two volatile chemicals and one water unstable chemical were removed from the list (see 46 FR 2266, January 8, 1981; 46 FR 10723, February 4, 1981) so that at present there are 126 priority toxic pollutants. This list is published as appendix A to 40 CFR part 423.

Another critical section of the 1972 FWPCA was section 304(a) (33 U.S.C. 1314(a)). Section 304(a)(1) provides, in pertinent part, that EPA

> * * * shall develop and publish * * * criteria for water quality accurately reflecting the latest scientific knowledge (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, * * * and (C) on the effects of pollutants on biological community diversity, productivity, and stability, * * *

In order to avoid confusion, it must be recognized that the Clean Water Act uses the term "criteria" in two separate ways. In section 303(c), which is discussed above, the term is part of the definition of a water quality standard. That is, a water quality standard is comprised of designated uses and the criteria necessary to protect those uses. Thus, States are required to adopt regulations or statutes which contain legally achievable criteria. However, in section 304(a), the term criteria is used in a scientific sense and EPA develops recommendations which States consider in adopting regulatory criteria.

In response to this legislative mandate and an earlier similar statutory requirement, EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were Water Quality Criteria (1968 "Green Book") and Quality Criteria for Water (1976 "Red Book"). EPA also sponsored a contract effort with the National Academy of Science—National Academy of Engineering which resulted in Water Quality Criteria, 1972 (1973 "Blue Book"). 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 list of 65 toxic pollutants and 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, since for many pollutants essential information was not available. 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. (See 45 FR 79318.) Since that initial publication, the aquatic life methodology was slightly amended (50 FR 30784, July 29, 1985) and additional criteria was proposed for public comment and finalized as Agency criteria guidance. EPA summarized the available criteria information in Quality Criteria for Water 1986 (1986 "Gold Book") which is updated from time-to-time. However, the individual criteria documents, 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) which the Agency recommends to protect aquatic life resources. For human health criteria, the document provides the appropriate reference doses, and if appropriate, the carcinogenic slope factors, and derives recommend criteria. The details of this process are described more fully in a later part of this Preamble.

Programmatically, EPA's initial efforts were aimed at converting a program focused on interstate waters into one addressing all interstate and intrastate surface waters of the United States. Guidance was aimed at the inclusion of traditional water quality parameters to protect aquatic life (e.g., pH, temperature, dissolved oxygen and a narrative "free from toxicity" provision), recreation (e.g., bacteriological criteria) and general aesthetics (e.g., narrative "free from nuisance" provisions). EPA also required State adoption of an antidegradation policy to maintain existing high quality or ecologically unique waters as well as maintain improvements in water quality as they occur.

The initial water quality standards regulation was actually a part of EPA's water quality management regulations implementing section 303(e) (33 U.S.C. 1313(e)) of the Act. It was not comprehensive and did not address toxics or any other criteria specifically. Rather, it simply required States to adopt appropriate water quality criteria necessary to support designated uses. (See 40 CFR 130.17 as promulgated in 40 FR 55334, November 28, 1975).

After several years of effort and faced with increasing public and Congressional concerns about toxic pollutants, EPA realized that proceeding under section 307 of the Act would not comprehensively address in a timely manner the control of toxics through either toxic pollutant effluent standards or effluent limitations guidelines because these controls are only applicable to specific types of discharges. EPA sought a broader, more generally applicable mechanism and decided to vigorously pursue the alternative approach of EPA issuance of scientific water quality criteria documents which States could use to adopt enforceable water quality standards. These in turn could be used as the basis for establishing State and EPA permit discharge limits pursuant to section 301(b)(1)(C) which requires NPDES permits to contain

> * * * any more stringent limitation, including those necessary to meet water quality standards * * *, or required to implement any applicable water quality standard established pursuant to this Act.

Thus, the adoption by States of appropriate toxics criteria applicable to their surface waters, such as those recommended by EPA in its criteria documents, would be translated by regulatory agencies into point source permit limits. Through the use of water quality standards, all discharges of toxics are subject to permit limits and not just those discharged by particular industrial categories. In order to facilitate this process, the Agency amended the water quality standards regulation to explicitly address toxic criteria requirements in State standards. The culmination of this effort was the promulgation of the present water quality standards regulation on November 8, 1983 (40 CFR part 131, 48 FR 51400).

The current water quality standards regulation (40 CFR part 131) is much more comprehensive than its predecessor. The regulation addresses in detail both the beneficial use component and the criteria component of a water quality standard. Section 131.11 of the regulation requires States to review available information and,

> * * * to identify specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use.

The regulation provided that either or both numeric and narrative criteria may be appropriately used in water quality standards.

EPA's water quality standards emphasis since the early 1980's reflected the increasing importance placed on controlling toxic pollutants. States were strongly encouraged to adopt criteria in their standards for the priority toxic pollutants, especially where EPA had published criteria guidance under section 304(a) of the Act.

Under the statutory scheme, during the 3-year triennial review period following EPA's 1980 publication of water quality criteria for the protection of human health and aquatic life, States should have reviewed those criteria and adopted standards for many priority toxic pollutants. In fact, State response to EPA's criteria publication and toxics initiative was disappointing. A few States adopted large numbers of numeric toxics criteria, although primarily for the protection of aquatic life. Most other States adopted few or no water quality criteria for priority toxic pollutants. Some relied on a narrative "free from toxicity" criterion, and so-called "action levels" for toxic pollutants or occasionally calculated site-specific criteria. Few States addressed the protection of human health by adopting numeric human health criteria.

In support of the November, 1983, water quality standards rulemaking, EPA issued program guidance entitled, Water Quality Standards Handbook (December 1983) simultaneously with the publication of the final rule. The foreword to that guidance noted EPA's two-fold water quality based approach to controlling toxics: chemical specific numeric criteria and biological testing in whole effluent or ambient waters to comply with narrative "no toxics in toxic amounts" standards. More detailed programmatic guidance on the application of biological testing was provided in the Technical Support Document for Water Quality Based Toxics Control (TSD) (EPA 440/4-85-032, September 1985). This document provided the needed information to convert chemical specific and biologically based criteria into water quality standards for ambient receiving waters and permit limits for discharges to those waters. The TSD focused on the use of bioassay testing of effluent (so-called whole effluent testing or WET methods) to develop effluent limitations within discharge permits. Such effluent limits were designed to implement the "free from toxicity" narrative standards in State water quality standards. The TSD also focused on water quality standards. Procedures and policy were presented for appropriate design flows for EPA's section 304(a) acute and chronic criteria. In 1991, EPA revised and expanded the TSD. (Technical Support Document for Water Quality-based Toxics Control, EPA 505/2-90-001, March 1991.) A Notice of Availability was published in the **Federal Register** on April 4, 1991 (56 FR 13827). All references in this Preamble are to the revised TSD.

The Water Quality Standards Handbook and the TSD are examples of EPA's efforts and assistance that were intended to help, encourage and support the States in adopting appropriate water quality standards for the protection of their waters against the deleterious effects of toxic pollutants. In some States, more and more numeric criteria for toxics were being adopted as well as more aggressive use of the "free from toxics" narratives in setting protective NPDES permit limits. However, by the time of Congressional consideration and action on the CWA reauthorization, most States had adopted few, if any, water quality standards for priority toxic pollutants.

State practices of developing case-by-case effluent limits using procedures that were not standardized in State regulations made it difficult to ascertain whether such procedures were consistently applied. The use of approaches to control toxicity that did not rely on the statewide adoption of numeric criteria for the priority toxic

pollutants generated frustration in Congress. Senator Robert T. Stafford, first chairman and then ranking minority member of the authorizing committee, noted during the Senate debate:

> An important problem in this regard is that few States have numeric ambient criteria for toxic pollutants. The lack of ambient criteria [for toxic pollutants] make it impossible to calculate additional discharge limitations for toxics * * *. It is vitally important that the water quality standards program operate in such a way that it supports the objectives of the Clean Water Act to restore and maintain the integrity of the Nation's Waters. (bracketed material added). A Legislative History of the Water Quality Act of 1987 (Pub. L. 100–4), Senate Print 100–144, USGPO, November 1988 at page 1324.

Other comments in the legislative history similarly note the Congressional perception that the States were failing to aggressively address toxics and that EPA was not using its oversight role to push the States to move more quickly and comprehensively. Thus Congress developed the water quality standards amendments to the Clean Water Act for reasons similar to those strongly stated during the Senate debate by a chief sponsor, Senator John H. Chafee,

> A cornerstone of the bill's new toxic pollution control requirements is the so called beyond-BAT program * * *. Adopting the beyond BAT provisions will assure that EPA continues to move forward rapidly on the program * * *. If we are going to repair the damage to those water bodies that have become highly degraded as a result of toxic substances, we are going to have to move forward expeditiously on this beyond-BAT program. The Nation cannot tolerate endless delays and negotiations between EPA and States on this program. Both entities must move aggressively in taking the necessary steps to make this program work within the time frame established by this Bill * * *. Ibid, at page 1309.

This Congressional impatience with the pace of State and EPA progress and an appreciation that the lack of State standards for toxics undermined the effectiveness of the entire CWA-based scheme, resulted in the 1987 adoption of stringent new water quality standard provisions in the Water Quality Act amendments.

2. The Water Quality Act Amendments of 1987 (Pub. L. 100–4)

a. Description of the New Requirements

The 1987 Amendments to the Clean Water Act added Section 303(c)(2)(B) which provides:

> 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.

b. EPA's Initial Implementing Actions for Sections 303(c) and 304(l)

The addition of this new requirement to the existing water quality standards review and revision process of section 303(c) did not change the existing procedural or timing provisions. For example, section 303(c)(1) still requires that States review their water quality standards at least once each 3 year period and transmit the results to EPA for review. EPA's oversight and promulgation authorities and statutory schedules in section 303(c)(4) were likewise unchanged. Rather, the provision required the States to place heavy emphasis on adopting numeric chemical-specific criteria for toxic pollutants (i.e., rather than just narrative approaches) during the next triennial review cycle. As discussed in the previous section, Congress was frustrated that States were not using the numerous section 304(a) criteria that EPA had developed, and was continuing to develop, to assist States in controlling the discharge of priority toxic pollutants. Therefore, for the first time in the history of the Clean Water Act, Congress took the unusual action of explicitly mandating that States adopt numeric criteria for specific toxic pollutants.

In response to this new Congressional mandate, EPA redoubled its efforts to promote and assist State adoption of water quality standards for priority toxic pollutants. EPA's efforts included the development and issuance of guidance to the States on acceptable implementation procedures for several new sections of the Act, including sections 303(c)(2)(B) and 304(l).

The 1987 CWA Amendments added to, or amended, other CWA Sections related to toxics control. Section 304(l) (33 U.S.C. 1314(l)) was an important corollary amendment because it required States to take actions to identify waters adversely affected by toxic pollutants, particularly those waters entirely or substantially impaired by point sources. Section 304(l) entitled "Individual Control Strategies for Toxic Pollutants," requires in part, that States identify and list waterbodies where the designated uses specified in the applicable water quality standards cannot reasonably be expected to be achieved because of point source discharge of toxic pollutants. For each segment so identified, the State is required to develop individual control strategies to reduce the discharge of toxics from point sources so that in conjunction with existing controls on point and nonpoint sources, water quality standards will be attained. To assist the States in identifying waters under section 304(l), EPA's guidance listed a number of potential sources of available data for States to review. States generally assembled data for a broad spectrum of pollutants, including the priority toxic pollutants, which could be useful in complying with sections 304(l) and 303(c)(2)(B). In fact, between February 1988 and October 1988, EPA assembled pollutant candidate lists for section 304(l) which were then transmitted to each jurisdiction. Thus, each State had a preliminary list of pollutants that had been identified as present in, or discharged to, surface waters. Such lists were limited by the quantity and distribution of available effluent and ambient monitoring data for priority toxic pollutants. This listing exercise further emphasized the need for water quality standards for toxic pollutants. Lack of standards increased the difficulty of identifying impaired waters. On the positive side, the data gathered in support of the 304(l) activity proved helpful in identifying those pollutants most obviously in need of water quality standards.

EPA, in devising guidance for section 303(c)(2)(B), attempted to provide States 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. The options EPA identified are described in the next Section of this Preamble. EPA's program guidance was issued in final form on December 12, 1988 but was not

substantially different from earlier drafts available for review by the States. The availability of the guidance was published in a Federal Register Notice on January 5, 1989 (54 FR 346).

3. EPA's Program Guidance for Section 303(c)(2)(B)

EPA's section 303(c)(2)(B) program guidance identified three options that could be used by a State to meet the requirement that the State adopt toxic pollutant criteria "* * * 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."

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.

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 found this Option attractive because it ensured 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 would also not be more costly to dischargers than other options because permit limits would only be based 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.

Option 2. Adopt chemical-specific numeric criteria for priority toxic pollutants that are the subject of EPA section 304(a) criteria guidance, where the State determines based on available information that the pollutants are present or discharged and can reasonably be expected to interfere with designated uses.

This option results in the adoption of numeric water quality standards for some subset of those pollutants for which EPA has issued section 304(a) criteria guidance based on a review of current information. To satisfy this Option, the guidance recommended that States use the data gathered during the section 304(l) water quality assessments as a starting point to identify those water segments that need water quality standards for priority toxic pollutants. That data would be supplemented by a State and public review of other data sources to ensure sufficient breadth of coverage to meet the statutory objective. Among the data available to be reviewed were: (1) Ambient water monitoring information, including those for the water column, sediment, and aquatic life (e.g., fish tissue data); (2) NPDES permit applications and permittee self-monitoring reports; (3) effluent guideline development documents, many of which contain priority toxic pollutant scans; (4) pesticide and herbicide application information and other records of pesticide or herbicide inventories; (5) public water supply source monitoring data noting pollutants with maximum contaminant levels (MCLs); and (6) any other relevant information on toxic pollutants collected by Federal, State, industry, agencies, academic groups, or scientific organizations. EPA also recommended that States selecting this option adopt a translator provision similar to that described in Option 3 but applicable to all chemicals causing toxicity, and not just priority toxic pollutants.

This Option 2 review resulted in a State proposing new or revised water quality standards and providing an opportunity for public review and comment on the pollutants, criteria, and water bodies included. Throughout this process, EPA's Regional Offices were available to assist States by providing additional guidance and technical assistance on applying EPA's recommended criteria to particular situations in the States.

Option 3. Adopt a procedure to be applied to a narrative water quality standard provision prohibiting toxicity in receiving waters. Such procedures would be used by the State in calculating derived numeric criteria which must 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.

The combination of a narrative standard (e.g., "free from toxics in toxic amounts") and an approved translator mechanism as part of a State's water quality standards satisfies the requirements of section 303(c)(2)(B). As noted above, such a procedure is also a valuable supplement to either option 1 or 2. There are several regulatory and scientific requirements EPA's guidance specifies are essential to ensure acceptable scientific quality and full involvement of the public and EPA in this approach. Briefly stated these are:

- The procedure (i.e., narrative criterion and translator) must be used to calculate numeric water quality criteria;
- The State must demonstrate to EPA that the procedure results in numeric criteria that are sufficiently protective to meet the goals of the Act;
- The State must provide for full opportunity for public participation during the adoption of the procedure;
- The procedure must be formally adopted as a State rule and be mandatory in application; and
- The procedure must be submitted for review and approval by EPA as part of the State's water quality standards regulation.

The scientific elements of a translator are similar to EPA's 304(a) criteria methodologies when applied on a site-specific basis. For example, aquatic criteria are developed using a sufficient number and diversity of aquatic species representative of the biological assemblage of a particular water body. Human health criteria focus on determining appropriate exposure conditions (e.g. amount of aquatic life consumed per person per day) rather than underlying pollutant toxicity. The results of the procedures are scientifically defensible criteria that are protective for the site's particular conditions. EPA's review of translator procedures includes an evaluation of the scientific merit of the procedure using the section 304(a) methodology as a guide.

Ideally, States adopting option 3 translator procedures should prepare a preliminary list of criteria and specify the waters the criteria apply to at the time of adoption. Although under option 3 the State retains flexibility to derive new criteria without revising the adopted standards, establishing this preliminary list of derived criteria at the time of the triennial review will assist the public in determining the scope of the adopted standards, and help ensure that the State ultimately complies with the requirement to establish criteria for all pollutants that can "reasonably be expected" to interfere with uses. EPA believes that States selecting solely option 3 should prepare an analysis (similar to that required of option 2 States) at the time of the triennial review identifying pollutants needing criteria.

EPA's December 1988 guidance also addressed the timing issue for State compliance with section 303(c)(2)(B). The statutory directive was clear: All State standards triennial reviews initiated after passage of the Act must include a consideration of numeric toxic criteria.

The structure of section 303(c) is to require States to review their water quality standards at least once each three year period. Section 303(c)(2)(B) instructs States to include reviews for toxics criteria whenever they initiate a triennial review. EPA initially looked at February 4, 1990, the 3-year anniversary of the 1987 CWA amendments, as a convenient point to index State compliance. The April 1990 Federal Register Notice used this index point for the preliminary assessment. However, some States were very nearly completing their State administrative processes for ongoing reviews when the 1987 amendments were enacted and could not legally amend those proceedings to address additional toxics criteria. Therefore, in the interest of fairness, and to provide such States a full 3-year review period, EPA's FY 1990 Agency Operating Guidance provided that "By the end of the FY 88–90 triennium, States should have completed adoption of numeric criteria to meet the section 303(c)(2)(B) requirements." (p.48.) The FY 88–90 triennium ended on September 30, 1990.

Clean Water Act section 303(c) does not provide penalties for States that do not complete timely water quality standards reviews. In no previous case has the EPA Administrator found that State failure to complete a review within three years jeopardized the public health or welfare to such an extent that promulgation of Federal standards pursuant to section 303(c)(4)(B) was justified. The pre-1987 CWA never mandated State adoption of priority toxic pollutants or other specific criteria. EPA generally relied on its water quality standards regulation (40 CFR 131.11) and its criteria and program guidance to the States on appropriate parametric coverage in State water quality standards to encourage State adoption of water quality standards. However, since the 1987 statutory amendments, the programmatic environment has changed. Beyond the increased Congressional and public concern, about the relative importance of toxic pollutant controls, there is increased evidence of toxic pollution problems in our Nation's waters. In response, the Agency in this rulemaking is proceeding pursuant to section 303(c)(4)(B) and 40 CFR 131.22(b) to rectify a longstanding program deficiency.

The current regulation at 40 CFR Part 131 in conjunction with the statutory language provides a clear and unambiguous basis and process for today's Federal promulgation.

C. State Actions Pursuant to Section 303(c)(2)(B)

In recent years, there has been substantial progress by many States in the adoption, and EPA approval, of water quality standards for toxic pollutants. Virtually all States have at least proposed new toxics criteria for priority toxic pollutants since section 303(c)(2)(B) was added to the CWA in February of 1987. Unfortunately, not all such State proposals address, in a comprehensive manner, the requirements of section 303(c)(2)(B). For example, some States have proposed to adopt criteria to protect aquatic life, but not human health; other States have proposed human health criteria which do not address major human exposure pathways. In addition, in some cases final adoption of proposed State toxics criteria which would be approvable by EPA has been substantially delayed due to controversial and difficult issues associated with the toxics criteria adoption process. For purposes of today's rulemaking, it is EPA's judgment that 43 States completed actions which fully satisfy the requirements of section 303(c)(2)(B).

In sum, States have devoted substantial resources, and have made substantial progress, in adopting new or revised numeric criteria for priority pollutants. In so doing, they have addressed a number of significant and difficult issues. These efforts have generated extensive examination by dischargers, States, environmental groups and the public on all aspects of the CWA water quality criteria and related issues. It amounts to a multi-year consideration of the issues that are central to this proposed and final rulemaking.

D. Determining State Compliance With Section 303(c)(2)(B)

1. EPA's Review of State Water Quality Standards for Toxics

The EPA Administrator has delegated the responsibility and authority for review and approval or disapproval of all State water quality standards actions to the 10 EPA Regional Administrators (see 40 CFR 131.21). State section 303(c)(2)(B) actions are thus submitted to the appropriate EPA Regional Administrator for review and approval. This de-centralized EPA system for State water quality standards review and approval is guided by EPA Headquarters Office of Water, which issues national policies and guidance to the States and Regions such as the annual Office of Water Operating Guidance and various technical manuals.

For purposes of evaluating State compliance with CWA section 303(c)(2)(B), EPA relied on the statutory language, the existing water quality standards regulation, and section 303(c)(2)(B) national guidance to provide the basis for EPA review. In some cases, individual Regions also used Regional policies and procedures in reviewing State section 303(c)(2)(B) actions. The flexibility provided by the national guidance, coupled with subtle differences in Regional policies and procedures, contributed to some differences in the approaches taken by States to satisfy section 303(c)(2)(B) requirements.

As discussed previously, EPA's final guidance on compliance with section 303(c)(2)(B) was developed to provide States with the necessary flexibility to allow State standards revisions that would complement the State's existing water quality standards program and still comply with section 303(c)(2)(B). As guidance, it described the range of acceptable approaches and EPA's recommendations. Some innovative State approaches were expected as well as differences in terms of criteria coverage, stringency and application procedures.

Although the guidance provided for State flexibility, it was also consistent with existing water quality standards regulation requirements of 40 CFR 131.11 that explicitly require State criteria to be sufficient to protect designated uses. Such water quality criteria also must be based on sound scientific rationale and support the most sensitive use designated for a water body.

The most complicated EPA compliance determinations involve States that selected EPA Options 2 or 3. Since most States use EPA's section 304(a) criteria guidance, where States select Option 1, EPA normally is able to focus Agency efforts on verifying that all available EPA criteria are included, appropriate cancer risk levels are selected, and that sufficient application procedures are in place (e.g. laboratory analytical methods, mixing zones, flow condition, etc.).

However, for States using EPA's Option 2 or 3, substantially more EPA evaluation and judgment was required because the Agency must evaluate which priority pollutants and, in some

cases, segments or designated uses, require numeric criteria. Under these options, the State must adopt or derive numeric criteria for priority toxic pollutants for which EPA has section 304(a) criteria, "* * * the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State * * *." The necessary justification and the ultimate coverage and acceptability of a State's actions vary State-to-State because of differences in the adequacy of available monitoring information, local waterbody use designations, the effluent and nonpoint source controls in place, and different approaches to the scientific basis for criteria.

In submitting criteria for the protection of human health, States were not limited to a 1 in 1 million risk level (10^{-6}). 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. If a State selects a criterion that represents an upper bound risk level less protective than 1 in 100,000 (i.e., 10^{-5}), however, the State needed to have substantial support in the record for this level. This support focused 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 evaluated all assumptions used by a State if the State chose to alter any one of the standard EPA assumption values.

Where States selected Option 3, EPA reviews must also include an evaluation of the scientific defensibility of the translator procedure. EPA must also verify that a requirement to apply the translator whenever toxics may reasonably be expected to interfere with designated uses (e.g., where such toxics exist or are discharged) is included in the State's water quality standards. Satisfactory application procedures must also be developed by States selecting Option 3.

In general, each EPA Region made compliance decisions based on whatever information was available at the time of the triennial review. For some States, information on the presence and discharge of priority toxic pollutants is extremely limited. Nevertheless, during the period of February 1988 to October 1990, to supplement State efforts, EPA assembled the available information and provided each State with various pollutant candidate lists in support of the section 304(l) and section 303(c)(2)(B) activities. These were based in part on computerized searches of existing Agency data bases.

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 in order 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 on-going 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).

In its 1988 section 303(c)(2)(B) guidance, EPA urged States, at a minimum, to use the information gathered in support of section 304(l) requirements as a starting point for identifying which priority toxic pollutants require adoption of numeric criteria. EPA also encouraged States to consider the presence or potential construction of facilities that manufacture or use priority toxic pollutants as a strong indication of the need for toxics criteria. Similarly, EPA indicated to States that the presence of priority pollutants in ambient waters (including those in sediments or in aquatic life tissue) or in discharges from point or nonpoint sources also be considered as an indication that toxics criteria should be adopted. A limited amount of data on the effluent characteristics of NPDES discharges was readily available to States. States were 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, Pub. L. 99–499.)

In summary, EPA and the States had access to a variety of information gathered in support of section 304(l), section 303(c)(2)(B), and section 305(b) activities. For some States, as noted above, such information for priority toxic pollutants is extremely limited. In the final analysis, the Regional Administrator made a judgment on a duly submitted State standards triennial review based on the State's record and the Region's independent knowledge of the facts and circumstances surrounding the State's actions. These actions, taken in consultation with the Office of Water, determined which State actions were sufficiently consistent with the coverage contemplated in the statute to justify approval. These approval actions include allowable variations among State water quality standards. EPA approval indicates that, based on the record, the State water quality standards met the requirements of the Act.

2. Determining Current Compliance Status

The following summarizes the process generally followed by the Agency in assessing compliance with section 303(c)(2)(B).

A State was determined to be in full compliance with the requirements of section 303(c)(2)(B) if,

a. The State had submitted a water quality standards package for EPA review since enactment of the 1987 Clean Water Act amendments or was determined to be already in compliance, and,

b. The State adopted water quality standards are effective under State law and consistent with the CWA and EPA's implementing regulations (EPA's December 1988 guidance described three Options, any one, or a combination of which EPA suggested States could adopt for compliance with the CWA and EPA regulations), and

c. EPA has issued a formal approval determination to the State.

States meeting these criteria are not included in this final rulemaking.

States which adopted standards following Option 1 generally have been found to satisfy section 303(c)(2)(B). An exception exists for selected States which attempted to follow Option 1 by adopting all EPA section 304(a) criteria by reference. EPA has withheld

approval for one State which has adopted such a reference into their standards because the adopted standards did not specify application factors necessary to implement the criteria (e.g., a risk level for carcinogens). Other States have achieved full compliance following options 1, 2, 3, or some combination of these options.

As of the date of signature of today's rule, the Agency has determined that 43 States and Territories are in full compliance with the requirements of section 303(c)(2)(B). Compliance status for all States and Territories is set forth in Table 1.

TABLE 1.—ASSESSMENT OF STATE COMPLIANCE WITH CWA SECTION 303(c)(2)(B)

State	Is State in compliance with section 303(c)(2)(B)?
Alabama	Yes.
Alaska	No.
Arizona	Yes.
Arkansas	No.
California	No.
Colorado	Yes.
Connecticut	Yes.
Delaware	Yes.
Florida	No.
Georgia	Yes.
Hawaii	Yes.
Idaho	No.
Illinois	Yes.
Indiana	Yes.
Iowa	Yes.
Kansas	No.
Kentucky	Yes (1).
Louisiana	Yes.
Maine	Yes.
Maryland	Yes.
Massachusetts	Yes.
Michigan	No.
Minnesota	Yes.
Mississippi	Yes.
Missouri	Yes.
Montana	Yes.
Nebraska	Yes.
Nevada	No.
New Hampshire	Yes.
New Jersey	No.
New Mexico	Yes (2).
New York	Yes.
North Carolina	Yes.
North Dakota	Yes.
Ohio	Yes.
Oklahoma	Yes.
Oregon	Yes.
Pennsylvania	Yes.
Rhode Island	No.
South Carolina	Yes.
South Dakota	Yes.
Tennessee	Yes.
Texas	Yes.
Utah	Yes.
Vermont	No.
Virginia	Yes.
Washington	No.
West Virginia	Yes.
Wisconsin	Yes.
Wyoming	Yes.
American Samoa	Yes.
Commonwealth of the Northern Mariana Islands.	Yes.
District of Columbia	No.

TABLE 1.—ASSESSMENT OF STATE COMPLIANCE WITH CWA SECTION 303(c)(2)(B)—Continued

State	Is State in compliance with section 303(c)(2)(B)?
Guam	Yes.
Puerto Rico	No.
Tr. Territories	Yes.
Virgin Islands	Yes.

Notes to Table 1

(1) At the initiation of this rulemaking, Kentucky was determined to be in compliance with the Act. On January 27, 1992, the Commonwealth of Kentucky deleted the water quality criteria for dioxin from the Kentucky water quality standards. Although EPA has not formally acted to disapprove Kentucky's action to delete the criteria, information is available which documents the need for dioxin criteria for the Commonwealth of Kentucky. Any potential EPA promulgation arising from a future EPA action to disapprove the deletion of the dioxin criteria for Kentucky will be through a rulemaking independent of today's rule.

(2) At the initiation of this rulemaking, New Mexico was determined to be in compliance with the Act. On October 8, 1991, New Mexico adopted revisions to its standards which affected compliance with acute toxicity criteria. On January 13, 1992, EPA disapproved the State's action, thus initiating the possibility of Federal promulgation should the State fail to adopt acceptable standards within 90 days from the EPA notice. Any potential EPA promulgation arising from this disapproval will be through a rulemaking independent of today's rule. EPA policy has been and continues to be that we prefer States and Territories to adopt their own standards consistent with the requirements of the Clean Water Act.

(3) EPA has become aware that several of the State water quality standards approved as complying with section 303(c)(2)(B) have been challenged in State courts for various reasons. Additional such challenges may occur in the future. In cases where such State rules are remanded or otherwise set aside, or intentionally withdrawn by the State for any reason, and the State does not pursue in good faith correcting such defects in a timely manner, it is EPA's intention to initiate appropriate rulemaking to put in place appropriate criteria for priority toxic pollutants to bring State water quality standards into compliance with the Clean Water Act.

E. Rationale and Approach for Developing the Final Rule

The addition of section 303(c)(2)(B) to the Clean Water Act was an unequivocal signal to the States that Congress wanted toxics criteria in the State's water quality standards. The legislative history notes that the "beyond BAT" program (i.e., controls necessary to comply with water quality standards that are more stringent than technology-based controls) was the cornerstone to the Act's toxic pollution control requirements.

The major innovation of the 1972 Clean Water Act Amendments was the concept of effluent limitation guidelines which were to be incorporated into NPDES permits. In many cases, this strategy has succeeded in halting the decline in the quality of the Nation's waters and, often, has provided improvements. However, the effluent limitation guidelines for industrial discharges and the similar technology-based secondary treatment requirements for municipal discharges are not capable, by themselves, of ensuring that the fishable-swimmable goals of the Clean Water Act will be met for all waters.

The basic mechanism to accomplish this in the Act is water quality standards. States are required to periodically review and revise these standards to achieve the goals of the Act. In the 1987 CWA amendments, Congress focused on addressing toxics in several sections of the Act, but special attention was placed on the section 303 water quality standards program requirements. Congress intended that the adoption of numeric criteria for toxics would result in direct improvements in water quality by forcing, where necessary, effluent limits more stringent than those resulting from technology-based effluent limitations guidelines.

As the legislative history demonstrates, Congress was dissatisfied with the piecemeal, slow progress being made by States in setting standards for toxics. Congress reacted by legislating new requirements and deadlines directing the States to establish toxics criteria for pollutants addressed in EPA section 304(a) criteria guidance, especially for those priority toxic pollutants that could reasonably be expected to interfere with designated uses. In today's action, EPA is exercising its authority under section 303(c)(4) to promulgate criteria where States have failed to act in a timely manner.

The previous section of this preamble explains EPA's approach to evaluating the adequacy of State actions in response to section 303(c)(2)(B). This section explains EPA's legal basis for issuing today's rule, and discusses EPA's general approach for developing the State-specific requirements in Section 131.36(d).

In addition to the Congressional directive and the legal basis for this action, there are a number of environmental and programmatic reasons why further delay in

establishing water quality standards for toxic pollutants is no longer acceptable.

Prompt control of toxic pollutants in surface waters is critical to the success of a number of Clean Water Act programs and objectives, including permitting, enforcement, fish tissue quality protection, coastal water quality improvement, sediment contamination control, certain nonpoint source controls, pollution prevention planning, and ecological protection. The decade long delay in State adoption of water quality standards for toxic pollutants has had a ripple effect throughout EPA's water programs. Without clearly established water quality goals, the effectiveness of many water programs is jeopardized. For too long, the absence of water quality standards has had a chilling effect on toxic control progress in many State and Federal programs.

Failure to take prompt action at this juncture would also undermine the continued viability of the current statutory scheme to establish standards. Excessive delay subverts the entire concept of the triennial review cycle which is intended to combine current scientific information with the results of previous environmental control programs to direct continuing progress in enhancing water quality.

Finally, another reason to proceed expeditiously is to bring closure to this long-term effort and allow State attention and resources to be directed towards important, new national program initiatives. Until standards for toxic pollutants are in place, neither EPA nor the States can fully focus on the emerging, ecologically-based water quality activities such as wetlands criteria, biological criteria and sediment criteria.

1. Legal Basis

Clean Water Act Section 303(c) specifies that adoption of water quality standards is primarily the responsibility of the States. However, Section 303(c) also describes a role for EPA of overseeing State actions to ensure compliance with CWA requirements. If the Agency's review of the State's standards finds flaws or omissions, then the Act authorizes EPA to initiate promulgation to correct the deficiencies (see section 303(c)(4)). The water quality standards promulgation authority has been used by EPA to issue final rules on nine separate occasions. These actions have addressed both insufficiently protective State criteria and/or designated uses and failure to adopt needed criteria. Thus, today's action is not unique, although it would affect more States and pollutants than previous actions taken by the Agency.

The Clean Water Act in section 303(c)(4) provides two bases for promulgation of Federal water quality standards. The first basis, in paragraph (A), applies when a State submits new or revised standards that EPA determines are not consistent with the applicable requirements of the Act. If, after EPA's disapproval, the State does not promptly amend its rules so as to be consistent with the Act, EPA must promulgate appropriate Federal water quality standards for that State. The second basis for EPA's action is paragraph (B), which provides that EPA shall promptly initiate promulgation "* * * in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of this Act." EPA is relying on both section 303(c)(4)(A) and section 303(c)(4)(B) as the legal basis for this rule.

Section 303(c)(4)(A) supports today's action for several States. These States have submitted criteria for some number of priority toxic pollutants and EPA has disapproved the State's adopted standards. The basis for EPA's disapproval generally has been the lack of sufficient criteria or particular criteria that were insufficiently stringent. In these cases, EPA has, by letter to the State, noted the deficiencies and specified the need for corrective action. Not having received an appropriate correction within the statutory time frame, EPA is today promulgating the needed criteria. The action in today's rule pursuant to section 303(c)(4)(A) may differ from those taken pursuant to section 303(c)(4)(B) by being limited to criteria for specific priority toxic pollutants, particular geographic areas, or particular designated uses.

Section 303(c)(4)(B) is the basis for EPA's requirements for most States. For these States, the Administrator has determined that promulgating criteria is necessary to bring the States into compliance with the requirements of the CWA. In these cases, EPA is promulgating, at a minimum, criteria for all priority toxic pollutants not addressed by approved State criteria. EPA is also promulgating criteria for priority toxic pollutants where any previously-approved State criteria do not reflect current science contained in revised criteria documents and other guidance sufficient to fully protect all designated uses or human exposure pathways, or where such previously-approved State criteria are not applicable to all appropriate designated uses. EPA's action pursuant to section 304(c)(4)(B) may include several situations.

In some cases, the State has failed to adopt and submit for approval any criteria for those priority toxic pollutants for which EPA has published criteria. This includes those States that have not submitted triennial reviews. In other cases, the State has adopted and EPA has approved criteria for either aquatic life or human health, but not both. In yet a third situation, States have submitted some criteria but not all necessary criteria. Lastly, one State has submitted criteria that do not apply to all appropriate geographic sections of the waters of the State.

The use of section 303(c)(4)(B) requires a determination by the Administrator "* * * that a revised or new standard is necessary to meet the requirements of * * *" the Act. The Administrator's determination could be supported in different ways.

One approach would be for EPA to undertake a time-consuming effort to research and marshall data to demonstrate the need for promulgation for each criteria for each stream segment or waterbody in each State. This would include evidence for each Section 307(a) priority toxic pollutant for which EPA has Section 304(a) criteria and that there is a "discharge or presence" which could reasonably "be expected to interfere with" the designated use. This approach would not only impose an enormous administrative burden, but would be contrary to the statutory scheme and the compelling Congressional directive for swift action reflected in the 1987 addition of section 303(c)(2)(B) to the Act.

An approach that is more reasonable and consistent with Congressional intent focuses on the State's failure to complete the timely review and adoption of the necessary standards required by section 303(c)(2)(B) despite information that priority toxic pollutants may interfere with designated uses of the State's waters. This approach is consistent with the fact that in enacting section 303(c)(2)(B) Congress expressed its determination of the necessity for prompt adoption and implementation of water quality standards for toxic pollutants. Therefore, a State's failure to meet this fundamental 303(c)(2)(B) requirement of adopting appropriate standards constitutes a failure "to meet the requirements of the Act." That failure to act can be a basis for the Administrator's determination under section 303(c)(4)(B) that new or revised criteria are necessary to ensure designated uses are adequately protected. Here, this determination is buttressed by the existence of evidence of the discharge or presence of priority toxic pollutants in

a State's waters for which the State has not adopted numeric water quality criteria. The Agency has compiled an impressive volume of information in the record for this rulemaking on the discharge or presence of toxic pollutants in State waters. This data supports the Administrator's determination pursuant to section 303(c)(4)(B). The record was available to the public for review during this rulemaking period and continues to be on file.

The Agency's choice to base the determination on the second approach is supported by both the explicit language of the statutory provision and by the legislative history. Congress added subsection 303(c)(2)(B) to section 303 with full knowledge of the existing requirements in section 303(c)(1) for triennial water quality standards review and submission to EPA and in section 303(c)(4)(B) for EPA promulgation. There was a clear expectation that these provisions be used in concert to overcome the programmatic delay that many legislators criticized and achieve the Congressional objective of the rapid availability of enforceable water quality standards for toxic pollutants. As quoted earlier, chief Senate sponsors, including Senators Stafford, Chaffee and others, wanted the provision to eliminate State and EPA delays and force aggressive action.

In normal circumstances, it might be argued that to exercise section 303(c)(4)(B) the Administrator might have the burden of marshalling conclusive evidence of "necessity" for Federally promulgated water quality standards. However, in adopting section 303(c)(2)(B), Congress made clear that the "normal" procedure had become inadequate. The specificity and deadline in section 303(c)(2)(B) were layered on top of a statutory scheme already designed to achieve the adoption of toxic water quality standards. Congressional action to adopt a partially redundant provision was driven by their impatience with the lack of State progress. The new provision was essentially a Congressional "determination" of the necessity for new or revised comprehensive toxic water quality standards by States. In deference to the principle of State primacy, Congress, by linking section 303(c)(2)(B) to the section 303(c)(1) three-year review period, gave States a last chance to correct this deficiency on their own. However, this Congressional indulgence does not alter the fact that section 303(c)(2)(B) changed the nature of the CWA State/EPA water quality standard relationship. The new provision and its legislative background indicate that the Administrator's determination to invoke his section 303(c)(4)(B) authority in this circumstance can be met by a generic finding of inaction on the part of a State and without the need to develop data for individual stream segments. Otherwise, the Agency could face a heavy data gathering burden of justifying the need for each Federal criterion and the process could stretch for years and never be realized. To interpret the combination of subsections (c)(2)(B) and (c)(4) as an effective bar to prompt achievement of statutory objectives would be a perverse conclusion and render section 303(c)(2)(B) essentially meaningless.

A second strong argument against requiring EPA to shoulder a heavy burden to exercise section 303(c)(4)(B) authority is that it would invert the traditional statutory scheme of EPA as national overseer and States as the entity with the greatest local expertise. The CWA provides States the flexibility to tailor water quality standards to local conditions and needs based upon their wealth of first-hand experience, knowledge and data. However, this allowance for flexibility is based on an assumption of reasoned and timely State action, not an abdication of State responsibility by failure to act. EPA does not possess the local expertise or resources necessary to successfully tailor State water quality standards. Therefore, the fact that the CWA allows States flexibility in standards development does not impose an inappropriate burden on EPA in the exercise of its oversight promulgation responsibilities. A broad Federal promulgation based on a showing of State inaction coupled with basic information on the discharge and presence of toxic pollutants meets the statutory objective of having criteria in places that are protective of public health and the environment. Without local expertise to help accurately narrow this list of pollutants and segments requiring criteria, there is no assurance of comparable protection. Nothing in the overall statutory water quality standards scheme anticipates EPA would develop this expertise in lieu of the States. EPA's lack of familiarity with local conditions argues strongly for a simple "determination" test to trigger section 303(c)(4)(B) promulgations. It also supports the concept of an across-the-board rulemaking for all priority toxic pollutants with section 304(a) criteria.

A final major reason supporting a simple determination to trigger 303(c)(4)(B) action is that comprehensive Federal promulgation imposes no undue or inappropriate burden on States or dischargers. It merely puts in place standards for toxic pollutants that are utilized in implementing Clean Water Act programs. Under this rulemaking, a State still retains the ability to adopt alternative water quality standards simply by completing its standards adoption process. Upon EPA approval of those standards, EPA will take actions to withdraw the Federally-promulgated criteria.

Federal promulgation of State water quality standards should be a course of last resort. It is symptomatic of something awry with the basic statutory scheme. Yet, when it is necessary to exercise this authority, as the compelling evidence suggests in this case, there should be no undue impediments to its use. Section 303(c)(4) is replete with deadlines and Congressional directives for the Administrator to act "promptly" in these cases. The statute indicates that the Administrator of EPA, is to "* * * promptly prepare and publish proposed regulations setting forth a revised or new water quality standard * * *" and "* * * shall promulgate any revised or new standard * * * not later than 90 days after he published such proposed standards, unless prior to such promulgation, such State has adopted a revised or new standard which the Administrator determines to be in accordance with the Act." The adoption of section 303(c)(2)(B) reinforced this emphasis on expeditious actions. EPA has demonstrated extensive deference to State primacy and a willingness to provide broad flexibility in their adoption of State standards for toxics. However, to fulfill its statutory obligation requires that EPA's deference and flexibility cannot be unlimited.

For the reasons just discussed, EPA does not believe it is necessary to support the criteria promulgated today on a pollutant specific, State-by-State, waterbody-by-waterbody basis. Nonetheless, over the course of the past several years in working with and assisting the States, the Agency has reviewed the readily-available data on the discharge and presence of priority toxic pollutants. While this data is not necessarily complete, it constitutes a substantial record to support a strong *prima facie* case for the need for numeric criteria for most priority toxic pollutants with section 304(a) criteria guidance in most States. In the absence of final State actions to adopt criteria pursuant to either Option 2 or 3 which meet the requirements for EPA approval, this evidence strongly supports EPA's decision to promulgate, pursuant to section 303(c)(4)(B), criteria

for all priority toxic pollutants not fully addressed by State criteria. The EPA data supporting this assertion is discussed more fully in the next section.

2. Approach for Developing the Final Rule

The State-specific requirements in § 131.36(d) were developed using one of two approaches. In the formal review of the adopted standards for certain States, EPA determined that specific numeric toxics criteria are lacking. For some, criteria were omitted from the State standards, even though in EPA's judgment, the pollutants can reasonably be expected to interfere with designated uses. In these cases where EPA specifically identified deficiencies in a State submission, this rule establishes Federal criteria for that limited number of priority toxic pollutants necessary to correct the deficiency.

For the balance of the States, EPA applies, to all appropriate State waters, the section 304(a) criteria for all priority toxic pollutants which are not the subject of approved State criteria. EPA also is promulgating Federal criteria for priority toxic pollutants where any previously-approved State criteria do not reflect current science contained in revised criteria documents and other guidance sufficient to fully protect all designated uses or human health exposure pathways, where such previously-approved State criteria do not protect against both acute and chronic equatic life effects, or where such previously-approved State criteria are not applicable to all appropriate State designated uses.

Absent a State-by-State pollutant specific analysis to narrow the list, existing data sources strongly support a comprehensive rulemaking approach. Information in the rulemaking record from a number of sources indicates the discharge, potential discharge or presence of virtually all priority toxic pollutants in all States. The data available to EPA was assembled into a "strawman" analysis designed to identify priority toxic pollutants that potentially require the adoption of numeric criteria. Information on pollutants discharged or present was identified by accessing various national data sources:

—Final section 304(l) short lists identifying toxic pollutants likely to impair designated uses;
—Water column, fish tissue and sediment observations in the Storage Retrieval (STORET) data base (i.e., where the pollutant was *detected*);
—The National Pollutant Discharge Elimination System's (NPDES) Permit Compliance System data base to identify those pollutants limited in direct dischargers' permits;
—Pollutants included on Form 2(c) permit applications which have been submitted by wastewater dischargers;
—Information on discharges to surface waters or POTWs from the Toxics Release Inventory required by the Emergency Planning and Community Right-To-Know Act of 1986 (Title III, P.L. 99–499);
—Pollutants predicted to be in the effluent of NPDES dischargers based on industry-specific analyses conducted for the Clean Water Act effluent guideline program.

The extent of this data supports a conclusion that promulgation of Federal criteria for all priority toxic pollutants with section 304(a) criteria guidance documents is appropriate for those States that have not completed their standards adoption process. This conclusion is supported by several other factors.

First, many of the available data sources have limitations which argue against relying on them solely to identify all needed water quality criteria. For example, the section 304(l) short lists only identified water bodies where uses were impaired by point source discharges; State 304(l) long lists did not generally identify pollutants causing use impairment by nonpoint sources. Other available data sources (i.e., NPDES permit limits) have a similar narrow scope because of their particular purposes. Even the value of those data bases designed to identify ambient water problems is restricted by the availability of monitoring data. In many States, the quantity, spatial and temporal distribution, and pollutant coverage of monitoring data is severely limited. For example, the most recent Water Quality Inventory Report to Congress included an evaluation of use attainment for only one-third of all river miles and less than one-half of lake acres. Even for those waters where use attainment status was reported, many assessments were based on data which did not include the chemical-specific information necessary to identify the priority toxic pollutants which pose a threat to designated uses. After evaluating this data, EPA concluded that it most likely understates the adverse presence or discharge of priority toxic pollutants.

Further evidence justifying a broad promulgation rulemaking can be found in the State actions to date in their standards adoption process. While many have not come to completion, the initial steps have led many States to develop or propose rulemaking packages with extensive pollutant coverage. The nature of these preliminary State determinations argues for a Federal promulgation of all section 304(a) criteria pollutants to ensure adequate public health and environmental protection against priority toxic pollutant insults.

The detailed assumptions and approach followed by EPA in writing the § 131.36(d) requirements for all jurisdictions are described below. In the following discussions, EPA refers to these assumptions and approach as "rules."

(1) No criteria are promulgated for States which have been fully approved by EPA as complying with the section 303(c)(2)(B) requirements.

(2) For States which have not been fully approved, if EPA has not previously determined which specific pollutants criteria/waterbodies are lacking from a State's standards (i.e., as part of an approval/disapproval action only), all of the criteria in Columns B, C, and D of the § 131.36(b) matrix are promulgated for statewide application to all appropriate designated uses, except as provided for elsewhere in these rules. That is, EPA brought the State into compliance with section 303(c)(2)(B) via an approach which is comparable to option 1 of the December 1988 national guidance for section 303(c)(2)(B).

(3) If EPA has previously determined which specific pollutants/criteria/waterbodies are needed to comply with CWA section 303(c)(2)(B) (i.e., as part of an approval/disapproval action only), the criteria in § 131.36(b) are promulgated for only those specific pollutants/criteria/waterbodies (i.e., EPA brought the State into compliance via an approach which is comparable to option 2 of the December 1988 national guidance for section 303(c)(2)(B)).

(4) For aquatic life, except as provided for elsewhere in these rules, all waters with designated aquatic life uses providing even minimal support to aquatic life are included in the rule (i.e., fish survival, marginal aquatic life, etc.).

(5a) For human health, except as provided for elsewhere in these rules, all waters with designated uses providing for public water supply protection (and therefore a potential water consumption exposure route) or minimal aquatic life protection (and therefore a potential fish consumption exposure route) are included in the rule.

(5b) Where a State has determined the specific aquatic life segments which provide a fish consumption exposure route (i.e., fish or other aquatic life are being caught and consumed) and EPA approved this determination as part of

a standards approval/disapproval action, the rule includes the fish consumption (Column D2) criteria for only those aquatic life segments, except as provided for elsewhere in these rules. In making a determination that certain segments do not support a fish consumption exposure route, a State must have completed, and EPA approved, a use attainability analysis consistent with the provisions of 40 CFR 131.10(j). In the absence of such an approved State determination, EPA promulgated fish consumption criteria for all aquatic life segments.

(6) Uses/Classes other than those which support aquatic life or human health are not included in the rule (e.g., livestock watering, industrial water supply), unless they are defined in the State standards as also providing protection to aquatic life or human health (i.e., unless they are described as protecting multiple uses including aquatic life or human health). For example, if the State standards include a use such as industrial water supply, and in the narrative description of the use the State standards indicate that the use includes protection for resident aquatic life, then this use is included in this rule.

(7) For human health, the "water + fish" criteria in Column D1 of § 131.36(b) are promulgated for all waterbodies where public water supply and aquatic life uses are designated, except as provided for elsewhere in these rules (e.g., rule 9).

(8) If the State has public water supplies where aquatic life uses have not been designated, or public water supplies that have been determined not to provide a potential fish consumption exposure pathway, the "water + organisms only" criteria in Column D1 of § 131.36(b) are promulgated for such waterbodies, except as provided for elsewhere in these rules (e.g., rule 9).

(9) EPA is generally not promulgating criteria for priority toxic pollutants for which a State has adopted criteria and received EPA approval. The exceptions to this general rule are described in rules 10 and 11:

(10) For priority toxic pollutants where the State has adopted human health criteria and received EPA approval, but such criteria do not fully satisfy section 303(c)(2)(B) requirements, the rule includes human health criteria for such pollutants. For example, consider a case where a State has a water supply segment that poses an exposure risk to human health from both water and fish consumption. If the State has adopted, and received approval for, human health criteria based on water consumption only (e.g., Safe Drinking Water Act Maximum Contaminant Levels (MCLs)) which are less stringent than the "water + fish" criteria in Column D1 of § 131.36(b), the Column D1 criteria are promulgated for those water supply segments. The rationale for this is to ensure that both water and fish consumption exposure pathways are adequately addressed and human health is fully protected. If the State has adopted water consumption only criteria which are more stringent or equal to the Column D1 criteria, the "water + fish" criteria in Column D1 criteria are not promulgated.

(11) For priority toxic pollutants where the State has adopted aquatic life criteria and previous to the 1987 CWA Amendments received EPA approval, but such criteria do not fully satisfy section 303(c)(2)(B) requirements, the rule includes aquatic life criteria for such pollutants. For example, if the State has adopted not-to-be-exceeded aquatic life criteria which are less stringent than the 4-day average chronic aquatic life criteria in § 131.36(b) (i.e., in Columns B2 and C2), the acute and chronic aquatic life criteria in § 131.36(b) are promulgated for those pollutants. The rationale for this is that the State-adopted criteria do not protect resident aquatic life from both acute and chronic effects, and that Federal criteria are necessary to fully protect aquatic life designated uses. If the State has adopted not-to-be-exceeded aquatic life criteria which are more stringent or equal to the chronic aquatic life criteria in § 131.36(b), the acute and chronic aquatic life criteria in § 131.36(b) are not promulgated for those pollutants.

(12) Under certain conditions discussed in rules, 9, 10, and 11, criteria listed in § 131.36(b) are not promulgated for specific pollutants; however, EPA made such exceptions only for pollutants for which criteria have been adopted by the State and approved by EPA, where such criteria are currently effective under State law the appropriate EPA Region concluded that the State's criteria fully satisfy section 303(c)(2)(B) requirements.

3. Approach for States that Fully Comply Subsequent to Issuance of this Final Rule

As discussed in prior Sections of this Preamble, the water quality standards program has been established with an emphasis on State primacy. Although this rule was developed to Federally promulgate toxics criteria for States, EPA prefers that States maintain primacy, revise their own standards, and achieve full compliance. EPA is hopeful this rule will provide additional impetus for non-complying States to adopt the criteria for priority toxic pollutants necessary to comply with section 303(c)(2)(B).

Removal of a State from the rule will require another rulemaking by EPA according to the requirements of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). EPA will withdraw the Federal rule without a notice and comment rulemaking when the State adopts standards no less stringent than the Federal rule (i.e., standards which provide, at least, equivalent environmental and human health protection). For example, see 51 FR 11580, April 4, 1986, which finalized EPA's removal of a Federal rule for the State of Mississippi.

However, if a State adopts standards for toxics which are less stringent than the Federal rule but, in the Agency's judgment, fully meet the requirements of the Act, EPA will propose to withdraw the rule with a Notice of proposed rulemaking and provide for public participation. This procedure would be required for partial or complete removal of a State from this rulemaking. An exception to this requirement would be when a State adopts a human health criterion for a carcinogen at a 10^{-5} risk level where the Agency has promulgated at a 10^{-6} risk level. In such a case, the Agency believes it would be appropriate to withdraw the Federal criterion without notice and comment because the Agency has considered in this rule that criteria based on either 10^{-5} or 10^{-6} risk levels meet the requirements of the Act. A State covered by this final rule could adopt the necessary criteria using any of the three Options or combinations of those Options described in EPA's 1989 guidance.

EPA cautions States and the public that promulgation of this Federal rule removes most of the flexibility available to States for modifying their standards on a discharger-specific or stream-specific basis. For example, variances and site-specific criteria development are actions sometimes adopted by the States. These are optional policies under terms of the Federal water quality standards regulation. Except for the water-effect ratio for certain metals, EPA has not incorporated either optional policy, in general, in this rulemaking; that is, EPA has not generally authorized State modification of Federal water quality standards. Each of these types of modifications will, in general, require Federal rulemaking on a case-by-case basis to change the Federal rule. Because of the time consuming nature of reviewing such requests, limited Federal resources, and the need for the Agency to move into other priority programs

areas in establishing environmental controls, EPA alerts the States and the public that a prompt Agency response to requests for variances and site-specific modifications to the Federal criteria is unlikely. The best course of action, if such provisions are desired in a State, is for a State to adopt its own standards and take advantage, if it so chooses, of the flexibility offered by these optional provisions.

The Federal criteria published today are effective in 45 days. However, this action does not change existing applicable State and EPA provisions related to permit issuance or reissuance as they affect schedules of compliance. EPA and the States may continue issuing permits containing enforceable compliance schedules for these Federally established water quality standards if it is consistent with State policy.

F. Derivation of Criteria

1. Section 304(a) Criteria Process

Under the authority of CWA section 304(a), EPA has developed methodologies and specific criteria to protect aquatic life and human health. These methodologies are intended to provide protection for all surface water on a national basis. As described below, there are site-specific procedures for more precisely addressing site-specific conditions for an individual water body. However, the water quality criteria are scientifically sound and will achieve the statutory objective of protecting designated uses even in the absence of these modification procedures. Although the site-specific procedures may allow for more precise criteria for certain waterbodies, these procedures are infrequently used because the Section 304(a) criteria recommendations are designed to protect all waterbodies and have proven themselves to be appropriate. The methodologies have been subject to public review, as have the individual criteria documents. Additionally, the methodologies have been reviewed and approved by EPA's Science Advisory Board of external experts. Additional comments on the methodologies were taken as part of this action and have been considered and responded to in developing this final rule. In addition, these comments will be considered in the Agency's ongoing effort to propose revised methodologies for public review and comment in fiscal year 1993.

EPA incorporated by reference into the record of this rule the aquatic life methodology as described in "Appendix B—Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses" (45 FR 79341, November 28, 1980) as amended by "Summary of Revisions to Guildlines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 FR 30792, July 29, 1985).

Note: Throughout the remainder of this rule, this reference is described as the 1985 Guidelines. Any page number references are to the actual guidance document, not the notice of availability in the **Federal Register**. The actual guidelines document was available through the National Technical Information Service (PB85–227049), is in the record of this rulemaking, and is abstracted in Appendix A of Quality Criteria for Water, 1986.

EPA also incorporated by reference into the record of this rule the human health methodology as described in "Appendix C—Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Criteria Documents" (45 FR 79347, November 28, 1980).

Note: Throughout the remainder of this Preamble, this reference is described as the Human Health Guidelines or the 1980 Guidelines.

EPA also recommends that the following be reviewed: "Appendix D—Response to Comments on Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses," (45 FR 79357, November 28, 1980); "Appendix E—Responses to Public Comments on the Human Health Effects Methodology for Deriving Ambient Water Quality Criteria" (45 FR 79368, November 28, 1980); and "Appendix B—Response to Comments on Guidelines for Deriving Numerical National Water quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 FR 30793, July 29, 1985). EPA also placed into the record the most current individual criteria documents for the priority toxic pollutants included in today's rule.

The primary focus of this rule is the inclusions of the water quality criteria for pollutant(s) in State standards as necessary to support water quality-based control programs. The Agency accepted comment on the criteria proposed for inclusion in this rule. However, Congress established a very ambitious schedule for the promulgation of the final criteria. The statutory deadline in section 303(c)(4) clearly indicates that Congress intended the Agency to move very expeditiously when Federal action is warranted.

The methodology used to develop the criteria and the criteria themselves (to the extent not updated through IRIS) have previously undergone scientific peer review and public review and comment, and have been revised as appropriate. For the most part, this review occurred before Congress amended the Act in 1987, to require the inclusion of numeric criteria for certain toxic pollutants in State standards. Congress acted with full knowledge of the EPA process for developing criteria and the Agency's recommendations under section 304(a). EPA believes it is consistent with Congressional intent to rely in large part on existing criteria rather than engage in a time-consuming reevaluation of the underlying basis for water quality criteria. Accordingly, the Agency stands by its prior decisions regarding its published methodology and criteria even after review of the comments received. It is the Agency's belief that this approach will best achieve the purpose of moving forward in promulgating criteria for States not in compliance with section 303(c)(2)(B) so that environmental controls intended by Congress can be put into place to protect public health and welfare and enhance water quality.

It should be noted that the Agency is initiating a review of the basic guidelines for developing criteria and that comments received during this rulemaking will be considered in that effort. Future revisions to the criteria guidelines will be reviewed by the Agency's Science Advisory Board and submitted to the public for review and comment following the same process that was used in issuing the existing methodological guidelines. Subsequent revisions of criteria documents and the issuance of any new criteria documents will also be subject to the public review.

2. Aquatic Life Criteria

Aquatic life criteria may be expressed in numeric or narrative forms. EPA's 1985 Guidelines describe an objective, internally consistent and appropriate way of deriving chemical-specific, numeric water quality criteria for the protection of the presence of, as well as the uses of, both fresh and marine water aquatic organisms.

An aquatic life criterion derived using EPA's section 304(a) method "might be thought of as an estimate of the highest concentration of a substance in water which does not present a significant risk to the aquatic organisms in the water and their uses." (45 FR 79341.) The term "their uses" refers to consumption by humans and wildlife (1985 Guidelines, page 48). EPA's guidelines are designed to derive criteria that protect aquatic communities by protecting most of the species and their uses most of the time, but not necessarily all of the species all of the time (1985 Guidelines, page 1). Aquatic communities can tolerate some

stress and occasional adverse effects on a few species so that total protection of all species all of the time is not necessary. EPA's 1985 Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of substantial overprotection or underprotection. As discussed in detail below, there are several individual factors which may make the criteria somewhat overprotective or underprotective. The approach EPA is using is believed to be as well balanced as possible, given the state of the science.

Numerical aquatic life criteria derived using EPA's 1985 Guidelines are expressed as short-term and long-term numbers, rather than one number, in order that the criteria more accurately reflect toxicological and practical realities. The combination of a criteria maximum concentration (CMC), a one-hour average acute limit, and a criteria continuous concentration (CCC), a four-day average concentration chronic limit, provide protection of aquatic life and its uses from acute and chronic toxicity to animals and plants, and from bioconcentration by aquatic organisms, without being as restrictive as a one-number criterion would have to be. (1985 Guidelines, pages 4–5.)

The two-number criteria are intended to identify average pollutant concentrations which will produce water quality generally suited to maintenance of aquatic life and their uses while restricting the duration of excursions over the average so that total exposures will not cause unacceptable adverse effects. Merely specifying an average value over a time period is insufficient unless the time period is short, because excursions higher than the average can kill or cause substantial damage in short periods.

A minimum data set of eight specified families is required for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria using native species, provided that the broad spectrum represented by the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available.

EPA's application of guidelines to develop the criteria matrix in the final rule is judged by the Agency to be applicable to all waters of the United States, and to all ecosystems (1985 Guidelines, page 4). There are waters and ecosystems where site-specific criteria could be developed, as discussed below, but it is up to States to identify those waters and develop the appropriate site-specific criteria.

Fresh water and salt water (including both estuarine and marine waters) have different chemical compositions, and freshwater and saltwater species rarely inhabit the same water simultaneously. To provide additional accuracy, criteria developed recently are developed for fresh water and for salt water.

Assumptions which may make the criteria underprotective include the fact that not all species are protected, the use of criteria on an individual basis, with no consideration of additive or synergistic effects, and the general lack of consideration of impacts on wildlife, due principally to a lack of data. Chemical toxicity is often related to certain receiving water characteristics, (pH, hardness, etc.) of a waterbody. Adoption of some criteria without consideration of these parameters could result in the criteria being overprotective.

3. Criteria for Human Health

EPA's section 304(a) human health guidelines attempt to provide criteria which minimize or specify the potential risk of adverse human effects due to substances in ambient water (45 FR 79347). EPA's section 304(a) criteria for human health are based on two types of biological endpoints: (1) Carcinogenicity and (2) systemic toxicity (i.e., all other adverse effects other than cancer). Thus, there are two procedures for assessing these health effects: one for carcinogens and one for non-carcinogens.

EPA's human health guidelines assume that carcinogenicity is a "non-threshold phenomenon," that is, there are no "safe" or "no-effect levels" because even extremely small doses are assumed to cause a finite increase in the incidence of the response (i.e., cancer). Therefore, EPA's water quality criteria for carcinogens are presented as pollutant concentrations corresponding to increases in the risk of developing cancer.

For pollutants that do not manifest any apparent carcinogenic effects in animal studies (i.e., systemic toxicants), EPA assumes that the pollutant has a threshold below which no effects will be observed. This assumption is based on the premise that a physiological mechanism exists within living organisms to avoid or overcome the adverse effects of the pollutant below the threshold concentration.

The human health risks of a substance cannot be determined with any degree of confidence unless dose-response relationships are quantified. Therefore, a dose-response assessment is required before a criterion can be calculated. The dose-response assessment determines the quantitative relationships between the amount of exposure to a substance and the onset of toxic injury or disease. Data for determining dose-response relationships are typically derived from animal studies, or less frequently, from epidemiological studies in exposed populations.

The dose-response information needed for carcinogens is an estimate of the carcinogenic potency of the compound. Carcinogenic potency is defined here as a general term for a chemical's human cancer-causing potential. This term is often used loosely to refer to the more specific carcinogenic or cancer slope factor which is defined as an estimate of carcinogenic potency derived from animal studies or epidemiological data of human exposure. It is based on extrapolation from test exposures of high dose levels over relatively short periods of time to more realistic low dose levels over a lifetime exposure period by use of linear extrapolation models. The cancer slope factor, $q1^*$, is EPA's estimate of carcinogenic potency and is intended to be a conservative upper bound estimate (e.g. 95% upper bound confidence limit).

For non-carcinogens, EPA uses the reference dose (RfD) as the dose response parameter in calculating the criteria. The RfD was formerly referred to as an "Acceptable Daily Intake" or ADI. The RfD is useful as a reference point for gauging the potential effects of other doses. Doses that are less than the RfD are not likely to be associated with any health risks, and are therefore less likely to be of regulatory concern. As the frequency of exposures exceeding the RfD increases and as the size of the excess increases, the probability increases that adverse effects may be observed in a human population. Nonetheless, a clear conclusion cannot be categorically drawn that all doses below the RfD are "acceptable" and that all doses in excess of the RfD are "unacceptable." In extrapolating non-carcinogen animal test data to humans to derive an RfD, EPA divides a no-observed-effect dose observed in animal studies by an "uncertainty factor" which is based on profession judgment of toxicologists and typically ranges from 10 to 10,000.

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 FR 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only.

The assumed exposure pathways in calculating the criteria are the consumption of 2 liters per day at the criteria concentration and the consumption of 6.5 grams per day of fish/shellfish contaminated at a level equal to the criteria concentration but multiplied by a "bioconcentration factor." The use of fish consumption as an exposure factor requires the quantification of pollutant residues in the edible portions of the ingested species. Bioconcentration factors (BCFs) are used to related pollutant residues in aquatic organisms to the pollutant concentration in ambient waters. BCFs are quantified by various procedures depending on the lipid solubility of the pollutant. For lipid soluble pollutants, the average BCF is calculated from the weighted average percent lipids in the edible portions of fish/shellfish, which is about 3%; or it is calculated from theoretical considerations using the octanol/water partition coefficient. For non-lipid soluble compounds, the BCF is determined empirically. The assumed water consumption is taken from the National Academy of Sciences publication "Drinking Water and Health" (1977). (Referenced in Human Health Guidelines, 45 FR 79356). The 6.5 grams per day contaminated fish consumption value is equivalent to the average per-capita consumption rate of all (contaminated and non-contaminated) freshwater and estuarine fish for the U.S. population. (See Human Health Guidelines, 45 FR 79348.)

EPA also assumes in calculating water quality criteria that the exposed individual is an average adult with body weight of 70 kilograms. The issue of concern is dose per kilogram of body weight. EPA assumes 6.5 grams per day of contaminated fish consumption and 2 liters per day of contaminated drinking water consumption for a 70 kilogram person in calculating the criteria. Persons of smaller body weight are expected to ingest less contaminated fish and water, so the dose per kilogram of body weight is generally expected to be roughly comparable. There may be subpopulations within a State, such as subsistence fishermen, who as a result of greater exposure to a contaminant, are at greater risk than the hypothetical 70 kilogram person eating 6.5 grams per day of maximally contaminated fish and shellfish and drinking 2 liters per day of maximally contaminated drinking water.

For example, individuals that ingest ten times more of a pollutant than is assumed in derivation of the criteria at a 10^{-6} risk level will be protected to a 10^{-5} level, which EPA has historically considered to be adequately protective. There may, nevertheless, be circumstances where site-specific numeric criteria that are more stringent than the State-wide criteria are necessary to adequately protect highly exposed subpopulations. Although EPA intends to focus on promulgation of appropriate State-wide criteria that will reduce risks to all exposed individuals, including highly exposed subpopulations, site-specific criteria may be developed subsequently by EPA or the States where warranted to provide necessary additional protection. (See Human Health Guidelines, Issue 8, 45 FR 79369.)

For non-carcinogens, oral RfD assessments (hereinafter simply "RfDs") are developed based on pollutant concentrations that cause threshold effects. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. (See Human Health Guidelines, 45 FR 79348.)

Criteria are calculated for individual chemicals with no consideration of additive, synergistic or antagonistic effects in mixtures. If the conditions within a State differ from the assumptions EPA used within the constraints of the Federal rule, the States have the option to perform the analyses for their conditions.

EPA has a process to develop a scientific consensus on oral reference dose assessments and carcinogenicity assessments (hereinafter simply cancer slope factors or slope factors). Reference doses and slope factors are validated by two Agency work groups (i.e., one work group for each) which are composed of senior Agency scientists from all of the program offices and the Office of Research and Development. These work groups develop a consensus of Agency opinion for RfDs and slope factors which are then used throughout the Agency for consistent regulation and guidance development. EPA maintains an electronic data base which contains the official Agency consensus for oral RfD assessments and carcinogenicity assessments which is known as the Integrated Risk Information System (IRIS). It is available for use by the public on the National Institutes of Health's National Library of Medicine's TOXNET system, and through diskettes from the National Technical Information Service (NTIS). (NTIS access number is PB 90-591330).

For the criteria included in today's rule, EPA used the criteria recommendation from the appropriate Section 304(a) criteria document. (The availability of EPA's criteria documents has been announced in various Federal Register Notices. These documents are also placed in the record for today's rule.) However, if the Agency has changed any parameters in IRIS used in criteria derivation since issuance of the criteria guidance document, EPA recalculated the criteria recommendation with the latest information, invited comment on the updating procedure and the numbers that would be derived from it. (This information is included in the record.) Thus, there may be differences between the original criteria guidance document recommendation, and those in this rule, but this rule presents the Agency's most current section 304(a) criteria recommendation. The recalculated human health numbers are denoted by an "a" in the criteria matrix in subsection 131.36(b) of today's rule.

A difficult and controversial problem facing both the States and EPA in attempting to comply with the requirements of section 303(c)(2)(B) involved selecting a criterion for 2,3,7,8-TCDD (dioxin). EPA, the States, dischargers, environmental groups and the public at large have been involved in discussions concerning the ambient level of protection that is protective of public health. At issue during the State debates on selecting criterion for dioxin and in comments to this rulemaking are scientific questions specific to dioxin such as determining the carcinogenic potency of the pollutant and the extent to which the pollutant tends to accumulate in fish tissues. Other issues are raised that are more generic to EPA's human health criteria. Most of these issues relate, directly or indirectly, to concerns expressed by dischargers regarding the cost of complying with water quality-based effluent limits for dioxin.

In order to base its regulatory decisions on the best available science, EPA continuously updates its assessment of the risk from exposure to contaminants. On September 11, 1991, EPA's Office of Research and Development (ORD) began reassessing the scientific models and exposure scenarios used to predict the risks of biological effects from exposure to low levels of dioxin. This reassessment has the potential to alter the risk assessment for dioxin and accordingly the Agency's

regulatory decisions related to dioxin. At this time, EPA is unable to say with any certainty what the degree or directions of any changes in risk estimates might be. Moreover, the results of the assessment and any potential impact on the criteria limit will not be known for quite some time.

Considerable comment was received that the Agency not include dioxin in the rule pending the results of the dioxin reassessment. However, no additional data was submitted by the commenters that adds to the information available upon which to make a decision. Based on information currently available to the Agency and in the face of known uncertainties, the limit promulgated today is within the range of scientific defensibility.

A State may adopt a different limit subsequent to this rule, following the normal procedures for adopting or revising water quality standards (40 FR 131). The adoption by a State of a new or revised criterion for dioxin, whether more or less stringent than the existing section 304(a) guidance, will be accepted by the Agency based on the results of the Agency's reassessment without any further justification. Once a State adopts a new dioxin criterion, the permitting authority, either EPA or the State (if authorized to administer a permit program), may change the effluent limitation for dioxin in a permit subject to the antibacksliding requirements of sections 402(o) and 303(d)(4) of the CWA and the antidegradation policy of the State.

This final rule includes criteria for dioxin. This action encourages and supports the ongoing efforts of fourteen States actively considering adopting criteria for dioxin. Most of these States are relying on the same data used by EPA in deriving its criterion for dioxin. In addition, dioxin limits are included as appropriate in Individual Control Strategies (ICS's) developed under section 304(l), so there should be no immediate regulatory action that will be based upon the promulgation of Federal criteria.

Moreover, as discussed in more detail in Section J, Executive Order 12291, example 5, it is unlikely that the practical impact of including dioxin at the 0.013 ppq level in this rule will affect the need for treatment and thus, is unlikely to be the basis for any incremental costs for pulp and paper mills to reduce dioxin discharges.

4. Section 304(a) Human Health Criteria Excluded

Today's rule does not contain certain of the section 304(a) criteria for priority toxic pollutants because those criteria were not based on toxicity. The basis for these particular criteria are organoleptic effects (e.g., taste and odor) which would make water and edible aquatic life unpalatable but not toxic. Because the basis for this rule is to protect the public health and aquatic life from toxicity consistent with the language and intent in section 303(c)(2)(B), EPA is promulgating criteria only for those priority toxic pollutants whose criteria recommendations are based on toxicity. The Section 304(a) human health criteria based on organoleptic effects for copper, zinc, 2,4-dimethylphenol, and 3-methyl-4-chlorophenol are excluded for this reason.

5. Cancer Risk Level

EPA's section 304(a) criteria guidance documents for priority toxic pollutants that are based on carcinogenicity present concentrations for upper bound risk levels of 1 excess cancer per 100,000 people (10^{-5}), per 1,000,000 people (10^{-6}), and per 10,000,000 people (10^{-7}). However, the criteria documents do not recommend a particular risk level as EPA policy.

In the April, 1990, Federal Register notice of preliminary assessment of State compliance, EPA announced its intention to propose this rule with an incremental cancer risk level of one in a million (10^{-6}) for all priority toxic pollutants regulated as carcinogens (55 FR 14351). This risk level was in fact proposed in the November 19, 1991 Federal Register Notice of proposed rulemaking. However, EPA's Office of Water's guidance to the States has consistently reflected the Agency's policy of accepting cancer risk policies from the States in the range of 10^{-6} to 10^{-4} (see 45 FR 79323, November 28, 1980; Guidance for State Implementation of Water Quality Standards for CWA section 303(c)(2)(B), November 12, 1988 (54 FR 346); see also document described in footnote 3 of this preamble). EPA reviews individual State policies as part of its water quality standards oversight function and determines if States have appropriately consulted their citizenry and applied good science in adopting water quality criteria.

In the proposal, EPA not only sought public comment on its decision to propose criteria based on a 10^{-6} risk level, but also specifically solicited comment on an alternate risk level of 10^{-5}. EPA received extensive comments that the proposed application of the criteria at the 10^{-6} risk level was contrary to Agency policy, contradicted other risk levels accepted by EPA in States included in the proposal, oversteps EPA authority by failing to recognize that such a decision more properly should be a State decision, given their primary authority to establish water quality standards, and that EPA should not include a risk level in the final rule.

Upon consideration of these comments, EPA agrees that establishing a single risk level for all States departs from Agency policy in the standards program. The application of the human health criteria in today's rule, on a State-by-State basis, therefore, has been changed. In today's rule, the risk level for each State is based on the best information available to the Agency as to each State's policy or practice regarding what risk level is, or should be, used in regulating carcinogens in surface waters. In most cases the risk levels were based on a State-adopted or formally proposed risk level, or in the case of Idaho, Rhode Island, and Nevada on an expression of State policy preference. EPA is therefore promulgating criteria at either the 10^{-5} or 10^{-6} risk level, either of which is consistent with EPA policy and with the requirements of the Clean Water Act.

The Agency recognizes that it made some of its decisions regarding the appropriate risk level on limited data. However, in the time available to the Agency, we relied on the best available information. The Agency believes it is important to move forward with this rule based on available information. To ensure that the Agency has selected the appropriate risk level for each State, the Agency is providing a final opportunity for the Governor of each State (or other official with authority to determine risk levels with respect to water quality criteria) to inform EPA if they believe a different risk level should be selected for their State.

Today's regulation will become effective 45 days from publication in the Federal Register. However, if within 30 days of publication of this rule in the Federal Register, the Governor or other appropriate official determines that the final rule is not based on the correct State policy or practice with regard to risk levels, the Governor (or other appropriate official) may request the Administrator in writing to adopt a different risk level for the State.

Note: The Governor is not constrained to requesting the Administrator to adopt a single risk level for all carcinogenic compounds. It is also acceptable for a State to select more than one risk level. For example, New Jersey is proposing to adopt 10^{-6} for Class A and B carcinogens, and 10^{-5} for Class C carcinogens. In this rule, EPA is promulgating the two risk level concept for New Jersey. The Governor must explain the basis for the request to change the risk level.

If EPA determines, after receipt of such a letter from the Governor or other appropriate State official, the State's preference is consistent with EPA policy, as set out in this rulemaking, and the requirements of the Clean Water Act, EPA will amend the rule accordingly.

As noted above, in this rulemaking EPA is adopting risk levels that it believes best reflects the expressed preferences of the covered States (10^{-6} or 10^{-5} for all carcinogens). If there were, however, no clear expression of preference by a State, EPA also believes it is reasonable for States to adopt a risk level of 10^{-5} for many of the covered carcinogens and a more stringent risk level of 10^{-6} for those carcinogens with substantially higher bioconcentration factors. Recognizing the current limitations of the scientific data available for this rulemaking, EPA believes it would be reasonable to conclude that carcinogens that bioaccumulate, particularly given the exposure of fishermen to such carcinogens, may justify a more protective risk level of 10^{-6} for the average fish consumer, but for other carcinogens a less conservative level (10^{-5}) may be appropriate.

6. Applying EPA's Nationally Derived Criteria to State Waters

To assist States in modifying EPA's water quality criteria, the Agency has provided guidance on developing site specific-criteria for aquatic life and human health (see Chapter 4, Water Quality Standards Handbook, Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses, and the Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents). This guidance can be used by the appropriate regulatory authority to develop alternative criteria. Where such criteria are more stringent than the criteria promulgated today, Section 510 of the Clean Water Act (33 U.S.C. 1370) allows their implementation and enforcement in lieu of today's promulgated criteria.

EPA's experience with such site-specific criteria has verified that the national criteria are generally protective and appropriate for direct use by the States. (See Response to Comments on the 1985 Aquatic Life Guidelines, Comment 57, 50 FR 30796, July 29, 1985.)

7. Application of Metals Criteria

A substantial number of comments were received requesting Agency guidance on the implementation of metals criteria for aquatic life. In response, the Agency has prepared guidance on this issue, which is described in general terms below, and which is being applied to the metals criteria being promulgated today. Responses to individual comments may be found in section I, comments 19 to 53.

In selecting an approach for implementing the metals criteria, the principal issue is the correlation between metals that are measured and metals that are biologically available and toxic, as discussed more fully in EPA's Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, U.S. EPA, 1992, Office of Science and Technology, May 1992. (Notice of availability published at 57 FR 24041, June 5, 1992.

In order to assure that the metals criteria are appropriate for the chemical conditions under which they are applied, EPA is promulgating the criteria in terms of total recoverable metal and providing for adjustment of the criteria through application of the "water-effect ratio" procedure as described and recommended in the above Guidance document. This procedure was developed in the early 1980's, and was originally set forth, along with several case study applications, as the Indicator Species procedure in Chapter 4 of the Water Quality Standards Handbook (U.S. EPA 1983 at page 4–12). EPA notes that performing the testing to use site-specific water-effect ratios is optional on the part of the States.

In natural waters metals may exist in a variety of dissolved and particulate forms. The bioavailability and toxicity of metals depend strongly on the exact physical and chemical form of the metal. Generally, dissolved metal has greater toxicity than particulate metal, and for some metals, such as copper, certain dissolved forms have greater toxicity than other dissolved forms. Because the speciation among the various forms of a particular metal may vary from place to place, the same metal concentration may cause different toxicity from place to place.

With one exception (selenium), EPA's metals criteria for aquatic life protection are developed from laboratory toxicity data. Use of laboratory toxicity testing is usually much more cost-effective for obtaining data on (1) the toxicity of substances to a variety of species, and (2) the effect of various water quality characteristics on toxicity. (See 1980 Aquatic Life guidelines, comment 21, 45 FR 79360. See also responses to comments 17, 18, 19, 20.) The dilution water used in laboratory toxicity tests is ordinarily low in particulate matter (i.e. suspended solids), and low in organic matter compared to many ambient waters. As a result, laboratory toxicity tests are ordinarily more likely to overestimate the toxicity than underestimate the toxicity of metals in some ambient waters, particularly fresh waters.

Because of the complexity of metals speciation and its effect on toxicity, the relationship between measured concentrations and toxicity is not precise. Consequently, any method that could be recommended would not guarantee precise comparability between concentrations measured in the field and concentrations employed in the toxicity tests underlying the criteria.

For metals criteria derived from laboratory toxicity tests, the best approach is to use a biological method to compare bioavailability and toxicity in receiving waters versus laboratory test waters (the water-effect ratio) and to adjust the criteria values accordingly. This involves running toxicity tests for at least two species, each preferably from a different family, measuring acute (and possibly chronic) toxicity values for the pollutant using (a) the local receiving water, and (b) standard laboratory toxicity testing water, which is also the source of toxicity test dilution water. A water-effect ratio is the acute (or chronic) value in site water divided by the acute (or chronic) value in standard laboratory water. An acute value is an LC50 from a 48–96 hour test, as appropriate for the species. A chronic value is a concentration resulting from hypothesis testing or regression analysis of measurements of survival, growth, or reproduction in life cycle, partial life cycle, or early life stage tests on aquatic species.

Chemical approaches for defining and comparing bioavailable metal are subject to greater uncertainty than the above biological approach.

Chemical approaches, such as dissolved and total recoverable metals are easier to apply than biological approaches. One approach that EPA has approved in State standards is to measure metals in ambient waters in terms of dissolved metal, and to compare such measurements to criteria appropriate for dissolved metal. Since effluent limits, for both technical and legal (see NPDES permits regulation, 40 CFR 122.45) reasons, should be expressed in terms of total recoverable metal, it is necessary to translate between the dissolved and total recoverable concentrations. EPA has not incorporated the alternative of dissolved

metals criteria into this rule, because the use of the water-effect ratio accomplishes the same ends but is technically superior and subject to fewer uncertainties than implementation of the criteria as dissolved concentrations.

The simplest approach for ambient metals standards is the use of the total recoverable analytical method without a water-effect ratio adjustment. This is a reasonable, albeit environmentally conservative strategy, for applying EPA's aquatic life criteria. Where the toxicity testing necessary to develop an alternative water-effect ratio has not been performed, this rule will apply the total recoverable analytical method without a water-effect ratio adjustment. This occurs because EPA assigns the water-effect ratio a value of 1.0, subject to being rebutted by toxicity testing results.

Because of the comments received, and because of the desire to achieve the greatest possible degree of accuracy, EPA has chosen to apply the total recoverable metals criteria unadjusted for site-specific water chemistry, unless the State adjusts the criteria through the use of a water-effect ratio as provided for in this rule. Allowance for water-effect ratio adjustment also satisfies the concerns of comments requesting consideration of dissolved criteria.

The water-effect ratio approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory test waters. It involves running toxicity tests for at least two species an appropriate number of times, as determined by the States, ordinarily on samples collected in at least two seasons (or more where large metal loadings are involved). As with other site-specific procedures, the basic analysis or testing may be performed by the State, a permittee, or any other interested party. Acute or chronic toxicity for the pollutant are measured using (a) the local receiving water where the criterion is being implemented, and (b) standard laboratory toxicity testing water, as the sources of toxicity test dilution water. The water-effect ratio is calculated as the acute or chronic value in site water divided by respective acute or chronic values in standard laboratory water. Ordinarily, the geometric mean water-effect ratio from the valid tests is used for calculation of the criterion, except where protection of sensitive species requires a more stringent value. Because the metal's toxicity in standard laboratory water is the basis for EPA's criterion, this comparison is used to adjust the national criterion to a site-specific value. Because the procedure is a biological measure of differences in water chemistry, the water-effect ratio, even when derived from acute tests, usually may be assumed to also apply to chronic criteria.

For criteria that do not vary with hardness, the criterion for a specific site equals the acute or chronic value tabulated in the rule (i.e., the matrix in 40 CFR 131.36(b)) multiplied by the site-specific water-effect ratio for that pollutant. The result may either reduce or increase the stringency of the criteria.

For criteria whose toxicity varies with hardness, the criterion for a specific site equals the criterion calculated at the design hardness (see 40 CFR 131.36(c)(4)), multiplied by the site-specific water-effect ratio.

The water-effect ratio is assigned a value of 1.0, unless scientifically defensible data clearly demonstrate that a value less than 1.0 is necessary or a value greater than 1.0 is sufficient to fully protect the designated uses of the water body from the toxic effects of the pollutant. Any data accepted for calculation of the water-effect ratio is to be generated through standard toxicity testing protocols (EPA recommends the methodology in Annual Book of ASTM Stds. 1991, Vol.11.04. ASTM. Philadelphia, PA.), using sampled ambient water representative of conditions in the affected water body, and using laboratory dilution water comparable to that used in toxicity tests underlying the criteria. The guidance documents cited at the beginning of this section provides more guidance on generating the information necessary to determine the correct value of the water-effect ratio. However, EPA intends within the next few months to provide additional guidance or performing the analyses necessary to develop scientifically defensible water-effect ratios for metals. As envisioned at this time, EPA will expand Chapter 4 in the Handbook to apply the appropriate procedures described there specifically to metals. EPA will look at the chemical characteristics of the laboratory water used in the toxicity tests included in the metals criteria data base, appropriate test organisms, analytical methods, safeguards against unintended metals contamination during toxicity testing, and appropriate data handling and statistics. While EPA believes the current guidance is adequate for application of the water-effect ratio, the additional guidance should help standardize procedures and make results more comparable and defensible.

The rule as promulgated is constructed as a rebuttable presumption. The water-effect ratio is assigned a value of 1.0 but provides that a State may assign a different value derived from suitable tests. As EPA has noted elsewhere, the actual decision as to the numeric value assigned to a water-effect ratio may be made during a State or EPA NPDES permit proceeding provided that adequate notice and opportunity for public participation is provided. It is the responsibility of the permit writing authority to determine whether to apply the water-effect ratio in an NPDES permit. However, EPA believes use of the ratio will lead to more appropriate permit limits. States may wish to allow permittees to fund State-administered studies necessary to develop the ratio for particular waterbodies.

EPA reviews State issued NPDES permits. To facilitate EPA consideration of a State-developed water-effect ratio, a State should specify in documentation supporting that action what decisions were made for critical parameters such as toxicity testing protocols used, frequency of testing, critical periods for sampling and testing, and analytical quality control and assurance. Each of the factors must be articulated in a record as a basis for a determination that the water-effect ratio is scientifically defensible.

The procedure applies only to aquatic life criteria derived from laboratory toxicity data. That is, it applies to the acute and chronic criteria (Columns B and C in 40 CFR 131.36(b)) for arsenic, cadmium, chromium, copper, lead, nickel, and zinc. It also applies to the acute criteria for mercury and silver, and the saltwater acute and chronic criteria for selenium. It does not apply to the chronic criteria for mercury, because they are residue based, or to the freshwater acute and chronic criteria for selenium, because they are field based.

The water-effect ratio is affected not only by speciation among the various dissolved and particulate forms, but also by additive, synergistic, and antagonistic effects of other materials in the affected site waters. As such, the water-effect ratio is a rather comprehensive measure of the effect of water chemistry on the toxicity of a pollutant. Because the procedure accounts for any reduction in bioavailability resulting from binding of the metal to particulate matter, all metals criteria have been appropriately expressed as total recoverable metal in this rule.

Where measured water-effect ratios are used in deriving NPDES permit limits, data from appropriate testing during the term of the permit should be accumulated so that the value of the water-effect ratio can be reevaluated each time the permit is reissued. Thus, were measured water-effect ratios are

involved, EPA recommends that NPDES permits establish monitoring requirements that include periodic determinations of water-effect ratios.

G. Description of the Final Rule and Changes From Proposal

1. Changes From Proposal

Several changes were made in the final rule from the proposal both as a result of Agency and State action with respect to the ongoing adoption of water quality standards by the States and because of the Agency's consideration of issues raised in specific public comments.

The States of Arizona, Colorado, Connecticut, Louisiana, New Hampshire, Virginia, the Commonwealth of the Northern Mariana Islands, and Hawaii are not included in the final rule as their standards were duly adopted and approved by EPA as fully meeting the requirements of section 303(c)(2)(B). Arizona's water quality standards were approved on March 2, 1992; Colorado's standards were approved by EPA on December 10, 1991; Connecticut on May 15, 1992; Louisiana on January 24, 1992; New Hampshire on June 25, 1992; Virginia on June 30, 1992; CNMI on January 13, 1992; and Hawaii on November 4, 1992. Copies of the approval letters are included in the record to this final rulemaking.

In addition, human health criteria adopted by the State of Arkansas were approved by EPA on January 24, 1992, and such criteria were removed from today's rule as it affects Arkansas. EPA is not promulgating and aquatic life criterion in Arkansas for arsenic because a review of monitoring data from 1985 to the present reveals no reason to conclude that arsenic will interfere with designated aquatic life uses. Additional details on EPA's action with respect to Arkansas may be found in Section I—Response to Public Comments, subsection 6.

Except for dioxin, criteria for the State of Florida for both human health and protection of aquatic life were approved by EPA on February 25, 1992. Florida is included in the rule only for the purposes of establishing a criterion for dioxin. More details on Florida's action are included in the Florida section of subsection 6 of the Response to Comments section of this preamble.

The criteria applicable to California have been revised to reflect a partial approval of the State's water quality standards on November 6, 1991. Additional comments with respect to California may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to the State of Washington was revised after discussion with the State as to EPA's interpretation of the uses designated by the State. The rule is now based on use categories rather than use classes. Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Alaska was modified to delete the assignment of criteria to a seafood processing use. This use falls under the standards program. However, because it applies to food preparation only, it is not appropriate to apply to it aquatic life or human health criteria. Additional aquatic life and human health criteria were added to several use classifications after discussions with the State clarified the State's use classifications. Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Idaho was modified to add additional criteria for the protection of primary contact recreation after discussions with the State concerning that use. Additional details may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Kansas was changed by removing the promulgation of silver for sections (2) (A), (B), (C), and (6)(C) as the State has an EPA approved aquatic life criterion more stringent than the EPA criterion. The human health criterion for silver was removed because EPA has withdrawn its silver human health criterion.

The rule as it applies to New Jersey was revised to reflect comments received from the New Jersey Department of Environmental Protection and Energy to add waters classified as Pinelands and to extend coverage of the criteria to the mainstem Delaware River and Delaware Bay (zones 1C–6). Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

Clarifications on several aspects of the rule with respect to implementation procedures are addressed in the response to public comments section of this preamble (section I).

Language was added in § 131.36(c)(4) dealing with the application of metals criteria as discussed in section F–7 of this preamble. We also added requirements to clarify how hardness should be handled in doing water-effect ratio determinations (see 131.36(c)(4)(iii), footnotes "e" and "m" to 131.36(b)).

The criteria for carcinogenic compounds included in this rule are applied at a risk level based on State preference as reflected by adopted or proposed standards, or in the case of Idaho, Nevada, and Rhode Island, on expression of State policy preference, rather than at an across-the-board 10^{-6} risk level as was proposed by the Agency. The rationale for this change is discussed in detail in section F–5 and there is additional discussion in the Response to Public Comment Section. The basis for EPA's selection of a risk level for an individual State is described in the following paragraphs:

Alaska: Risk Level: 10^{-5}

In July 1992, the State proposed human health water quality based on achieving a 10^{-5} risk level for two carcinogens: Dioxin and chloroform. Also, on November 16, 1992, the Commissioner of the Alaska Department of Environmental Conservation wrote the Director, Water Division, in EPA Region X, and indicated that ". . . I also had this matter reviewed by our Attorney General's Office, and hereby confirm the appropriateness of utilizing a 10^{-5} risk level for Alaska in the National Toxics Rule."

California: Risk Level: 10^{-6}

Standards adopted by the State contained in the Enclosed Bays and Estuaries Plan, and the Inland Surface Waters Plan, approved by EPA on November 6, 1991, and the Ocean Plan approved by EPA on June 28, 1990, contain a risk level of 10^{-6} for carcinogens. The total number of toxic pollutants differs in each plan but approximately 60–65 pollutants are covered.

District of Columbia: Risk Level: 10^{-6}

In 1985 the District adopted water quality criteria for human health, based solely on exposure through water consumption. The criteria were based on a 10^{-6} risk level. See D.C.M.R. title 21, chapter 1102.8(I).

Florida: Risk Level: 10^{-6}

The State adopted human health criteria for all toxic pollutants, except dioxin, and received EPA approval on February 25, 1992, at a risk level of 10^{-6}.

Idaho: Risk Level: 10^{-6}

On November 12, 1992, the Administrator of the Division of Environmental Quality, Idaho Department of Health and Welfare, indicated in a letter to the EPA Assistant Administrator for Water that while Idaho would be publishing proposed standards for public review and

comment in the next several months. . . . "Until we know what standard the public in Idaho prefers, we believe it is prudent to adopt the more protected standards of ten to the minus six."

EPA Region X is the permit issuing authority for the State and applies 10^{-6} for water quality based human health requirements. These permits have been certified by the State under section 401 as meeting water quality standards.

Kansas: Risk Level: 10^{-6}

The State completed a series of public hearings in August 1992 on proposed water quality standards revisions and is now processing public comments leading to the final, formal adoption hearing scheduled for January 1993. Formal adoption is scheduled for February 1993. The risk level in the current proposed standards is 10^{-6}. See proposed K.A.R. 28–16–28e(c)(4)(B).

Michigan: Risk Level: 10^{-5}

For several years Michigan has been controlling toxics through application of the Guidelines for Rule 57. These guidelines are applied at a 10^{-5} risk level. See R 323, 1057(2)(d).

Nevada: Risk Level: 10^{-5}

On November 3, 1992, EPA received a letter from the Administrator of the Division of Environmental Protection, Department of Conservation and Natural Resources, ". . . that the public health risk level that DEP would prefer to see in federal regulations is 10^{-5} (one in one hundred thousand), unless a state can provide substantial support in the record that a risk level of 10^{-4} (one in ten thousand) is appropriate and protective. This gives states the flexibility to use a more conservative 10^{-6} risk level if they see fit, but without requiring it when it is not necessary."

New Jersey: Risk Level: 10^{-6} For Class A and B Carcinogens, 10^{-5} For Class C Carcinogens

New Jersey, on October 20, 1992, solicited public comment on proposed surface water quality standards. The comment period is to close on December 18, 1992. The proposed human health criteria for carcinogens are established on a two-tiered system for risk levels. See proposed N.J.A.C. 7:9B–1.5(a)4. The State previously had indicated their intention to do this in a letter to EPA on December 19, 1991.

Puerto Rico: Risk Level: 10^{-5}

In 1990, the State proposed and held public hearings on criteria for human health using a 10^{-5} risk level. Subsequently, the proposed standards were revised. Just recently the State completed public hearings on the most recent revision to standards. The standards are under review by the Environmental Quality Board. The risk level remains at 10^{-5}.

Rhode Island: Risk Level: 10^{-5}

On November 2, 1992, the EPA Regional Administrator received a letter from the Director, Department of Environmental Management, that, along with the Department of Health, the State's "* * * policy choice on the promulgation of the human health criteria is for the adoption of a cancer risk level of 10^{-5}." The Director also indicated that "* * * future modifications of this risk level, whether it be to 10^{-4} or 10^{-6}, could be considered on a pollutant and subpopulation basis to produce a site specific risk assessment and protection of human health."

Vermont: Risk Level: 10^{-6}

On May 27, 1991, State submitted to EPA final water quality standards which reference the EPA section 304(a) criteria to be applied at a 10^{-6} risk level. However, the effective date of these standards is not until January 1, 1995. This delayed effective date was the reason Region I advised the State that the State did not comply with section 303(c)(2)(B).

Washington: Risk Level: 10^{-6}

During the summer of 1992, the State formally proposed and held public hearings on revisions to its water quality standards. The standards, scheduled for adoption in late November 1992, include a risk level of 10^{-6}.

On December 18, 1991, in its official comments on the proposed rule, the Department of Ecology urged EPA to promulgate human health criteria at 10^{-6}. Specifically, "The State of Washington supports adoption of a risk level of one in one million for carcinogens. If EPA decides to promulgate a risk level below one in one million, the rule should specifically address the issue of multiple contaminants so as to better control overall site risks."

The final phrase in § 131.36(c)(2) relating to the applicability of the rule was amended by deleting the text beginning "but only * * *" EPA received numerous comments that the Federal criteria should be implemented consistently with current State practices. EPA amended the language because the Agency had not intended to be inconsistent with the provisions of the water quality standards regulation (40 CFR 131.21(c)), which provides that a State water quality standard remains in effect even though disapproved by EPA, until the State revises it or EPA promulgates a rule that supersedes the State water quality standards.

Although not directly resulting in a change to the rule, this preamble clarifies, at the public's request, whether schedules of compliance were applicable to this rule. In Section E–3 EPA clarifies that schedules of compliance for these criteria are not provided for in these rules, but that such schedules of compliance are available in NPDES permits if authorized by State regulations. See *In the Matter of Star-Kist Caribe, Inc.*, NPDES Appeal No. 88–5, Before the Environmental Appeals Board, EPA. May 26, 1992.

Several deletions were made to the proposed human health criteria as a result of the Agency's review of data submitted in public comments and to reflect the pertinent impact of other relevant Agency actions. The revisions are as follows:

(1) Criteria for three pollutants included in the matrix of the proposed rule are not included in the final rule for (A) acenaphthylene, (B) benzo(ghi)perylene, and (C) phenanthrene. The criteria for these pollutants were removed because they are not recognized by the Agency as carcinogenic compounds nor do they have a reference dose that would allow the Agency to calculate a criterion level.

(2) Silver: The human health criteria for silver were deleted from this final rule because the criteria were developed based on a cosmetic effect impact and not a toxicity endpoint.

(3) Cadmium, Chromium, Selenium and Beryllium: As described below, the Agency has determined that the proposed criteria for these contaminants are no longer scientifically defensible and accordingly has withdrawn these criteria pending evaluation of relevant data regarding their toxicity. EPA notes that the criteria promulgated for aquatic life will provide adequate protection for human health in most instances.

(4) Methyl Chloride, Lead and 1,1,1, Trichloroethane: As described below, the Agency has determined that there is currently an insufficient basis for calculating human health criteria for these three contaminants. Accordingly, EPA has withdrawn the proposed criteria for these contaminants pending further analysis.

In addition to the above changes, the Agency is today withdrawing the human health criteria recommendations previously published in the 1980 Ambient Water Quality Criteria Documents for silver, cadmium, chromium, selenium, beryllium, lead,

methyl chloride, and 1,1,1, Trichloroethane. Summaries of the human health criteria were also published in Quality Criteria for Water, 1986. These summaries are also being officially withdrawn today.

EPA's final rule establishes a new § 131.36 in 40 CFR part 131 entitled, "Toxics Criteria for Those States Not Fully Complying with Clean Water Act, section 303(c)(2)(B)."

2. Scope

Subsection (a), entitled "Scope", clarifies that this Section is not a general promulgation of the section 304(a) criteria for priority toxic pollutants but is restricted to specific pollutants in specific States.

3. EPA Criteria for Priority Toxic Pollutants

As proposed, subsection (b) presents a matrix of the applicable EPA criteria for priority toxic pollutants. Section 303(c)(2)(B) of the Act addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act. As discussed earlier in this preamble, the section 307(a) list of toxics contains 65 compounds and families of compounds, which potentially include thousands of specific compounds. The Agency uses the list of 126 "priority toxic pollutants" for administrative purposes (see 40 CFR 131.36(b) herein). Reference in this rule to priority toxic pollutants, toxic pollutants, or toxics refers to the 126 priority toxic pollutants.

However, EPA has not developed both aquatic life and human health section 304(a) criteria for all of the 126 priority toxic pollutants. The matrix in paragraph (b) contains human health criteria in Column D for 91 priority toxic pollutants which are divided into criteria (Column 1) for water consumption (i.e., 2 liters per day) and aquatic life consumption (i.e., 6.5 grams per day of aquatic organisms), and Column 2 for aquatic life consumption only. The term aquatic life includes fish and shellfish such as shrimp, clams, oysters and mussels. The total number of priority toxic pollutants with criteria promulgated today differs from the total number of priority toxic pollutants with section 304(a) criteria because EPA has developed and is promulgating chromium criteria for two valence states with respect to aquatic life criteria. Thus, although chromium is a single priority toxic pollutant, there are two criteria for chromium for aquatic life. However, the human criterion is based on total chromium consistent with Agency policy. See pollutant 5 in § 131.36(b).

The matrix contains aquatic life criteria for 30 priority pollutants. These are divided into freshwater criteria (column B) and saltwater criteria (Column C). These columns are further divided into acute and chronic criteria. The aquatic life criteria are considered by EPA to be protective when applied under the conditions described in the section 304(a) criteria documents and in the "Technical Support Document for Water Quality-based Toxics Control." For example, waterbody uses should be protected if the criteria are not exceeded, on average, once every three year period. It should be noted that the criteria maximum concentrations (the acute criteria) are one-hour average concentrations and that the criteria continuous concentrations (the chronic criteria) are four-day averages. It should also be noted that for certain of the metals, the actual criteria are equations which are included as footnotes to the matrix. The toxicity of these metals are water hardness dependent and may be adjusted by determining appropriate water-effect ratios. The values shown in the table are based on a hardness expressed as calcium carbonate of 100 mg/l and a water-effect ratio of 1.0. Finally, the criterion for pentachlorophenol is pH dependent. The equation is the actual criterion and is included as a footnote. The value shown in the matrix is for a pH of 7.8 units.

Several of the freshwater aquatic life criteria are incorporated into the matrix in the format used in the 1980 criteria methodology which uses a final acute value instead of a continuous maximum concentration. This distinction is noted in footnote (g) to the table.

4. Applicability

Section 131.36(c) establishes the applicability of the criteria for each included State. It provides that the criteria promulgated for each State supersede and/or complement any State criteria for that toxic pollutant. EPA believes it has not superseded any State criteria for priority toxic pollutants unless the State-adopted criteria are disapproved or otherwise insufficient. The approach followed by the Agency in preparing § 131.36(d) is described in section E.2, and further rationale is provided in section E.3 of this preamble.

EPA's principal purpose today is to promulgate the toxics criteria necessary to comply with section 303(c)(2)(B). However, in order for such criteria to achieve their intended purpose the implementation scheme must be such that the final results protect the public health and welfare. In section F of this preamble a discussion focused on the factors in EPA's assessment of criteria for carcinogens. For example, fish consumption rates, bioaccumulation factors, and cancer potency slopes were discussed. When any one of these factors is changed, the others must also be evaluated so that, on balance, resulting criteria are adequately protective.

Once an appropriate criterion is selected for either aquatic life or human health protection, then appropriate conditions for calculating water quality-based effluent limits for that chemical must be established in order to maintain the intended stringency and achieve the necessary toxics control. EPA has included in this rule appropriate implementation factors necessary to maintain the level of protection intended. These factors are included in subsection (c).

For example, in order to do steady state waste load allocation analyses, most States have low flow values for streams and rivers which establish flow rates below which numeric criteria may be exceeded. These low flow values became design flows for sizing treatment plants and developing water quality-based effluent limits. Historically, these so-called "design" flows were selected for the purposes of waste load allocation analyses which focused on instream dissolved oxygen concentrations and protection of aquatic life. With the publication of the 1985 Technical Support Document for Water Quality Based Toxics Control (TSD), EPA introduced hydrologically and biologically based analyses for the protection of aquatic life and human health.[1] EPA recommended either of two methods for calculating acceptable low flows, the traditional hydrologic method developed by the U.S. Geological Survey and a biological based method developed by EPA. The results of either of these two methods may be used.

Some States have adopted specific low flow requirements for streams and rivers to protect designated uses against the effects of toxics. Generally these have followed the guidance in the TSD. However, EPA believes it is essential to include design flows for steady state analyses in today's rule so that, where

[1] These concepts have been expanded subsequently in guidance entitled "Technical Guidance Manual for Performing Wasteload Allocations, Book 6, Design Conditions," USEPA, Office of Water Regulations and Standards, Washington, DC. (1986). These new developments are included in Appendix D of the revised TSD. The discussion here is greatly simplified and is provided to support EPA's decision to promulgate baseline application values for instream flows and thereby maintain the intended stringency of the criteria for priority toxic pollutants.

States have not yet adopted such design flows, the criteria promulgated today would be implemented appropriately. The TSD also recommends the use of three dynamic models to perform wasteload allocations. Dynamic wasteload models do not generally use specific steady state design flows but accomplish the same effect by factoring in the probability of occurrence of stream flows based on the historical flow record. For simplicity, only steady state conditions will be discussed here. Clearly, if the criteria were implemented using inadequate design flows, the resulting toxics controls would not be fully effective, because the resulting ambient concentrations would exceed EPA's criteria.

In the case of aquatic life, more frequent violations than the once in 3 years assumed exceedences would result in diminished vitality of stream ecosystems characteristics by the loss of desired species such as sport fish. Numeric water quality criteria should apply at all flows that are equal to or greater than flows specified below. The low flow values are:

Aquatic Life
acute criteria (CMC) 1 Q 10 or 1 B 3
chronic criteria (CCC) 7 Q 10 or 4 B 3

Human Health
non-carcinogens 30 Q 5
carcinogens harmonic mean flow

Where:
1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically;
1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model);
7 Q 10 is the lowest average 7 consecutive day low-flow with an average recurrence frequency of once in 10 years determined hydrologically;
4 B 3 is biologically based and indicates an allowable exceedence for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);
30 Q 5 is the lowest average 30 consecutive day low flow with an average recurrence frequency of once in 5 years determined hydrologically; and
the harmonic mean flow is a long term mean flow value calculated by dividing the number of daily flows analyzed by the sum of the reciprocals of those daily flows.

EPA is promulgating the harmonic mean flow to be applied with human health criteria for carcinogens. The concept of a harmonic mean is a standard statistical data analysis technique. EPA's model for human health effects assumes that such effects occur because of a long-term exposure to low concentration of a toxic pollutant. For example, two liters of water per day for seventy years. To estimate the concentrations of the toxic pollutant in those two liters per day by withdrawal from streams with a high daily variation in flow, EPA believes the harmonic mean flow is the correct statistic to use in computing such design flows rather than other averaging techniques.[2]

All waters, whether or not suitable for such hydrologic calculations but included in this rule (including lakes, estuaries, and marine waters), must attain the criteria promulgated today. Such attainment must occur at the end of the discharge pipe, unless the State has a mixing zone regulation. If the State has a mixing zone regulation, then the criteria would apply at the locations stated in that regulation. For example, the chronic criteria (CCC) must apply at the geographically defined boundary of the mixing zone. Discussion of and guidance on these factors are included in the revised TSD in chapter 4.

EPA is aware that the criteria promulgated today for some of the priority toxic pollutants are at concentrations less than EPA's current analytical detection limits. Analytical detection limits have never been an acceptable basis for setting standards since they are not related to actual environmental impacts. The environmental impact of a pollutant is based on a scientific determination, not a measuring technique which is subject to change. Setting the criteria at levels that reflect adequate protection tends to be a forcing mechanism to improve analytical detection methods. (See 1985 Guidelines, page 21.) As the methods improve, limits closer to the actual criteria necessary to protect aquatic life and human health became measurable. The Agency does not believe it is appropriate to promulgate criteria that are not sufficiently protective.

EPA does believe, however, that the use of analytical detection limits are appropriate for determining compliance with NPDES permit limits. This view of the role of detection limits was recently articulated in guidance for translating dioxin criteria into NPDES permit limits which is the principal method used for water quality standards enforcement.[3] This guidance presents a model for addressing toxic pollutants which have criteria recommendations less than current detection limits. This guidance is equally applicable to other priority toxic pollutants with criteria recommendations less than current detection limits. The guidance explains that standard analytical methods may be used for purposes of determining compliance with permit limits, but not for purposes of establishing water quality criteria or permit limits. Under the Clean Water Act analytical methods are appropriately used in connection with NPDES permit limit compliance determinations. Because of the function of water quality criteria, EPA has not considered the sensitivity of analytical methods in deriving the criteria promulgated today.

EPA has added provisions in paragraph (c)(3) to determine when fresh water or saltwater aquatic life criteria apply. In response to comments, this provision was expanded to incorporate a time parameter to better define the critical condition. The structure of the paragraph is to establish presumptively applicable rules and to allow for site-specific exceptions where the rules are not consistent with actual field conditions. Because a distinct separation generally does not exist between fresh water and marine water aquatic communities, EPA is establishing the following: (1) The fresh water criteria apply at salinities of 1 part per thousand and below at locations where this occurs 95% or more of the time; (2) marine water criteria apply at salinities of 10 parts per thousand and above at locations where this occurs 95% more of the time; and (3) at salinities between 1 and 10 parts per thousand the more stringent of the two apply unless EPA approves the application of the freshwater or saltwater criteria based on a biological assessment. The percentiles included here were selected to minimize the chance of overlap, that is, one site meeting both criteria. Determination of these percentiles can be done by any reasonable means such as interpolation between points with measured data or by the application of calibrated and verified mathematical models (or hydraulic models). It is not EPA's intent

[2] For a description of harmonic means see "Design Stream Flows Based on Harmonic Means," Lewis A. Rossman, J. of Hydraulics Engineering, Vol. 116, No. 7, July, 1990. This article is contained in the record for this proposal.

[3] Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States, memorandum from the Assistant Administrator for Water to the Regional Water Management Division Directors and NPDES State Directors, May 21, 1990.

to require actual data collection at particular locations.

In the brackish water transition zones of estuaries with varying salinities, there generally will be a mix of freshwater and saltwater species. Generally, therefore, it is reasonable for the more stringent of the freshwater or saltwater criteria to apply. In evaluating appropriate data supporting the alternative set of criteria, EPA will focus on the species composition as its preferred method.

This assignment of criteria for fresh, brackish and marine waters was developed in consultation with EPA's research laboratories at Duluth, Minnesota and Narragansett, Rhode Island. The Agency believes such an approach is consistent with field experience.

In paragraph (c)(4)(i) EPA included a limitation on the amount of hardness that EPA can allow to antagonize the toxicity of certain metals (see footnote (e) in the criteria matrix in paragraph (b) of the rule). The data base used for the Section 304(a) criteria documents for metals do not include data supporting the extrapolation of the hardness effects on metal toxicity beyond a range of hardness of 25 mg/l to 400 mg/l (expressed as calcium carbonate). Thus, the aquatic life values for the CMC (acute) and CCC (chronic) criteria for these metals in waters with a hardness less than 25 mg/l, must nevertheless use 25 mg/l when calculating the criteria; and in waters with a hardness greater than 400 mg/l, must nevertheless use 400 mg/l when calculating the criteria.

In paragraph (c)(4), subparagraphs (i) and (ii) are the same as proposed. Subparagraph (iii) was added to incorporate the water-effect ratio guidance described in Section F-7 of this preamble.

Subsection (d) lists the States for which rules are being promulgated. For each identified State, the designated water uses impacted (and in some cases the specific waters covered) and the criteria are identified. In all cases, the criteria are applied to use designations adopted by the States; EPA has not promulgated any new use classifications in this rule although the Agency has the authority to do so.

H. (Reserved)

I. Response to Public Comments

The Response to Public Comment Section is organized into several subsections, as follows:

1. Legal Authority
2. Science
3. Economics
4. Implementation
5. Timing and Process
6. State Issues

I. Legal Authority

1. *Comment:* Several comments were received that in various ways suggested that EPA exceeded its authority in proposing to establish Federal water quality standards for States because it was alleged standards are to be developed by the States. These comments tended to emphasize the primary role attributed to States under the Clean Water Act in establishing standards with some going so far as to indicate that States should have full and unrestrained authority to act. In this mode, a comment was offered that all the Clean Water Act requires is a good faith effort on the part of a State to meet the statutory requirement. A related comment suggested that EPA can promulgate standards only after specifically disapproving a State's standard. There were opposing views offered suggesting that EPA not only has the authority to act, it is obliged to act.

Response: The Clean Water Act assigns States the primary role in establishing water quality standards and EPA has continually supported that role before Congress in reauthorization hearings on the Clean Water Act. The Act, however, also defines a role for EPA in terms of reviewing and either approving or disapproving State-adopted standards and of promulgating Federal standards. Sections 303(c) (3) and (4) of the Act clearly indicate that Congress did not intend States to have full and unrestrained authority to set standards. EPA's action in developing this rulemaking is not to be taken as a change in EPA policy in dealing with the States. Our policy continues to be that we prefer States to adopt their own standards but we will use our promulgation authority when warranted. EPA believes that the need to control the discharge of toxic pollutants to protect human health and the environment, the establishment of the statutory requirement for addressing toxic pollutants, and the responsibility for EPA review of State water quality standards for consistency with the Clean Water Act coupled with the inclusion of a process for Federal promulgation in the Act strongly supports EPA's promulgation authority. Moreover, this elaborate process also makes clear that Congress intended that States do more than just evidence a good faith effort.

As described in detail in section E of this Preamble, the Clean Water Act authorizes and establishes a timetable for Federal promulgation action. Under the Clean Water Act, States must adopt water quality standards to protect public health and welfare and enhance the quality of water. Section 303(c)(4) of the Clean Water Act authorizes the Administrator of EPA to promulgate Federal standards applicable to a State when: (1) The State submits standards for EPA approval and EPA determines that the State standards fail to meet the requirements of the Act, or (2) in any case where the Administrator determines a new or revised standard is necessary to meet the requirements of the Act. EPA's implementing regulations also make clear that the Administrator may take action to promulgate either when a State fails to adopt changes specified in a disapproval or in any case where the Administrator determines a new or revised standard is necessary (40 CFR 131.22). Both these provisions are used to support this action. Although in fact EPA did notify the States in a Federal Register notice of April 19, 1990, and in a letter to the Administrator of the responsible State agency of each potentially affected State on April 9, 1990, the Administrator is not required in exercising the authority of section 303(c)(4) to specifically disapprove a State's standard when exercising the authority to promulgate Federal standards. Historically, in eight of the nine Federal promulgation actions completed, the Agency based its action on disapproval of State standards but in the ninth instance, a criterion for chloride in the Commonwealth of Kentucky, there was no disapproval involved (see 52 FR 9102, March 20, 1987).

2. *Comment:* Closely related to the above comments were others that asserted that EPA is empowered to promulgate Federal standards only on a State-by-State, waterbody-by-waterbody, pollutant-by-pollutant approach, and that Congress did not intend that national standards be developed. In the same vein, it was suggested that it would be easier for the public to respond if each State were proposed in a separate rule.

Response: Neither EPA nor the States are directed by either the statute or the implementing water quality standards regulation to establish standards in the manner suggested by the first comment. EPA's implementing regulation and policies certainly allow EPA to act in this way but it is not required to do so. Section 131.22(b) of the water quality standards regulation specifically indicates that the Administrator "* * * may propose and promulgate a regulation applicable to one or more states * * *."

We do not see this action as establishing national standards as it

expressly limits the application of the criteria in the final rule to the States named in the rule. (40 CFR 131.36(a))

As explained more fully in the preamble, water quality standards consist of designated beneficial uses of a State's waters and the criteria necessary to protect those uses. The comment urges a waterbody-by-waterbody approach. For purposes of this rulemaking, EPA is presuming that the States have adequately made such designated use determinations for its waters. EPA is merely adding criteria for priority toxic pollutants on a State-by-State basis sufficient to protect the State's designated uses. EPA believes its approach accomplishes the commenters objectives but in a more comprehensive manner. Moreover, EPA doesn't believe this approach is more burdensome on dischargers in affected States. Because permit limits are incorporated into NPDES permits only for constituents having a reasonable potential to exceed State water quality standards, a discharger does not receive a limit in its permit unless its discharge contains the pollutant. Thus, comprehensive criteria coverage in water quality standards does not translate into unnecessary permit limits.

EPA is unpersuaded that somehow it would have been easier or more efficient for the public to comment on twenty-two separate rules covering the same issues than to deal with the issues in a single rulemaking. It would most likely result in EPA receiving the same type comments on each separate rule which would do nothing other than increase the administrative burden to EPA and further delay getting water quality standards in place.

3. *Comment:* A comment was made that several proposals for reauthorizing the Clean Water Act considered by Congress in 1991 contemplated giving EPA authority to promulgate Federal standards thus indicating that EPA does not have such authority now.

Response: A response to a comment above describes EPA's current authority to act under terms of the Clean Water Act. The principal CWA reauthorization bills considered by Congress in 1991 would neither question nor limit this existing authority. Rather they would alter the water quality standards program as it now exists by providing specific deadlines for States to act in adopting standards based on recommendations published by EPA and then mandating Federal promulgation by a date certain. Rather than suggesting that EPA does not now have such authority, these proposals support EPA's view that Congress is becoming increasingly impatient with the slow pace at which States adopt new criteria recommendations issued by EPA under section 304(a) and is willing to consider supplementing EPA's current discretionary promulgation authority.

4. *Comment:* Several comments suggested that EPA's promulgation action should be limited to the waterbodies and pollutants reported on the section 304(l) lists or information contained in section 305(b) Water Quality Inventory Reports. The basic thrust of these comments were that such lists, prepared by the States, contain sufficient information necessary to identify all potential toxic problem areas within the State. Some of these commenters also suggested these limited sources were more accurate than the broader approach relied on in EPA's proposal.

Response: A detailed description of the approach the Agency followed in developing this final rule is included in section E–2 of this preamble. As indicated in that section, EPA used information from a variety of sources in determining which criteria to include in the rule for each State. The Agency did not rely on a single source, such as 304(l), 305(b), or any other set of information.

Each of the data sources suggested by the commenters are valuable tools which serve specific purposes under the Clean Water Act. However, as described in section E–2, each source has limitations either as to coverage of waterbodies or sources of pollution, extent of information included, or a narrow focus because of their particular purpose. Even when information from a variety of sources is used as described as the Agency's "strawman", there remain inherent weaknesses in the underlying data.

EPA believes there is a greater possibility of achieving the statutory purpose of protecting water uses by relying on a range of available data sources rather than selecting one or two narrow databases. EPA believes that by not directing the Agency to use the results of the other statutory sections the commenters identified, and by use of the "could reasonably be expected to interfere" language, Congress directed the Agency to be more inclusive rather than less inclusive in the applicable criteria coverage. Thus, EPA urged a low threshold for inclusion of priority toxic pollutants in the guidance transmitted to the States.

5. *Comment:* One commenter argued that EPA's strawman systematically overestimates the presence of priority toxic pollutants because of its use of industry wide default assumptions for particular SIC codes. The commenter further argues that comparisons between the number of toxics adopted in States who evaluated available data for toxics and established criteria based on that data to the results of the strawman predictions show that a substantially smaller number of pollutants resulted. The commenter urged that only section 304(l) short list pollutants should be used for this rule.

Response: EPA's strawman analysis was designed to use all of the Agency's data bases to develop candidate lists of toxics on a State specific basis. States were urged to use this information as a starting point in evaluating the need for particular priority toxic pollutants.

EPA intentionally designed the analysis to yield a list of suspected priority toxic pollutants that would not understate the potential presence of such pollutants. As noted in the preamble, State monitoring information, for example, as used in the section 305(b) water quality reports, is not comprehensive in either geographic or parametric coverage. That is the reason EPA used the industry profile data—to maximize the data base.

Thus, EPA was providing the States with a listing that identified potential toxics and where those were potentially located. The State was encouraged to verify the lists. EPA has not used the list to identify pollutants for States included in this rulemaking. Rather EPA has viewed the analysis as supporting its contention that priority toxics exist in State waters and therefore, a broad promulgation for priority toxic pollutants is justified.

In arguing for limiting the promulgation to the section 304(l) short list pollutants, the commenter failed to compare the criteria the example State adopted in its water quality standards versus the pollutants identified in its section 304(l) short list. The State used as an example placed substantially more criteria in their standards than in their section 304(l) short list. The reason for this disparity is because the threshold for inclusion in water quality standards is much lower than for inclusion in the section 304(l) short list.

6. *Comment:* EPA solicited comment concerning the acceptability of the review process used by EPA to determine compliance with the Act—this process is described in section D of this preamble. EPA received few public comments in response to this request, beyond the general comment that EPA exceeded its authority to promulgate Federal standards, an issue addressed earlier in this section. One view offered was that the review process used by the Agency makes it difficult to evaluate whether adequate consistency was

applied by the Regions in evaluating acceptability of State standards.

Response: Each State's water quality standards submission is different. They require case specific review for adequacy and consistency with environmental and human health requirements and statutory and regulatory provisions. The statute allows for State flexibility. Given these factors, EPA established broad guidance parameters and Regional Offices reviewed each submission for consistency. EPA Headquarters staff exercised oversight on this process to assure appropriate inter-Regional consistency. This process did not produce identical standards in each State but that is not required. All State standards that were approved were judged by EPA to meet the twin tests of protection of water body uses and scientific defensibility.

Both the criteria development and the standards programs are iterative programs and EPA expects to request States to continue to focus on adopting criteria for additional toxic pollutants and revising existing criteria in future triennial reviews which new information indicates is appropriate. In no sense should States or the regulated community assume that the task of addressing pollution from toxics is completed by what the States have adopted or EPA is promulgating in the way of criteria for toxic pollutants.

7. *Comment:* EPA did not propose criteria for inclusion in State standards when the criteria were based on organoleptic effects. The Agency specifically solicited comment on this issue. Most of the comments received indicated that EPA was correct in not including such criteria in the rule. There were several comments to the contrary indicating that such criteria should be included because the pollutants are on the section 307(a) list and EPA did issue a criteria recommendation for the pollutant under section 304(a). Therefore, they argue that the requirements of section 303(c)(2)(B) apply.

Response: In the final rule, EPA has not included criteria for pollutants where the section 304(a) criteria recommendation was based on organoleptic effects. Such effects cause taste and odor problems which may increase treatment costs in drinking water or the selection by the public of alternative but less protective sources of drinking water and may cause tainting of or off flavors in fish flesh and other edible aquatic life reducing their marketability and resource value. EPA is also aware that some States have adopted such criteria in their standards. Nonetheless, because section 303(c)(2)(B) focuses on toxicity of the priority toxic pollutants, EPA believes its rule should likewise focus on toxicity. The 304(a) criteria documents for these pollutants do not recommend a criteria based on toxicity and therefore such criteria are outside the intent of a rulemaking for section 303(c)(2)(B).

This decision notwithstanding, it should be noted that the criteria based on organoleptic effects still represent the Agency's best scientific recommendations at this time and are within the range of scientific acceptability for a State's use.

8. *Comment:* One commenter asserted that EPA's Option 3 (i.e. adoption of a narrative standard coupled with a translator mechanism to compute a derived numeric limit) of its December 1988 guidance on complying with the Act does not meet the legal requirements of section 303(c)(2)(B). It is argued that EPA should therefore disapprove all State water quality standards which rely solely on a narrative "free from" toxics water quality standard and a translator mechanism. A related comment is that this translator procedure may be appropriate as a supplement to adopting specific numeric criteria.

Response: The legality of Option 3 is not an issue in this rulemaking. We are not promulgating any water quality standards based on Option 3. Option 3 is only a potential issue in the subsequent approval of standards for those States which are not included in this rule.

Nevertheless, as noted in the December 1988 guidance, EPA believes the combination of a narrative standard along with a translator mechanism as a part of a State's water quality standards can satisfy the substantive requirements of the Clean Water Act. Such translators would need to be 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.

EPA's guidance presented several factors that EPA expected to be incorporated into a translator process in order to comply with the Act. In essence, EPA expected that the technical mechanism used would need to be equivalent to a criteria development protocol. That is, it would need to include an appropriate number of sensitive species using suitable testing and analytical methodologies. If established and applied correctly, EPA has indicated that it could meet the legal requirements of section 303(c)(2)(B). The central objective of section 303(c)(2)(B)—establishing chemical specific numeric limits—is achieved by this approach. There is no statutory bar to it and the Agency sees no reason not to continue to support this approach by States.

Ultimately, EPA believes all State toxic control programs will be strengthened by adoption of both chemical specific standards and a translator mechanism for those pollutants where water quality criteria have yet to be developed.

9. *Comment:* EPA invited comment on whether to promulgate a translator mechanism for the States in this final rule. A translator mechanism would enable the States to derive numeric limits for pollutants beyond those in this promulgation based on a State's general narrative criterion. The Agency received comments both supporting and opposing this approach.

Response: While a translator mechanism could be a valuable supplement to State standards to deal with toxics for which no section 304(a) criteria recommendation is available, it is not necessary for EPA to promulgate a translator at this time to meet the objectives of section 303(c)(2)(B). Today's promulgation of chemical specific criteria fulfills that obligation. For that reason a translator mechanism is not included in today's final action. However, EPA believes that such a mechanism should be available in all States. Therefore, in revisions to the basic water quality standards regulation, EPA may propose a requirement for a translator mechanism which would be applicable to all jurisdictions included in the standards program.

10. *Comment:* Comments were received that EPA is attempting to establish use classifications in this rule and that such action is a right belonging to a State.

Response: The use classifications to which Federal criteria are applied in this rule are the classifications established and defined by each State affected by the rule. EPA is not creating State use classifications nor assigning use classifications to any water bodies in this rule. In the few instances described in Section G of this preamble, appropriate adjustments to uses and criteria were made as necessary to accurately reflect State use classifications. Further, EPA believes the regulated community is fully aware of the uses adopted by a State and to which water bodies the uses apply. Specific revisions in the rule pertaining to State use classifications are discussed

in subsection 6 of the Response to Public Comments Section.

11. *Comment:* During the pendency of this rulemaking, several States asked if adopting an emergency rule would be sufficient to allow removal of the State from the final promulgation. Several States also indicated they should be removed from the rule because they had plans to adopt standards.

Response: Emergency rulemaking actions by States are not judged by EPA as sufficient basis for removal from this rulemaking. In most cases, State emergency rules have a limited duration and expire at a date certain. There is no assurance that enforceable permanent water quality standards would be in-place at that time. If EPA were to allow emergency rulemakings to be the basis for removal from this package, given the long delays to date by these States, there is the strong possibility promulgation action would have to be commenced again by EPA in the near future. The delays and related program disruptions experienced by EPA have already been too great. There has to be closure on the standards adoption portion of our toxic control efforts. Reliance on temporary emergency State actions would not produce that closure.

There is also the question of legal vulnerability to the adoption of emergency rules and whether the State emergency rule procedures allow for sufficient public review. Moreover, the emergency rules adopted would have to fully comply with the Act. States which contend they should be dropped from this rule because they now plan to adopt standards remain in this rule because EPA has no reasonable means of being assured standards will be adopted as planned. Since passage of the amendments in 1987, many State plans for standards adoption have not been completed as anticipated. When States complete approvable adoptions, EPA will take timely action to remove the promulgation as applicable to that State.

12. *Comment.* One commenter asserted that States do not have the necessary legal authority under State law to use national water quality standards in State permits.

Response. Without more information, we cannot determine the precise concerns of this commenter. However, section 402(b) of the Clean Water Act requires that States approved to administer the National Pollutant Discharge Elimination System (NPDES) program must have adequate authority to issue permits which comply with any applicable requirements of section 301 of the Act. Among those requirements are limitations to meet water quality standards, and the criteria promulgated today are "* * * applicable water quality standard(s) established pursuant to this Act." Section 301(b)(1)(C).

Once promulgated, Federal standards will be the basis of all environmental control programs designed to meet water quality standards. States which had inadequate criteria for toxics will have a much more complete basis for determining if there are toxic contamination problems in their waters. If problems are identified, the State and EPA will need to work together to see if the sources of these problems can be identified and controlled. The most direct impact will be on NPDES permits for individual point source discharges. The permitting agency, whether it be the State or EPA will have to determine on a case-by-case basis whether to re-open an individual permit or wait until a permit expires before introducing new limits.

13. *Comment.* One commenter described ongoing judicial and administrative proceedings to establish the authority of the state to set permit limits for dioxin by interpreting the state's narrative criterion using EPA's section 304(a) dioxin guidance. The commenter indicated that the state has consistently implemented its narrative water quality criterion to control dioxin discharges by interpreting that criterion using EPA's guidance. It is the commenter's view that if the state prevails in the ongoing litigation, it will effectively have a numeric criterion for dioxin.

Response The critical flaw in the commenter's argument is that the State does not have in-place an EPA-approved numeric criterion for dioxin, or an approved translator to generate a numeric criteria for dioxin. Moreover, conclusion of the litigation would not establish an approved numeric criterion, even if the State were to prevail. EPA understands that States often implement their narrative criteria by interpreting those criteria using EPA guidance. EPA supports this process by the States. However, section 303(c)(2)(B) is clear that States are to adopt numeric water quality criteria for toxic pollutants. The purpose of this rulemaking is to finally establish the necessary numeric toxic criteria in all States, and only those states with the necessary approved numeric criteria are excluded from the rule.

2. Science

The response to comments in this subsection are included under the following headings: (A) General Comment, (B) Aquatic Life Criteria, and (C) Human Health Criteria.

A. General Comments

14. *Comment:* Numerous comments were received that EPA's water quality criteria were published as scientific guidance and were never intended to be used as regulatory provisions without modification to reflect local environmental conditions. Related comments indicated that because the criteria were published as guidance, the public comment received on the draft water quality criteria documents were restricted since reviewers did not anticipate their use as enforceable limits.

Response: Water quality criteria are published as scientific information or guidance under section 304(a) of the Act because that is what the Clean Water Act specifies. EPA's implementing water quality standards regulation recognizes that the section 304(a) criteria may be used as a basis for States to establish enforceable standards. See 40 CFR 131.11(b). To imply that the section 304(a) criteria are merely informational and not directly related to establishing water quality standards under section 303(c) is not only reading the Act in an crabbed manner, it also ignores 26 years of program history which demonstrates that States generally rely on the criteria recommended by EPA in establishing standards. Moreover, this rulemaking is the process which transforms these recommendations into enforceable regulatory requirements for specific States. Any specific issues related to establishing these criteria as applicable to State standards could have been raised during this rulemaking even if the issues were raised or considered in the earlier publication of criteria documents.

Furthermore, although the EPA water quality standards regulation allows State modification of water quality criteria to reflect local, site-specific conditions, it is not a requirement to do so. EPA is also not obligated to modify criteria to reflect local environmental conditions although ideally EPA would consider any data submitted in support of establishing a site-specific criterion in determining whether site-specific criteria would be appropriate. In addition, EPA believes the methodology and the extensive data base used by the Agency results in deriving national criteria that will be protective for most species in virtually all waterbodies throughout the country. (See 1985 Guidelines, page 4.)

Congress has given substantial credibility to the section 304(a) criteria as well. For example, in section 301(h)(9) applicants must meet the

section 304(a) criteria as if they were regulatory.

Finally, it should be noted that when announcing the availability of draft and final criteria documents, it is stated in the EPA announcement that such criteria may form the basis for enforceable standards. EPA believes that adequate notice of the uses of the section 304(a) criteria has been provided to the public.

15. *Comment:* Commenters suggested in general that the EPA criteria are outdated and need to be revised extensively to reflect the latest scientific information available before they can be appropriately used in rulemaking. For a few pollutants data were submitted to substantiate this claim. (See response to comments on specific pollutants below.)

Response: EPA does not agree with these comments for several scientific, programmatic, and statutory reasons. Scientific information is constantly evolving. Additional research is always being done, test methods and theories improve, and more precise analytical methods become available. There can be a long lag time between conducting the research, analyzing the data, issuing the criteria documents for review, revising the documents, and working through the State or Federal administrative processes to adopt standards. There comes a point in this process, where the administering agencies, both EPA and the States, have to act using the existing criteria recommendations based on the methodology by which they are derived, and put standards into place so that control programs can be implemented to protect the health of the public and the environment. One basic reason why criteria and standards is an iterative process is to continuously evaluate and incorporate new information. Through this process, many of EPA's criteria have been updated since issuance of the formal criteria documents.

Moreover, once standards are in place, applications can be made through the mathematical models used to derive total maximum daily loads and wasteload allocations. These determinations are associated with the NPDES permits process and result in permit limits being established that have sufficient latitude to adequately account for other than major adjustments to individual criteria recommendations.

Finally, it must be recognized that Federal promulgation is the end of the process to establish water quality standards, not the beginning. In this case, the beginning was in 1980 when most of the criteria and the first generation criteria development methodologies were issued. By 1983, due to lack of response by the States, EPA revised its basic water quality standards regulation to put primary emphasis on the adoption of water quality criteria and control of toxic pollutants. This too failed to engender adequate State response which in turn led to the directive from Congress contained in section 303(c)(2)(B). Now, five years later, and two years after the States should have taken action, this final rule completes the process of establishing the first set of comprehensive standards for toxic pollutants. This final Federal promulgation ends this current effort but the revision of criteria based on new research, the revision of applicable standards, alterations in analytical methods, and the evolution of control technologies will continue.

EPA asserts, as we have elsewhere in this preamble, that the promulgation process established under the Clean Water Act is a process designed to bring to closure the act of putting enforceable standards into place as basis for environmental control programs designed to protect public health and the environment. The promulgation process is not designed or intended to be the vehicle for a reevaluation of the scientific underpinnings of water quality criteria. It is also not the process for protracting the debates about the scientific merits of various pollutants. That debate is essential, necessary, and is constantly ongoing but as a separate activity. The promulgation process envisioned must go forward and the Agency must make decisions based on the available data. It is clearly a means to end such debates and to get environmental controls started based on available information.

EPA believes the criteria promulgated today are scientifically sound as they are based upon a technically and scientifically acceptable methodology. Detailed descriptions of the formulation of aquatic life criteria and human health criteria are included in section F (1,2, and 3). As discussed below, we have made some revisions to the criteria based on public comments. Our criteria for both human health and aquatic life provide a reasonable amount of protection with only a small possibility of substantial overprotection or underprotection.

To completely review all the criteria as some suggested would take a minimum of several years during which time the human health and environmental problems associated with the continued discharge of toxic pollutants would worsen. There is no predetermined result from an extended review—some criteria might become more stringent, some less, some might remain the same. In the meantime, the States that failed to comply with the Act are rewarded for their failure. These States have delayed while 43 of the jurisdictions included in the program have adopted water quality standards for the most part relying on EPA's section 304(a) criteria guidance.

As indicated in this preamble, we are currently re-examining our basic criteria development methodology, which is a normal course of action for the Agency. We anticipate some changes will be made and we assume some changes in the criteria will be made over the years. This, however, is no reason to suspend action now.

16. *Comment:* The use of information contained in the Agency's Integrated Risk Information System (IRIS) to update human health criteria was questioned by several commenters. The central concerns were that the information contained in the system was not subject to external peer and public review, the background information contained in IRIS is not readily available for review, and the public had little chance to review the results of the recalculations.

Response. A detailed discussion of the IRIS may be found in Section F–3 of this preamble. To summarize the salient points: (1) Reference doses and cancer classifications are validated by two Agency work groups composed of senior Agency scientists from all other program offices (i.e., internal peer review), (2) the consensus opinion for reference doses and slope factors are then used throughout EPA for consistent regulation and guidance development, (3) the data are available through the TOXNET System maintained by NIH and through diskettes available from the National Technical Information Service (NTIS), (4) the information used to recalculate the section 304(a) criteria in today's rule was included in the record of this rulemaking, and (5) through the proposal of this rule, the public had an opportunity to review and comment on the revised criteria. In addition, some of the RfD values and the cancer potency slope factors undergo public review during rulemaking for other Agency programs such as drinking water, pesticides, and Superfund. Thus, EPA believes that adequate notice about IRIS and its use in Agency programs has been provided to the public, at least as it concerns its use in this rulemaking.

17. *Comment:* Several commenters indicated that the criteria should be subjected to a peer and public review process similar to that followed by the Agency in issuing proposed criteria

under section 405 of the Act concerning the disposal of wastewater solids.

Response: The proposed regulations for the disposal of wastewater solids represented the first time EPA proposed such standards, and was the first time a methodology and specific criteria were proposed by EPA for wastewater solids. Therefore, the extensive review for that proposed regulation was appropriate. The situation is not the same for the criteria promulgated in today's rule. EPA and the States have been regulating the discharge of pollutants into surface waters for many years. The methodologies for deriving criteria for the protection of both human health and aquatic life were peer and publicly reviewed in 1980. The aquatic life guidelines were revised with peer and public review in 1985. Both methodologies are currently being reviewed for possible revisions. As discussed elsewhere in this section, this rulemaking makes use of the existing criteria and therefore is not the most effective vehicle for revising either the methodologies or the actual criteria.

18. *Comment:* Several commenters objected that applying criteria as standards when the criteria are below analytical detection limits is unreasonable because this may force the imposition of unreasonable permit limits and "false positive" indications of non-compliance. Others suggested that it was not clear how detection limits affect permit limits and compliance. There were also comments supporting EPA's position as described in the proposal.

Response: In consideration of statutory requirements that water quality standards are to be protective of designated stream uses, EPA has determined that consideration of analytical detectability would not be an appropriate factor to consider when calculating the water quality criteria component of water quality standards. This has been the Agency's position since the inception of the water quality standards program in 1965.

Although the sensitivity of analytical methods are not appropriate for setting water quality criteria, they may be appropriate in determining compliance with permit limits based water quality standards. It should also be noted that by the time standards are converted into permit limitations after calculating total maximum daily load and wasteload allocations, the actual permit limit may be in the range of standard analytical methods cited by EPA in 40 CFR part 136.

EPA's criteria development methods for aquatic life are generally based on laboratory bioassays with sensitive aquatic life. The results from these tests are analyzed by mathematical procedures outlined in EPA's criteria methodology guidelines. EPA human health criteria are developed from protocols generally using toxicity studies on laboratory animals such as mice and rats. Thus, EPA's criteria are effect-based without regard to chemical analytical methods or techniques.

Because water quality standards developed pursuant to section 303(c) of the Clean Water Act are not self-enforcing, the measurement of these chemicals in a regulatory sense is generally in the context of an NPDES permit limitation. The permit issuing authority, either a State or EPA, in conjunction with the permittee establishes the analytical methodology to be used in determining compliance with the permit limit.

As noted in footnote 3 of this preamble, EPA has issued guidance on how constituents with water quality criteria specified at less than the sensitivity of official analytical methods (i.e., those listed in 40 CFR part 136) are established in permits.

EPA's water quality standards regulation at 40 CFR 131.11 requires that criteria be adopted by States at concentrations necessary to protect designated uses. The criteria promulgated today meet that requirement while EPA's policy with respect to regulatory compliance takes analytical sensitivity and precision into consideration.

B. Aquatic Life

19. *Comment:* A few comments questioned the role of biological criteria in the standards program with one commenter suggesting that establishing numeric limits is contrary to achieving the biological goals of the Clean Water Act.

Response: Together, chemical and physical characteristics and biological integrity define the overall ecological integrity of an aquatic ecosystem. State regulatory agencies should strive to fully integrate all three approaches since each has its respective capabilities and limitations. EPA's position is that each approach as represented by whole effluent toxicity testing, chemical specific criteria, and bioassessment approaches is independently applicable (see Policy on Use of Biological Assessments and Criteria in the Water Quality Program, U.S. EPA, May 1991). A description of the integration of these approaches along with a detailed analysis of the capabilities and limitations of each approach may be found in the Technical Support Document for Water Quality-based Toxics Control, March 1991. See TSD Section 1.5 beginning on page 20, and references cited therein.

20. *Comment:* A commenter argued that EPA's proposed national aquatic life criteria will be overprotective for many surface waters because they do not account for site-specific conditions. At a minimum, any federal water quality criteria must take into account broad aquatic life categories.

Response: The development of EPA's criteria is based on a broad aquatic life data set. The 1985 guidelines recommend that eight species from eight separate families be used in the development of the freshwater and saltwater criteria. While it is always beneficial to have more data, EPA's peer reviewed guidelines establish that criteria developed from this minimum data set adequately protect aquatic communities (1985 Guidelines, see section III, p. 22). The apparent level of protection is different for each kind of effect (acute or chronic toxicity to animals, toxicity to plants, etc.) because of the quality and quantity of information. An attempt was made to take into account such things as the importance of the effect, the quality of the available data, and the probable ecological relevance of the test methods. The present approach to aquatic toxicity allows conclusions to be made about the ability of a substance to adversely affect aquatic organisms and their uses whenever the minimum data set are satisfied. See also the discussion on metals speciation in Section F-7 and the response to comment below.

21. *Comment:* One commenter asserted that EPA has incorrectly concluded that the Section 304(a) criteria are appropriate for most waters because there have been few occasions where site-specific water quality criteria have been applied.

Response: EPA's determination that Section 304(a) criteria are generally applicable is not based on a lack of site-specific criteria modification studies as asserted by the commenter. EPA has conducted a series of field applicability studies to determine the correlation between chemical specific criteria and receiving water impacts. (Technical Support Document for Water Quality-based Toxics Control, March, 1991 at p. 2). These test results indicate a good correlation between the laboratory concentrations and expected field results. The water quality criteria are not threshold values. One should not expect that once these values are exceeded, the result is a measurable impact on aquatic life. The aquatic life criteria embody conservative assumptions so that small excursions

above the criteria will not result in adverse impacts. The data indicate that if ambient water quality criteria are met, organisms in the receiving water are protected from adverse impacts.

22. *Comment:* Comment was received that EPA should clarify that the aquatic life water quality criteria for arsenic are based on the trivalent form of arsenic.

Response: The arsenic criteria promulgated today are applied on total recoverable inorganic arsenic. The 1985 arsenic criteria document is derived from data on Arsenic (III). However, because there is no readily available or practical analytical method to quantify the various forms of arsenic in monitoring applications for aquatic life, EPA has concluded that it is reasonable to quantify environmental arsenic concentrations as total recoverable inorganic arsenic. (EPA Methods 206.2, 206.3, 206.4, 206.5.)

In addition, EPA reevaluated the acute and chronic toxicity data on the two most prevalent forms of arsenic in aquatic systems (trivalent and pentavalent arsenic) in the Arsenic criteria document. These data show that arsenic (III) and arsenic (V) toxicity is similar for both sensitive freshwater and saltwater species. For five of the six freshwater species and all of the saltwater species used in the arsenic calculation where there was comparable information on acute and chronic toxicity, values were within a factor of two or three. Certain plants, for example *Selenastrum capricornutum* (alga), are 45 times more sensitive to arsenic (V) than to arsenic (III). Therefore, it is reasonable to combine forms of arsenic to specify the criteria. The measurement of total recoverable arsenic has both toxicological and practical advantages and appropriately represents the aquatic life toxicities of arsenic compounds.

23. *Comment:* Several commenters asserted that criteria based on laboratory tests are overprotective when applied in the field. Another commenter quoted laboratory study reports stating that the results are applicable only to the particular water tested.

Response: EPA agrees that waters used for laboratory toxicity testing are generally cleaner than many natural systems. In cases where ambient waters contain constituents which alter the toxicity of chemicals, an increase in accuracy may be provided by rerunning the toxicity tests in site water. (For example, the water-effect ratio approach for metals promulgated today.) In most instances, this correction will be small. (TSD, March 1991, p.2). Therefore, applying the criteria values developed from laboratory testing provides an acceptable level of accuracy, and this approach is used by most States. In the context of this rule it represents a technically acceptable approach to cover a variety of waters, and the only feasible one. (See also the response to comments for the 1980 Guidelines, Nos. 17 and 19, 45 FR 79359, November 28, 1980.)

In response to the second comment, the scientist running the specific toxicity test referenced by the comment noted that its accuracy is only guaranteed for the specific water tested. However, applying these tests to other waters is an acceptable approximation. (See response to public comments for the 1980 Guidelines, 45 FR 79359–79360, comment #20 and #21.) Additionally, laboratory toxicity testing is the most reasonable and practical way to develop a database which is large enough to develop criteria, and diverse enough in species, which generally represent a larger source of variability.

While most States have not chosen to perform site-specific toxicity tests, any State may develop site specific-criteria. These criteria will be more appropriate and tailored to the site for setting NPDES permit limits than EPA's national criteria. Because they are amended water quality standards, site specific criteria are subject to EPA review. Other than the water-effect ratio for metals which is promulgated today, State-developed site specific-criteria do not replace the criteria promulgated in today's rule unless the site specific-criteria are approved by EPA as meeting the requirements of the Act and EPA amends the rule adopted today.

24. *Comment:* Comment was received that the proposed rule includes some aquatic life criteria computed using the 1980 guidelines methodology and others were computed using the 1985 guidelines methodology. It was asserted that the simplistic approach of the 1980 methodology ignores the scientific improvements of the 1985 guidelines. The commenter urged that these criteria should be updated to provide consistent methodology and adherence to the statutory requirement of section 304(a).

Response: As the commenter noted, some of the aquatic life criteria in this rule are based on 1980 guidelines. EPA reviewed the data base for these criteria and determined that in general they could not be recalculated by the 1985 guidelines because of differences in data base requirements between the two guidelines used species specific requirements whereas the 1985 guidelines expanded this to broader taxonomic categories.) EPA believes that the data used in the 1980 criteria document are sound. As a practical matter, a reasonable approximation to a criteria maximum concentration can be obtained by simply dividing the final acute values in the matrix by 2. The criteria in the matrix in today's rule were not changed from the results of the respective 1980 and 1985 methodologies. Therefore, EPA has reconsidered these aquatic life criteria at the commenter's request and considers them to be within the acceptable range based on uncertainties associated with computing water quality criteria. These criteria are protective of aquatic life and are scientifically sound.

The development of aquatic life criteria is a dynamic process which responds to the influence of improved science. It is expected that this science will be constantly evolving as new analytical techniques become available and new studies are evaluated. To this end, EPA is also reviewing the current methodology for developing aquatic life criteria. The current methodology will be reviewed, and if needed, revised to incorporate the latest concepts of aquatic toxicology.

25. *Comment:* A commenter asserted that the proposed aquatic life criteria may be underprotective since they fail to account for synergism and additivity and fail to consider wildlife impacts.

Response: EPA agrees that the aquatic life criteria do not deal with simultaneous exposure to more than one pollutant. This is largely because few data are available, the data which are available do not allow for development of useful principles and there are so many possible combinations of pollutants present to prevent development of appropriate guidance. EPA has considered the effects of multiple toxics discharged into receiving waters. (Technical Support Document for Water Quality-based Toxics Control; March 1991.) The studies cited in the TSD indicate that the median combined effect of a mixture of acutely toxic pollutants in receiving water is additive. EPA recommends, that in the absence of site-specific data, regulatory authorities consider combined acute toxicity to be additive. Thus, the combined acutely lethal toxicity to fish and other aquatic organisms is approximately the simple addition of the proportional contribution from each toxicant.

However, available data do not indicate additivity for chronic toxicity. EPA further recommends that chronic toxicity not be considered additive, and that each toxic be considered individually.

Synergism has not been demonstrated to be an important factor in the toxicity of effluents. Field studies or effluent toxicity and laboratory tests with

specific chemicals support an inference that synergism is a rare phenomenon. (See TSD, page 24.) (See also response to comments in the 1980 Guidelines, Comment #9, 45 FR 79358, November 28, 1980.) Theoretically, antagonism is just as likely to occur, which might suggest that the criteria are overly protective in an environment exposed to contaminant mixtures.

EPA considers the criteria, when applied with the appropriate frequency and duration of exposure, to adequately protect wildlife. Three of the aquatic life criteria in this rulemaking are based on wildlife toxicity and exposure, (Selenium, DDT and Polychlorinated Biphenyls). EPA is in the process of developing a wildlife criteria development methodology to provide further guidance for wildlife concerns. Once this tool is developed, EPA will have a method of focusing criteria on wildlife issues.

26. *Comment:* Several commenters argue that the criteria do not apply to semi-arid ecosystems. None of the guidance issued to date expressly address the means to apply those criteria to semi-arid ecosystems found in Arizona. Ephemeral streams and effluent-dominated waters are distinct classes of waters that should be regulated to protect the aquatic species that typically inhabit them.

Response: Water quality criteria are toxicity based values, usually chemical specific. The criteria are based on toxic effects to a broad taxonomic group and do not consider the types of water bodies, such as semi-arid ecosystems, they may be applied to. Aquatic life criteria, when implemented as part of water quality standards, are meant to be protective of aquatic life. These standards are applied to specific waterbodies through designated uses. For this rulemaking, EPA assumes that States correctly define designated uses and the specific waterbodies to which those uses apply. EPA agrees that ephemeral streams and effluent dominated waters are distinct classes of waters. If a State feels an aquatic life use designation is appropriate for these waterbodies, then the aquatic life criteria will apply to protect that use. If not, then they will not apply. EPA is not promulgating designated uses for State waters. EPA is only applying appropriate aquatic life criteria to waters that States designated for aquatic life protection.

27. *Comment:* Comment was made that EPA should allow an alternate methodology for calculating the Final Acute Value when dealing with small data sets.

Response: EPA has considered alternate methods for calculating the Final Acute Value (FAV). The present methodology was developed by the Agency's guidelines committee, subjected to outside peer and public review, and is a reasonable technique. EPA develops a Final Acute Value on as large a data set as available. The guidelines generally require eight separate families for derivation of acute values (1985 Guidelines, p. 23). EPA considers this to be an adequate data set for calculation of the FAV. As the data set grows it only provides additional confidence of the scientific basis for calculating the Final Acute Value. The present methodology has been reviewed both within and outside the EPA for scientific merit. EPA considers the present methodology to be sound. The guidelines are presently under review. The method suggested by the commenter is relatively new, and it and other statistical bases for criteria development are being reviewed in the Agency's current effort in reviewing the criteria development guidelines. It is intended that the guidelines reflect the best science and to that end EPA will consider all aspects to continue to provide a sound and scientifically based methodology.

28. *Comment:* Comment was received that the aquatic life criteria and guideline methodology, contrary to EPA's assertions, have not undergone sufficient scientific peer review.

Response: EPA does not agree. The criteria and underlying methodology guidelines were widely distributed to interested parties. These drafts were made available to and thoroughly discussed with experts within EPA, industry, and academia. These interactions have provided many useful comments and information which greatly improved the scientific basis of the criteria and methodologies. The methodologies were further reviewed by an independent Science Advisory Board which EPA considers to constitute external peer review. (SAB Water Quality Criteria, A Report of the Water Quality Criteria Subcommittee, April 1985). The SAB noted that since EPA's initial efforts in developing water quality criteria, the process has undergone considerable evolution. The SAB felt that each revision represented a more sophisticated and realistic approach. EPA encourages and makes every reasonable attempt to include as much of the scientific community as practical in carrying out its responsibility under the Clean Water Act.

29. *Comment:* Comment was received that EPA states in the proposal that the methodology for developing aquatic life criteria have been approved by the Science Advisory Board (SAB); however this approval was not unqualified.

Response: In its comments on EPA's 1985 guidelines, the SAB committee noted that EPA had developed a more scientifically sophisticated and realistic set of guidelines. (SAB Water Quality Criteria, A Report of the Water Quality Criteria Subcommittee, April 1985.) It noted approvingly that EPA considers such issues as mode of exposure, level of protectiveness and ecosystem protection. It further noted that the guidelines took advantage of advances in recent scientific research. The report, being a critique, did note areas where the guidelines could be improved and areas where additional research might be helpful. Overall the SAB report was supportive of the Agency's aquatic life criteria development guidelines.

30. *Comment:* Numerous comments were received with regard to the metals criteria. It was noted that the draft rule did not make clear what analytical method was to be used for implementation and that metals criteria should not be interpreted in terms of total recoverable or acid soluble metal. It was asserted that dissolved criteria would be more appropriate, and in many cases effluent limits based on dissolved metals only would be more appropriate. Many commenters urged that the rule should implement the metals criteria using the site-specific water-effect ratio, in order to target the bioavailable fraction of pollutant.

Moreover, it was asserted that the copper criteria document states that organic carbon has a strong effect in reducing copper toxicity, and that the copper criterion should be recalculated for waters having TOC greater than 2–3 mg/L. Furthermore, it was argued, the toxicity of several metals are related to pH, total organic carbon (TOC), speciation, as well as the hardness.

The commenters asserted that the criteria are overly protective when applied to the field, and are overly protective because they are not site-specific.

Another commenter argued that the criteria are underprotective because they do not account for synergism or additive effects.

Response: These diverse and recurring comments have been aggregated above because they deal in large measure with the phenomenon that the same metal concentration may cause different toxicity from place to place due to chemical differences from place to place. In natural waters metals may exist in a variety of dissolved and particulate forms. As discussed

elsewhere in the preamble, the bioavailability and toxicity of a metal depends strongly on its exact physical and chemical form. See Section F.7. It also depends on the site-specific chemistry of the water, and on the other materials contained in the water.

Because of (a) the complexity of metals speciation, (b) the varying degrees of bioavailability and toxicity of the many forms and complexes, and (c) the additive, synergistic, and antagonistic influences of other materials in the water, there is no one chemical method that can assure that a unit of concentration measured in the field would always be toxicologically equivalent to a unit of concentration occurring in the laboratory toxicity tests underlying the criteria. Consequently, simply choosing a particular chemical method (such as total recoverable metal or dissolved metal) to measure attainment of the metals criteria would not assure the appropriateness of the criterion for the water chemistry of the various sites at which the criteria apply.

In response to comments, EPA is implementing the criteria in terms of total recoverable metal while calculating the criteria value using the water chemistry adjustment provided by the "water-effect ratio" procedure for certain metals as described and reocmmended in its current Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, May 1992. This approach takes into account, directly, water characteristics such as total organic carbon, pH, metals speciation and hardness, as suggested by the commenter.

The water-effect ratio approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory test waters. It involves running toxicity tests for at least two species, measuring LC50s for the pollutant using (a) the local receiving water collected from the site where the criterion is being implemented, and (b) laboratory toxicity testing water made comparable to the site water in terms of chemical hardness. Because the water-effect ratio procedure, described in the above referenced guidance, provides a biological measure of differences in water chemistry, the ratio between site water and lab water LC50s is used to adjust the national acute and chronic criteria to site-specific values.

Because the water-effect ratio is a comprehensive measure of differences in bioavailability and toxicity, including the differences between dissolved and particulate bioavailability, it will produce a more appropriate criterion than simply expressing the criteria as dissolved metal. Some metals, such as copper and silver, can exist in a variety of dissolved forms that differ greatly in toxicity. The water-effect ratio is the best procedure EPA currently has for measuring such differences.

The water-effect ratio is also a reasonable method now available for accounting for synergistic and additive effects of pollutants. Regardless of whether a value less than or greater than one is measured for the water-effect ratio, synergistic and additive effects of other pollutants in the site water are working against the antagonistic effects of any metal binding agents present.

EPA recognizes that the comprehensive qualities of the water-effect ratio do come at a cost. The procedure will yield results that are locally the most appropriate, but it is more difficult and expensive than a purely chemical approach. Consequently, performing such an analysis is not mandatory. In the absence of acceptable data, the rule assigns the ratio a value of 1.0, which yields no change in the national criteria. The rule also stipulates that the water-effect ratio cannot be set at a value different than 1.0 unless such value protects the water body from the toxic effects of the pollutant, and is derived from suitable tests on samples appropriately representative of the water body. Consequently, inadequacies, uncertainties, or ambiguities in the data will also result in the water-effect ratio being set at 1.0.

The type of specific data needed to implement the method is described in guidance: The 1992 Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, and the 1983 Water Quality Standards Handbook. As discussed in Section 7 of the preamble, EPA is currently developing more specific procedures and methods to assist States in implementing the water-effect ratio approach.

31. *Comment:* A commenter asserted that laboratory tests using artificial testing conditions have little or no direct applicability to actual discharges and receiving water situations, therefore the criteria are overprotective.

Response: Laboratory tests are not conducted in pure water and pollutants are not solely in a free ionic form (complexed by nothing but water). (For example, laboratory waters are described in some detail in various standard protocols for doing toxicity testing, e.g., American Society for Testing Materials (ASTM), Standard E729, "Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.") Laboratory waters have low, but still significant, levels of organic carbon and suspended particles that are in the range of a significant number of receiving waters. In the case of heavy metals, for example, certain particulate forms may be partially bioavailable and particulate forms in effluents may become dissolved after discharge into receiving waters. It is not appropriate to attribute toxicity solely to a particular form of metal: This has never been clearly demonstrated for any metal, being only questionably inferred under very restrictive conditions. (See response to public comment for the 1980 Guidelines, comment nos. 17, 19 & 20; 45 FR 79359.)

Because water quality criteria are derived to be protective in almost all situations, they may be overprotective in some situations. Moreover, site water effects may be most prevalent for heavy metals, this rule thus provides for site-specific determination of criteria values for metals based on local water-effect ratios.

32. *Comment:* EPA's aquatic life criteria for metals do not take into account the effect that water chemistry and metals speciation has on toxicity. EPA should withdraw criteria (such as zinc and copper), and provide criteria that vary with pH, total organic carbon (TOC), and other factors that affect speciation and toxicity.

Response: While it is true that speciation and site water chemistry can modulate toxicity and that the national criteria do not account for most of these factors, we do not agree with the comment that we should withdraw the criteria. There is inadequate data on enough species and conditions to adjust for all important factors in the national criteria, although current work is trying to address this situation. However, this uncertainty is insufficient reason to not issue and apply criteria; criteria are sufficiently applicable without modification to most receiving waters and can be appropriately adjusted for other waters by the water-effect ratio approach. The purpose of water effect calculation is to provide a means for setting the value appropriate for the site-specific water chemistry, where sufficient data are available. By providing for such a calculation in the rule, the criteria thereby appropriately incorporate such factors.

33. *Comment:* EPA's aquatic life criteria do not take into account acclimation. As a result, the criteria are overly protective.

Response: Acclimation is the ability of organisms to tolerate higher concentrations or pollutants or other conditions, developed through an exposure to such chemical or condition

without apparent adverse effects. Studies with fish have not documented large changes in sensitivity because of acclimation effects, the typical factor being about two. Furthermore, significant changes have usually been reported under very restrictive and unusual exposure conditions—a prolonged exposure in a narrow concentration range near chronic toxicity values followed by a sharp rise to acutely toxic concentrations. Acclimation of individuals under most exposure conditions would be less and does not persist for long once exposures drop significantly below toxic levels. To try to account for such conditions in nationally applicable criteria is not feasible. Adaptation of populations can occur due to natural selection, but is not well described; in any event, it cannot be accounted for in any generally applied presumptive standard but only documented on a site specific basis.

34. *Comment:* Several commenters asserted that the metals criteria are below natural background levels, as shown by EPA's own studies. Thus, such criteria are overprotective and invalid.

Response: EPA studies which examine USGS data, appear to indicate that the natural background concentrations in undisturbed watersheds at times exceed the criteria for copper, lead, zinc, iron, and aluminum. However, recent work by USGS and by others (for example, Windom et al. in Environ. Sci. Technol. Vol. 25, 1137) indicates that much of this data, that is the copper, lead, and zinc data, are not valid. The measured concentrations of these metals are largely artifacts of external contamination of the sample during collection and processing. At this time USGS has suspended collecting data on these metals nationwide, until improved methods can be implemented in their central laboratories.

EPA notes that USGS generates a large portion of the data available for the nation's ambient waters, and that the federally approved protocols are used by a variety of other agencies that collect ambient data. Consequently, it appears likely that many waters may be improperly determined not to be attaining the metals criteria.

Based on USGS results, the data for the metals on the priority toxic pollutant list most likely to be affected by external contamination are arsenic, beryllium, cadmium, copper, mercury, lead, and zinc. The nickel data is unlikely to be affected. USGS suspects that filtering artifacts, rather than contamination, may produce anomalies in dissolved data for other metals not in today's rule. USGS has not yet ascertained quality of its selenium and silver data. Moreover, EPA has reviewed the data used in establishing the EPA metals criteria and does not believe these criteria are affected by the analytical problems noted by USGS. (Erickson, 1992, personal communication, in EPA's record).

To assure the reliability of the data in the lower microgram per liter range, priority toxic pollutant metals should be sampled and analyzed using protocols that involve ultra-clean reagents, ultra-clean Teflon or polyethylene labware, and ultra-clean laboratory environments.

EPA is not aware of reliable analytical data showing excursion of aquatic life criteria by natural background concentrations of the metals covered by this rule.

35. *Comment:* Commenters asserted that the acute and chronic averaging periods are unnecessarily restrictive, and were set in an arbitrary manner. As the acute criteria are derived from 48–96 hour tests, the EPA's one-hour averaging period for acute criteria cannot be correct. As the chronic criteria are derived from 30–360 day tests, the EPA's four-day period for chronic criteria cannot be correct. Pollutant specific averaging periods should be used, based on the latest scientific information, including the 1983 work of Mancini (Water Res. 17: 1355), which dealt with the effects of time varying concentrations.

Response: The quality of ambient water typically varies in response to variations in effluent quality, stream flow, and other factors. Organisms in the receiving water are not experiencing essentially constant exposure as in laboratory bioassays, but fluctuating exposures which may include short periods of high concentrations potentially causing adverse effects. EPA's criteria formulations therefore include an exposure period for concentration averaging which must be sufficiently short to limit elevated concentrations that might cause harm to aquatic life.

The 1-hour average exposure for the criteria maximum concentration (CMC) was derived to protect against the effects of fast acting toxicants like ammonia and cyanide. Thus, short-term spike increases in certain of these toxicants have been observed to cause toxic effects. (See 1991 Technical Support Document, appendix D.)

The 4-day averaging period for the criteria continuous concentration (CCC) is based on the shortest duration in which chronic effects are sometimes observed for certain species and toxicants. The most important consideration in establishing duration criteria is how long the exposure concentrations can exceed the criterion without affecting the endpoint of the test (e.g., survival, growth or reproduction). EPA believes 4 days should be fully protective even for the fastest acting toxicants.

The approach of Mancini (or similar modeling cited in Chapter 2 of EPA's Technical Support Document) is certainly a promising one for establishing averaging periods. It and similar methods are being evaluated for incorporation as options into new water quality criteria guidelines. However, the validity and applicability of these methods are still not completely resolved. Applying Mancini's model to available toxicity data forces an analyst to immediately deal with problems of delayed mortality and limitations on observation times. The fit of the model to data is also only approximate and requires professional judgment in appropriately applying it.

Because of such considerations, EPA's current approach remains reasonably protective and is therefore appropriate.

36. *Comment:* Commenters asserted that the three-year return interval is too stringent for marginal excursions of water quality criteria. As a result the criteria are overprotective. It is argued that: EPA's Technical Support Document has cited information on recovery from severe or catastrophic acute stresses as the basis for its recommended return interval for both acute and chronic criteria; EPA's criteria, however, are intended to avoid even slight stresses; and cites on EPA draft staff analysis showing that a three-year return interval for slight excursions results in a billion-year return interval for a severe stress.

Response: EPA is promulgating its proposed general rules of applicability (40 CFR 131.36(c)(2)) for the return interval based on guidance contained in chapter 2 and appendix D of the TSD. As discussed in the TSD, EPA expects the three-year return interval to provide "a very high degree of protection" (TSD at page 36). The three-year return interval approximates the same degree of protection as a once-in-ten-year seven-day average low flow design condition (7Q10), the use of which has historical precedent and is in many State water quality standards. (*Id.*)

Given the state of the science, and the limitations of available data, EPA as a matter of policy, takes the position that it should assure adequate protection and takes a conservative approach. This policy is also consistent with and recognizes historic program practices

and procedures used by both the Agency and the States in implementing the water quality standards and related implementation programs. (Guidelines for Developing or Revising Water Quality Standards, April 1973, p.7.)

The draft EPA staff analysis referred to by the commenter was prepared solely as background information for discussions by the committee reviewing the methodological guidelines. EPA neither confirms or rejects the calculations.

37. *Comment:* The Guidelines indicate that criteria may be derived using data that have not undergone formal peer review, but the Guidelines do not offer meaningful guidance to determine the acceptability of test results. Inappropriate data are used to derive criteria.

Response: Toxicity tests methods have changed over time to improve precision and accuracy. This requires use of judgment in evaluation of test acceptability and results. EPA utilizes the Guidelines and professional judgment to reject unacceptable data (see Unused Data sections of Criteria Documents). Reservations about data are considered when judging acceptability of results in the context of criteria development. EPA also receives public comments on the criteria documents.

EPA's criteria for accepting or rejecting data do not depend on whether the data were published in peer-reviewed journals. The guidance provided in the 1985 Guidelines is predicated on more explicit review considerations than may be provided by most publishers of peer-reviewed journals addressing toxicity tests with aquatic organisms. EPA has observed that the public comments have also raised specific technical issues regarding the validity of peer-reviewed results.

Occasionally values in publications are not used because they are not biologically important or statistically different. In addition, recalculation of authors raw data may occur. This is part of the judgment required by criteria document preparers.

All published and unpublished references cited in aquatic life criteria documents are on file at EPA's Duluth or Narragansett laboratories.

38. *Comment:* A commenter asserted that analysis indicates that databases that have few genus mean acute valves (GMAVs) produce significantly more restrictive final acute valves (FAVs). The commenter asserts that EPA needs to increase the size of such databases to avoid promulgation of excessively restrictive water quality criteria.

Response: This comment summarizes hypothetical calculations in which the effect of the number of tested genera on the FAV were examined. It concludes that because the FAV changes as this number changes, the database size is insufficient.

EPA disagrees with the commenter's interpretation of the analysis. The commenter studied the effect of database size by changing the insensitive species while keeping the four most sensitive species the same (Commenter number 133, Appendix A., page 26). It is therefore quite expected and proper that the FAV would change as indicated. The FAV is designed to protect the fifth percentile in the sensitivity of organisms (see 1985 Guidelines, section IV, p. 26) (also 50 FR 30784, at pg. 30794; July 29, 1985). Using available suitable tests as representative of the species that are to be protected is the most reasonable feasible approach to establishing criteria values. If the sample size is 8, the four most sensitive values must be considered representative of half of the species that are to be protected and the fifth percentile would be expected to be somewhat below the lowest value. If the sample size is 32, the four most sensitive values are representative of the lowest 12.5% of the species and the fifth percentile would be expected to be near the middle of these values. And it is not just the fifth percentile that is expected to change but the entire distribution—for a sample size of 8 the mean will be near the highest of the four most sensitive values; for a sample size of 32 the mean would be far above the four most sensitive values (near the sixteenth most sensitive value).

Therefore, the response of the FAV cited in this comment is fully expected and appropriate; it in no way indicates a deficiency in the procedure or the database requirements. Similarly, the response of the FAV cited in site-specific calculations is also reasonable. If site calculations are based on fewer species and if these species tend to be more sensitive on average than the total dataset, the FAV should be lower.

39. *Comment:* A comment was received that most of the data used to derive the criteria were not developed for that purpose.

Response: The reason a toxicity test was originally conducted is not important. If the data are considered to be pertinent, of acceptable quality, and meet our protocols and other data requirements in the 1985 Guidelines, they should be used in the derivation of water quality criteria. Moreover, as stated in the 1985 Guidlines, p. 26, "confidence in a criterion usually increases as the amount of pertinent data increases."

40. *Comment:* A commenter asserted that since EPA has acknowledged that species can exhibit a significant substance tolerance range and inter-laboratory variability, the databases for many of the criteria must be significantly improved before they can be considered suitable for use in the promulgation of water quality standards. The commenter cited. Schimmel, S.C., 1981. Results: Interlaboratory Comparison—Acute Toxicity Tests Using Estuarine Organisms (EPA–600/4–81–001).

Response: Inter- and intra-laboratory variation is expected and unavoidable. Variation that causes imprecision is undesirable, but is not nearly as undesirable as is error that causes bias (Lemke, A.E.; 1981; Inter-Laboratory Acute Testing; EPA 600/3–87–005). More data are always desirable, and EPA welcomes the submission of additional high quality pertinent data, whether or not they have been peer-reviewed. The guidelines for deriving water quality criteria for aquatic life specify minimum data requirements that are intended to ensure reasonable confidence in the appropriateness of the resulting criteria.

The Science Advisory Board review referenced earlier at comment 29 accepted the EPA aquatic life 1985 Guidelines which permit the use of a single test to fulfill the minimum data base requirement. The results cited by the commenter when referring to a study conducted by Schimmel, 1981, were used by the Agency in developing the revised aquatic life guidelines in 1985. The guidelines specifically allow the use of a single-species test to fulfill the requirement for a species mean acute value. (1985 Guidelines, p. 29.)

41. *Comment:* A commenter asserted that very few of the studies used to develop the criteria cited any assessment of precision or accuracy and there was no standardization of testing protocols. Consequently, the commenter believes that the data are inadequate for the promulgation of water quality standards; and that only data from current testing protocols should be used.

Response: There is no way to fully assess the accuracy of a toxicity test because the "real" toxicity of the test material cannot be known. Various lines of evidence including results of toxicity tests and correlations between species and between test materials can help increase confidence in an estimate of toxicity. Studies of inter- and intra-laboratory variation are conducted to allow assessments of precision. Very

few, if any, studies are perfect, even if they exactly followed a "current testing protocol"; the acceptability of each study must be judged individually. Studies that follow approved methodology are more likely to be high quality, but some are not; some studies that deviate from approved methodology do provide useful information.

42. *Comment:* A commenter suggested that EPA provided no data to support its contention that acute-chronic ratios are similar in fresh and salt water.

Response: As quoted by the commenter, the 1985 Guidelines, p. 15, states that "When data are available to indicate that these ratios and factors are probably similar, they are used interchangeably." The guidelines do not contend that acute-chronic ratios are similar; the guidelines state that the ratios should be considered similar only when data are available to support the decision of similarity. Ratios are usually considered to be dissimilar if the range is greater than a factor of 10 (1985 Guidelines, p. 45).

43. *Comment:* A commenter asserted that EPA should establish a separate warm-water cadmium criterion, because the national criterion is set based on rainbow trout, a cold-water fish.

Response: The commenter misconstrues EPA's criteria development protocol. EPA's aquatic life guidelines require data for the family Salmonidae as one of the minimum eight species required to calculate a water quality criterion (1985 Guidelines, Section III, p. 23). EPA did not base its criteria for cadmium solely on rainbow trout data. (Rainbow trout is a member of the family Salmonidae.) EPA used this data to meet one of the requirements for tested species required by the guidelines (Ambient Water Quality Criteria for Cadmium-1984, Table 2, p. 6). Moreover, a review of toxicity data in EPA's criteria document does not indicate that the sensitivities of so-called coldwater for warmwater species differ significantly (Ambient Water Quality Criteria for Cadmium-1984, Table 2, pp. 46–47). EPA had no scientific basis to develop separate cadmium criteria based on the division of aquatic species into coldwater or warmwater types.

44. *Comment:* A commenter argued that because EPA did not follow its own Guidelines, EPA should withdraw the lead criteria document, update and complete the species database, and recalculate an appropriate freshwater lead criterion.

Response: EPA recognizes that the lead criterion is based on seven rather than eight freshwater acute tests as recommended in the aquatic life guidelines. EPA has determined that the criteria are valid and that an additional test would not cause a sufficiently large change in the criteria (in the computation formula [see page 97, appendix 2 of the Aquatic Life Guidelines] increasing N, the number of species tested, by one with an LC50 value that is higher than the four most sensitive values only increases the acute criterion from 34 to 37 µg/l, at a hardness of 50). (See Memorandum to the Record, Kennard Potts, March 12, 1992.) This change does not warrant withdrawing the current criteria. This decision to establish the criterion based on seven tests is consistent with Section 12—Final Review, paragraph B, page 57 of the Guidelines, which allow "On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, should be derived using appropriate modifications of these Guidelines."

45. *Comment:* A commenter asserted that there is a significant error in the lead saltwater acute database, and it has implications on the validity (or lack thereof) of the saltwater acute-chronic ratio for lead.

Response: EPA recognized the error in the ambient water quality criteria document for lead in the genus mean acute value (GMAV) for *Fundulus* and corrected that error in the criteria matrix included in the proposed rule. The result of this correction was to increase the criteria maximum concentration (CMC) to 220 µg/l and criteria continuous concentration (CCC) to 8.5 µg/l.

The use of the acute-chronic ratio (ACR) of 51.29 for lead is reasonable, given the available information (see p. 9, Ambient Water Quality Criteria for Lead). The GMAV for *Mysidopsis* included in the criteria document for lead (p. 26), is ranked 7th of the 11 genera tested for lead toxicity. Therefore, *Mysidopsis* might be considered among the less sensitive genera as suggested by the commenter. However, the GMAV for *Mysidopsis* is less than 10 times the value for *Mytilus* suggesting the acute sensitivities of two genera are not greatly different. (*Ibid.*)

Other factors are more important than species sensitivity in selecting the final acute to chronic ratio (FACR) for lead. EPA did not believe that the data from chronic tests with freshwater species clearly demonstrated that acute-chronic ratios changed with acute sensitivity for the following reason. Acute values for the copepod (*Acartia*), amphipod (*Ampelisca*) and dungeness crab (*Cancer*) are within a factor of less than 2 times the value for *Mytilus*. EPA then assumed that the ratio was not related to acute sensitivity. Even if an ACR of 2.0 could be justified for larval molluscs and lead, this value should not be applied to crustaceans when an experimentally derived value for *Mysidopsis* and *Daphnia* are available. See Table 3, Ambient Water Quality Criteria for Lead.

The commenter felt EPA was inconsistent in its use of ACR values from toxicity tests and the ACR of 2.0, when the most acutely sensitive organism is larval molluscs. EPA used acute-chronic ratios from toxicity tests for lead and silver and the value of 2.0 for copper (see ambient water quality criteria documents for lead and copper, and the draft water quality criteria document for silver, 55 FR 19988, May 14, 1990. The reason experimental ACR values were selected for lead instead of the value of 2.0 are described above.

46. *Comment:* A commenter suggested that the saltwater silver criterion is not valid and submitted test results to support this claim.

Response: Some of the data presented by the commenter (Number 80) to show problems in the silver data base actually supports its validity. Acute and chronic values for *Mysidopsis* are within the range reported by others. Silver's acute toxicity to sheepshead minnows is at silver's solubility. This probably accounts for the large range in reported silver toxicity. For these species only flow-through tests with measured silver concentrations were used. The data submitted in the public comment did not include information on the test conditions, and would not be used in criteria derivation without that information. See Ambient Water Quality Criteria Document for Silver, 1980; see also draft criteria document referenced in 55 FR 19988, May 14, 1990.

Results from silver tests from Cardin (1986) where control mortalities exceeded 10% were not used. In tests with copepods and larval silversides and flounder, control mortality of <20% is judged acceptable by those who conduct tests with fragile life stages of these species. Control survival requirements for chronic tests (ASTM protocol) are more liberal than those for acute tests.

EPA's rapid chronic toxicity protocols are not appropriate test methods for deriving chronic values for water quality criteria derivation because they are not true chronic tests. Only early life-stage tests with fish and partial and entire life-cycle tests with fishes and invertebrates are acceptable as provided

for in the 1985 Guidelines, section VI, part E, pages 37–39.

47. *Comment:* Comment was received that the proposed silver numeric standards should be revised to apply to the free silver ion. The commenter asserted that available information demonstrates that only the free silver ion is highly toxic to aquatic organisms while most other common forms of silver, whether soluble or insoluble, are several orders of magnitude less toxic.

Response: It would be appropriate to interpret the criterion in terms of the free silver ion only if all the silver that was included in the measured or nominal concentrations of silver in the pertinent toxicity tests would have been measured as free silver ion. Some silver would be complexed by such things as chloride, hydroxide, or carbonate in acute toxicity tests. Moreover, the feeding of the organisms in the chronic tests would result in complexation of at least some silver. This has been postulated as the explanation as to why (a) the addition of food to an acute toxicity test raises the EC50 for daphnids and (b) silver has appeared to be more toxic to daphnids in some acute toxicity tests than in comparable chronic tests. Absent a criterion that correctly applies to the free silver ion, the water-effect ratio procedure incorporated into today's rule is an appropriate means to deal with differences in toxicity caused by silver speciation.

48. *Comment:* A comment was made that the numeric silver standards should not be proposed until EPA's May 14, 1990 proposed revisions to the current ambient silver water quality criteria are finalized to reflect comments about the current science as submitted for the record of that proposal.

Response: EPA agrees with some of the comments on the May 14, 1990 proposed silver criteria. As a result, additional testing is planned and a revised document for silver will be prepared, but this is not anticipated in the near future. With this rule, EPA is promulgating its 1980 criteria for silver, because the Agency believes the criteria is protective and within the acceptable range based on uncertainties associated with deriving water quality criteria. In addition, the water-effect ratio promulgated in this rule offers development of appropriate site-specific criteria.

49. *Comment:* A commenter asserted that in the studies of Calabrese and Nelson 1974, Calabrese et al. 1973, and Coglianese 1982, the properties of the dilution water significantly affected the metals toxicity.

Response: EPA agrees that there may be differences in metals toxicity between laboratory test waters and ambient waters. For this reason, EPA has incorporated use of water-effect ratios in this rule (see Section F–7 of this preamble and an earlier response to public comment).

50. *Comment:* A comment was made that EPA should not use the metals toxicity data from Dinnel et al. 1983, who were evaluating alternative conditions in order to refine the testing protocol.

Reponse: EPA disagrees. Valid toxicity data can come from tests used to develop test methodologies and EPA determined that the Dinnel, et al. toxicity data was valid toxicity data. For example, see draft Ambient Water Quality Criteria for Silver, September 24, 1987.

51. *Comment:* A commenter argued that the metals toxicity data from Eisler 1977 are not valid because they involve 168-hour static tests. The currently recommended maximum duration for such tests is 48 hours.

Reponse: EPA disagrees. Most values reported in criteria documents are 96-hour LC50s for adult clams. EPA considers the Eisler data to be from valid and reliable tests even though they were based on other than 96-hour tests.

52. *Comment:* Comment was received that the 20–25 degree Celsius temperatures and 12:12 hour light cycle used to obtain the metals toxicity data of Lussier 1985, do not match current mysid protocol's 26–27 degree Celsius temperature and 16 hour light:8 hour dark light cycle.

Response: The submitted comments provided no data to show the effect of temperature or lighting on the chronic value. EPA does not consider Lussier's results to be artifacts because test conditions duplicate conditions found in nature.

53. *Comment:* The zinc and chromium toxicity data of Nelson 1972 should not be used because it involves an endpoint not recognized by EPA approved protocols.

Reponse: EPA disagrees. The test endpoint (the development of a hinge after 48 hours) is the same as that of the American Society for Testing Materials (ASTM), which is a standard, recognized protocol.

C. Human Health Criteria

The guideline references in the sub-section refer to Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Quality Criteria Documents, 45 FR 79347, November 28, 1980. The short reference in this sub-section is "the 1980 Guidelines."

54. *Comment:* A comment was received that use of the harmonic mean flow is a new technique and is not consistent with the way sampling is in fact done.

Response. Harmonic mean flow determinations have been adopted because the underlying hydrology support this analytical procedure. Such flows are applied only to human health criteria where human exposure is expected over a long period of time. It is derived by analyzing the pollutant mass a consumer would received by, for example, consuming a uniform amount of water everyday from a natural waterbody receiving a uniform mass loading of a pollutant.

Theoretical development as shown in the reference cited in footnote 2 of the preamble of the proposed rule (56 FR 58438) demonstrates that actual human exposure is best ascertained by using harmonic mean flow to account for concentration variation in computing the actual exposure to a pollutant.

55. *Comment:* The exposure assumptions used by EPA in developing human health criteria do not account for the variability of the population nor the consideration of exposure to more than one chemical and more than one exposure route.

Response: The EPA assumed exposure model was based on estimates or measures of national norms (see preamble discussion on human health criteria, Section F–3 and 1980 Guidelines, 45 FR 79347, Nov. 28, 1980). EPA has suggested in these and other documents that States select more appropriate fish and other aquatic life consumption rates for local populations. Some States have done so.

EPA's risk calculations aim to protect individuals exposed at an average level (*Ibid*). Thus, EPA does the calculation for average daily consumption of 2 liters of water and 6.5 grams of aquatic life for a 70 kg size individual over a 70-year lifetime. Then the Agency selects a conservative risk level (e.g., 10^{-6} or 10^{-5}) for such an average person.

People who do not fit this norm are subjected to more or less exposure to the pollutants of concern. For example, assuming a criterion based on a 10^{-6} risk level, a person who consumes 65 grams of contaminated aquatic life per day from ambient water at the criterion level would be protected at the 10^{-5} risk level, still well within EPA's desired risk range.

The effects of multiple toxicants is a more difficult problem. The science of toxicology has not developed generic ways to combine multiple risks. For

specific chemicals, analysis would focus on whether the same organ and mode of toxicity were implicated. For example, it may be more significant if two chemicals both caused liver cancer as compared with a situation where one chemical was carcinogenic and the other caused other systemic effects. Thus, a case-by-case approach is currently the only feasible approach available.

EPA has clearly delineated the human health models it uses. That is, one for systemic toxicity and one for carcinogenicity. The Agency's accepted factors are available in the Integrated Risk Information System (IRIS) and in the section 304(a) water quality criteria documents, and in the 1980 Guidelines, page 79353. Locally specific risk can be estimated using the readily available information based on monitoring data for local public water supplies or fish tissue analysis for specific chemicals.

However, in a rule affecting large areas of the country, EPA's view is that it should focus on the average exposure, as a protective basis for this rule. States may take subsequent action to provide the means to account for specific cases. This rule attains that goal.

56. *Comment:* Since EPA is undertaking a dioxin reassessment, it should not be included in this rule.

Response: We believe there are sound reasons for proceeding to promulgate dioxin criteria. First, the dioxin criteria are within the range of scientific defensibility. EPA's action will also encourage and support the fourteen States now considering adopting a dioxin criterion to complete their action. Most of those States are relying on the same data used by EPA to derive its criterion. Individual Control Strategies developed under section 304(l) of the Act contain limits on dioxin as appropriate, so there will be no immediate impact from this promulgation. It is too early in the process of scientific reassessment to support major changes in either the substance or timing of regulatory decisions related to dioxin.

It should also be pointed out that 42 states and territories have adopted criteria or translator procedures for dioxin; EPA approved 40 of those actions.

57. *Comment:* Several commenters raised questions concerning the methodology used to develop the human health criteria. Some stated that the CWA methodology did not reflect changes in risk assessment and therefore was obsolete. Some commenters noted the differences between the risk ranges under the CWA and the SDWA and argued that the acceptable range of cancer risk should be the same under both statutes. Several commenters discussed specific contaminants and argued that the regulatory levels under the CWA and SDWA should be the same. One commenter provided a list of contaminants where drinking water standards were more stringent than the proposed criteria and urged that criteria should be established equal to drinking water MCLs.

Response: EPA has developed risk assessment methodologies to protect human health from contaminants in drinking water and ambient waters. Although there are some differences in the methodologies, both are scientifically defensible. Both methodologies stem from Agency risk assessment values for noncancer effects (the Reference Dose or Rfd) and for cancer effects (the cancer potency factor, q1*). See Water Quality Criteria documents (the 1980 Guidelines), 45 FR 793180 (November 28, 1980) and 56 FR 3526 (January 30, 1991) (SDWA Phase II regulations).

Both methodologies follow the Agency's Guidelines for Carcinogen Risk Assessment (the Cancer Guidelines), 51 FR 33992 (September 24, 1986). Under both programs, the Agency takes the position that there is no threshold for carcinogenic effect unless there is convincing evidence to the contrary. Both programs therefore recommend that contaminant concentration for carcinogens should be zero based on this "no threshold" presumption. See SDWA Phase II regulations at 56 FR 3533 and the 1980 Guidelines at 45 FR 79324.

The nature of the human exposure to contaminants is somewhat different in the two programs, and the assumptions used in the methodologies reflect those differences. Under the SDWA, it is protection from exposure to contaminants in drinking water that is the concern. The maximum contaminant level goals (MCLGs) reflect the level of contamination where "no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety." 42 U.S.C. 300g-1(b)(4). For those contaminants that are not suspected of posing carcinogenic risk for drinking water, the Agency bases the MCLG on noncancer effects and adjusts the RfD to reflect drinking water consumption of an average of two liters of tap water per day by a 70 kg adult. This value is further adjusted by exposure assumptions; the key assumption in the drinking water program is that significant exposure to a contaminant comes from sources other than drinking water (*e.g.*, ingestion of food, inhalation), and it is prudent to allow for the contingency that other exposure may occur. While EPA uses actual exposure data where they are available, the Agency assumes, as a default position, that drinking water contributes 20%–80% of the total exposure to a contaminant. 56 FR 3532. MCLs can also be adjusted for non-health reasons, such as treatability and detectability.

Under CWA section 304(a), EPA developed human health criteria to protect for exposure to ambient water contaminants. In this case, exposure comes from ingestion of surface water and consumption of aquatic organisms which are assumed to have bioconcentrated pollutants from the water in which they live. Accordingly, the 1980 Guidelines assumes the consumption of two liters of water and the ingestion of 6.5 grams of fish per day, and the bioconcentration potential of a contaminant in fish tissue may be a significant factor in the human health criteria value. The exposure assumption in the 1980 Guidelines differs from that in the drinking water program. If data were available on exposure to a contaminant from other media such as air or non-aquatic diet, such data could be used in setting criteria. Absent such data, EPA assumes, as a default position, that ambient water (i.e., aquatic exposure and organism ingestion) contributes 100% of the exposure to a contaminant. 1980 Guidelines, 45 FR 79323. EPA considers both methods to be protective of human health for their respective exposure scenarios.

EPA agrees with commenters that the Agency has chosen somewhat different risk levels in the two programs for determining MCLs and criteria for carcinogens, but does not agree that the different levels indicate major scientific differences. Under the SDWA, it is EPA policy to establish MCLs at a range associated with excess risks of one in ten thousand (10^{-4}) to one in one million (10^{-6}). In the CWA water quality criteria documents, the Agency presents a range of concentrations corresponding to incremental cancer risks of one in one hundred thousand (10^{-5}) to one in ten million (10^{-7}); the risk ranges are presented only as information. Under the usual process in which States develop water quality criteria, the risk management decision on an appropriate risk level is made by each State. In these circumstances, States have the flexibility to choose a risk level as long as the decision is well documented, was subject to public notice and comment, and protects water uses. In this rulemaking, EPA proposed criteria with an incremental cancer risk level of one

in a million (10^{-6}) for carcinogens. Today's action promulgates a risk level for each State to reflect the State's risk management decision where such a decision is discernable. See discussion in section F-5 of the preamble. In the Agency's view, the considerable overlap between the risk ranges in the two programs indicates that they are not significantly different.

Accordingly, EPA does not agree with commenters' arguments that the Agency must have identical risk assessments under the CWA and SDWA. At the same time, the Agency is studying the extent to which both methodologies might start with the same presumptions. If any changes to the methodologies seem appropriate, the changes would be proposed for public comment. In the meantime, because both methodologies stem from the same Agency risk assessment values, RfD and q1*, they are considered appropriate for deriving human health criteria for water contaminants. Therefore, as a general matter, EPA does not intend to revise the human health criteria unless and until there are changes in the 304(a) methodology.

One commenter urged the Agency to establish human health criteria equal to MCLs when the 304(a) methodology resulted in less stringent criteria. The commenter provided a list of contaminants for which the proposed criteria are less stringent than proposed or promulgated drinking water regulations for the contaminants (MCLs), and recommended that EPA promulgate water quality criteria equal to the MCLs for antimony, cadmium, nickel, selenium, silver, thallium, cyanide, ethylbenzene, toluene, 1,1,1-trichloroethane, benzylbutylphthalate, hexachlorocyclopentadiene, and 1,2,4-trichlorobenzene. EPA notes that there are five other contaminants in this proposed rulemaking for which the SDWA regulatory levels (either final or proposed) are more stringent than the proposed human health criteria; these are chromium, lead, chlorobenzene, trans-1, 2-dichloroethylene, and o-dichlorobenzene.

The fact that the numeric standards for these contaminants are different under the two programs is not a sufficient basis for replacing the proposed human health criteria with criteria equal to the MCLs. As discussed above, the methods used to derive the human health values under both the SDWA and the CWA are generally considered protective of human health. The differences that occur in the regulatory standards under the two statutes result from the assumptions used in their respective methodologies, particularly the default values chosen to estimate exposure. These assumptions are reasonable policy choices for implementing the statutory directives of the two programs. Since the CWA section 1980 Guidelines are adequately protective of human health, EPA does not consider it necessary to undertake a large scale revision of the proposed criteria in this rule to make them correspond to the SDWA standards. Moreover, EPA does not agree that MCLs are an appropriate value for a human health criterion since MCLs are partially based on feasibility considerations, including the availability of technology to achieve the regulatory level and the cost of such treatment. It is the MCLG that reflects solely health considerations. Accordingly, the Agency will not promulgate criteria equal to MCLs in lieu of less stringent proposed human health criteria. Except as noted below, the human health criteria are promulgated as proposed.

The Agency does find it necessary to withdraw the proposed human health criteria for seven contaminants pending further consideration. In the case of three contaminants—1,1,1-trichloroethane, methyl chloride, and lead—there is currently an insufficient basis for calculating human health criteria. For cadmium, chromium, selenium, and beryllium, the proposed criteria are no longer scientifically defensible. EPA is withdrawing the criteria while it evaluates all relevant data regarding the toxicity of these contaminants. The Agency's basis for deferring action on the human health criteria for these contaminants is discussed further below. For several of these contaminants, the Agency is today promulgating aquatic life criteria that are more stringent than the proposed human health criteria. However, the Agency recognizes that in limited circumstances, there might be regulatory voids in the absence of promulgated human health criteria. To minimize this potential problem, the Agency has added a footnote, footnote n, to the table setting out the criteria in § 131.36(b) that directs permit authorities to specifically address these contaminants in NPDES permit actions using the States' existing narrative "free from toxicity" criteria.

(A). 1,1,1-Trichloroethane

No public comments were received on the proposed human health criteria for this contaminant. However, in response to other comments, EPA evaluated the proposed criteria and has decided not to promulgate human health criteria. EPA proposed the human health criteria using an RfD based on inhalation data. However, the Agency has withdrawn that RfD from the IRIS database since it is generally not appropriate to use inhalation data to estimate oral risk. As noted above, EPA bases the proposed criteria on Agency-wide RfDs in IRIS. Since no such RfD currently exists, there is no basis to support the proposed values.

(B). Methyl Chloride

58. *Comment:* A commenter stated that the criteria should not be based on carcinogenicity but on systemic toxicity. Another commenter stated that it is inappropriate to establish criteria for methyl chloride based on the carcinogenicity for chloroform.

Response: EPA agrees there are now data available on methyl chloride itself, and it is no longer scientifically defensible to rely on surrogate data for chloroform. EPA is currently evaluating a q1* and RfD for methyl chloride for developing an RfD. In view of the availability of chemical specific data and the ongoing risk assessment process, EPA does not believe it is appropriate to promulgate human health criteria for methyl chloride at this time.

(C). Selenium

59. *Comment:* One commenter noted that in the case of selenium, EPA proposed a human health criterion of 100 ug/l even though the current MCL for selenium if 50 ug/l (the same as the MCLG). The commenter believes the numbers should be the same and urged EPA to set the human health criterion at the MCL.

Response: As discussed above, EPA does not intend to replace proposed criteria with criteria equal to the MCL solely because the latter is the more stringent level. However, in the case of selenium, the Agency has determined that further consideration should be given to recent data on selenium before setting the human health criteria. Selenium is an essential nutrient in humans and plays a vital role in cell metabolism. See Health Criteria Document for Selenium, (May 1989). In such instances, the Agency must evaluate evidence of the compound's essentiality as well as evidence of toxicological effects. The Agency's Science Advisory Board has noted that synergistic effects—the interaction between selenium and other inorganic chemicals—are an important consideration in determining regulatory standards. Moreover, there are individuals who, whether from diet or supplements, consume significantly more selenium than EPA estimates of average consumption levels.

During the development of drinking water regulations for selenium, the Agency discussed new epidemiological data that were becoming available. See 56 FR 3526 at 3538–39 (January 30, 1991). In view of these new data, the numerous complex issues concerning essentiality, the consumption of elevated levels by some members of the population, and the need to ensure a protective level, EPA is unable to determine the scientific defensibility of the human health criteria, and therefore will not promulgate human health criteria for selenium at this time.

(D). Beryllium

60. *Comment:* One commenter stated that EPA's beryllium criterion is too low (i.e., 0.0077 ug/l). The commenter alleged three serious flaws in the proposed criterion for beryllium. These are: (1) Beryllium does not pose a carcinogenic risk by ingestion; (2) EPA's use of animal inhalation and injection data to support a cancer risk by human ingestion is arbitrary and capricious and is not consistent with EPA's methodology in setting human health criteria for other metals; and (3) the proposed criteria are less than natural ambient levels as well as EPA's proposed drinking water standards and would have very significant and unwarranted economic impacts.

The commenter further argued the defects in the data upon which EPA relies are so fundamental that the classification of beryllium as a Group B2 substance is unreasonable; and the EPA should classify beryllium in Group D for purposes of its potential ingestion carcinoganicity, and should adopt a human health criterion for beryllium of 1.6 mg/l, based upon a no-observed adverse effects calculation for a non-carcinogenic substance. Information on the Agency's classification system for carcinogens is included in U.S. Environmental Protection Agency (EPA), 1986, Guidelines for Carcinogen Risk Assessment. 51 FR 33992, September 24, 1986.

Response: EPA does not agree with the commenter's argument that the Agency's weight of evidence classification of beryllium as a B2 carcinogen is incorrect. There is clear evidence of carcinogenicity through inhalation or injection in monkeys, rats and rabbits, and animal studies showing tumors at sites different from the route of exposure. On this basis, the Agency has concluded that the overall weight of evidence in beryllium studies proves sufficient evidence of carcinogenicity to support a B2 classification. Drinking Water Criteria Document for Beryllium, September 1991. However, the Agency has determined that it is necessary to give further consideration to the toxicity and carcinogenicity of beryllium through ingestion before promulgating human health criteria. In the final drinking water rulemaking regarding beryllium (see 57 FR 31776, July 17, 1992), Agency analysis of the ingestion route of exposure failed to provide definitive evidence that correlates ingestion with tumor appearance. Drinking Water Criteria Document at I–7. The Agency has determined that these ingestion analyses are relevant in this rulemaking and therefore the proposed criteria are not scientifically defensible. The Agency will give additional consideration to the question of whether beryllium in water could pose a carcinogenic risk to humans before issuing criteria and accordingly, will not promulgate criteria for beryllium.

(E). Lead

61. *Comment:* A commenter noted that EPA proposed a 50 ppb-lead human health criteria for consumption of water and organisms. The commenter argued that a 50 ppb criteria is not compatible with EPA's overall lead control strategy reflected under the drinking water standards, and recommended a 5 ppb lead health criteria.

Response: As noted above, differences in the proposed human health criteria and regulatory levels under the SDWA methodology are not, in themselves sufficient basis for revising the criteria. In this case, the original basis for the 1980 Guidelines and, in turn, the proposed criteria was however the MCL. In 1991, EPA promulgated a zero MCLG and treatment technique for lead in drinking water, which will, when effective, replace the current MCL. The treatment technique includes a 15 ppb lead action level at the tap.

In view of drinking water regulatory action, EPA has determined that it is not appropriate to promulgate a human health criteria based on a drinking water MCL that no longer reflects the Agency's position. The Agency has given preliminary consideration to other numeric values but has not yet reached a consensus on an appropriate human health criteria. Accordingly, EPA is not promulgating human health criteria for lead at this time.

(F). Cadmium

62. *Comment:* A commenter noted that EPA had proposed criteria for cadmium that were less stringent than the MCLs. The commenter urged EPA to set the criteria at the MCL level.

Response: As noted above, differences in the two regulatory levels is not a sufficient basis for using the more stringent MCL. However, the Agency has determined that it is necessary to give further consideration to the toxicity of cadmium from exposure to water in terms of the bioconcentration potential of this contaminant. As discussed earlier, one of the factors used to calculate the human health criteria is consumption of aquatic organisms. It is, therefore, particularly important that the Agency ensure that the criteria adequately reflect the bioconcentration of cadmium. EPA is currently addressing this issue in other regulatory actions (*e.g.*, sewage sludge and the Great Lakes initiative) and expects that the data and analyses being developed in these efforts will be of value in further examination of the human health criteria. Accordingly, the proposed criteria are not scientifically defensible and EPA will not promulgate human health criteria for cadmium.

(G). Chromium

63. *Comment:* A commenter noted that in the case of chromium with valences of plus VI and III, EPA proposed human health criteria of 170 and 33,000 µg/l, but that the Agency had promulgated a total chromium MCL of 100 µg/l. The commenter urged the Agency to take a similar position here.

Response: As noted above, the fact that the numeric values for CWA and SDWA regulatory actions are different is not a sufficient basis for revising the CWA criteria. However, in this instance, EPA has determined that the proposed criteria are not scientifically defensible. New information concerning the conversion of chromium III to a more toxic chromium VI during the chlorination process should be considered in setting the criteria as well. (See 56 FR 3526 at 3737, January 30, 1991). Accordingly, EPA will not promulgate the proposed human health criteria for chromium.

For other reasons, proposed human health criteria were withdrawn for four pollutants.

(H). Silver

64. *Comment:* Several commenters stated that silver should no longer be classified as a toxic pollutant for human health concerns and that no further regulation for silver is appropriate. Commenters also addressed the issue that the proposed silver criteria should be revised to delete human health as a toxicity-based criterion to be consistent with the recent deletion of the MCL for silver under the Safe Drinking Water Act. (56 FR 3526, January 30, 1991.)

Response: EPA deleted the human health criteria for silver, because the

only potential adverse effect from exposure to silver in drinking water is argyria (a discoloration of the skin). EPA considers argyria a cosmetic effect since it does not impair body function. However, free silver ion is highly toxic to fish. Therefore, to protect aquatic life, silver will be regulated with aquatic life criteria as promulgated in today's rule.

(I). Acenaphthylene, Phenanthrene, Benzo(g,h,i)Perylene

65. *Comment:* Several comments were received which stated that (1) the EPA has expanded the list of polynuclear aromatic hydrocarbon (PAH) compounds to be regulated as carcinogens. Specifically, the commenters do not agree with the Agency that acenaphthylene, phenanthrene, benzo(g,h,i)perylene, and chrysene should be treated as carcinogens, and (2) the proposed rule establishes human health criteria for a diverse class of compounds (such as polynuclear aromatic hydrocarbons) based solely on structural similarity, and the assumption that all of the compounds are of equal toxicity to the most potent compound within the "class."

Response: The Agency agrees with the several comments that the water quality criteria for acenaphthylene, phenanthrene, and benzo(g,h,i)perylene should be based on non-carcinogenic effects of these chemicals since inadequate toxicity data are available to assess carcinogenic potential of these chemicals. However, there are insufficient toxicity data available to provide risk assessment for these three compounds at this time. Therefore, they have been deleted from this rule.

The Agency does not agree with the comment regarding chrysene. Chrysene has shown carcinogenicity in several animal studies. (U.S. EPA, 1991. Drinking Water Criteria Document for Polynuclear Aromatic Hydrocarbons (PAH's) Office of Water.) Chrysene produced tumors (as did other PAHs included in this rule) in several mouse strains when applied topically in assays for complete skin carcinogenicity or in initiation/promotion protocols. Several early studies employing intramuscular or subcutaneous injection of mice and rats produced negative or equivocal results. Three studies wherein neonatal mice of two strains were exposed intraperitoneally reported increased tumor incidence in liver and other sites (*Ibid*). Chrysene produced mutations in *Salmonella* and chromosome aberrations and morphologic transformation in mammalian cells.

The Agency recognizes that carcinogenicity of various PAHs vary with each PAH, however, Benzo(a)pyrene being the most potent carcinogen of this class, was used to develop criteria for all the PAHs.

(J). Other Pollutants

66. *Comment:* A commenter requested that EPA explain the origin of the use of safety (uncertainty) factors.

Response: The safety factors (now referred to as uncertainty factors [UF]) used in calculation of the Acceptable Daily Intake (how referred to as the Reference Dose [RfD]) were developed from the National Academy of Science guidelines (1977) with modification by the EPA. These factors are similar to those used by the World Health Organization (Food Chemistry Toxicology, Vol. 27, No. 4, pp. 273–274, 1989). The EPA is presently working on new approaches to calculation (estimation) of a RfD (ADI).

The term "safety factor" (now UF) was initially used by the Food and Drug Administration (FDA). They used no-effect levels (in mg/kg of diet) from chronic animal feeding studies and divided by 100 to get an Acceptable Daily Intake (ADI) level. For less-than-lifetime (or sub-chronic) studies, they divided the no-effect level by 1000. The National Academy of Science recommended that EPA use a similar approach and outlined the use of 10-fold UFs for intra- and interspecies variation. An additional 10-fold UF is also included to calculate a lifetime number from a less-than-lifetime study. The term "RfD (Reference Dose)" is now used by the EPA instead of the ADI. The above referenced information is included in the Agency's Risk Assessment Guidelines published at 51 FR 33992, September 24, 1986.

67. *Comment:* A commenter stated that EPA should not use Structure-Activity Relationships (SAR) techniques to regulate chemicals, such as methyl chloride, when data on the specific chemical are available.

Response: The EPA uses SAR only when data on specific chemicals of a chemical group are lacking (see 1980 Guidelines, Section D, page 79355). SAR is a technique used to compare the toxicity of individual chemical in the group with the known toxicity of one member of the group based on chemical structural similarities. For example, SAR was used in criteria development for polynuclear aromatic hydrocarbons (PAHs), polychlorinated bi-phenyls (PCBs), and tri-halomethanes (THMs) because the EPA does not have adequate health data on most of the chemicals in the class under review. For a detailed discussion on methyl chloride, see previous comment.

68. *Comment:* A commenter stated that *the toxicities of inorganic arsenic* (As) and the organic arsenic derivatives present in fish may be quite different.

Response: EPA agrees with the commenter—the organic arsenic forms are known to be less acutely toxic then inorganic arsenic forms ("Threshold Carcinogenicity Using Arsenic as an Example," Advances In Modern Environmental Toxicology, 15:133–158, 1988). In addition, since the organic forms found in fish appear to be excreted as the parent molecules, they are likely to have less long-term toxicity. A footnote has been added to section 131.36(b) stating that the criteria for arsenic refers to the inorganic form only.

69. *Comment:* A commenter stated that the arsenic standard is based on an IRIS recalculation that has never been open for public inspection.

Response: The 0.018 µg/l (water and aquatic life consumption) and 0.14 µg/l (aquatic life consumption) criteria were calculated from the unit risk factor of $5x10^{-5}$ $(\mu g/l)^{-1}$. The unit risk factor of $5x10^{-5}$ $(\mu g/l)^{-1}$ is on IRIS and available for public inspection. Although EPA incorrectly indicated in the proposal that the criterion was calculated using an addendum to the prior criteria document and not IRIS, in fact the addendum included the IRIS information and this information was in the record. There is an IRIS submission desk for public comments. Moreover, this rulemaking provided an opportunity for public comment.

70. *Comment:* A commenter claims that the EPA's Science Advisory Board (SAB) is critical of EPA's criteria for arsenic.

Response: The SAB stated that "at doses below 200 to 250 µg As^{+3}/person/day there is a possible detoxication mechanism" and recommended that EPA "develop a revised risk assessment based on estimates of the delivered dose on non-detoxified arsenic." (EPA–SAB–EHC–89–038. Letter from SAB to William Reilly, September 28, 1989.)

Since it is not known exactly when and how arsenic can be considered to be detoxified, EPA cannot, at present, calculate this "delivered non-detoxified" dose. It has been postulated by Marcus and Rispin ("Threshold carcinogenicity using arsenic as an example" Adv. Modern Environ. Toxicol. 15:133–158, 1988) that methylation is a detoxification process. While methylation certainly decreases the acute lethality of arsenic, we do not have enough toxicity data to regard the mono- and dimethylated methobolites as "non-toxic".

71. *Comment:* A commenter noted that no significant health effects from

arsenic exposure has been found in the U.S., as compared to the effects seen in Taiwan.

Response: The cancer potency for arsenic is calculated using standard Agency methods. The available U.S. epidemiology studies are small and do not have the statistical power to state whether the effects and risks in the U.S. are dissimilar to those that have been reported in Taiwan.

72. *Comment:* A commenter questioned the effects of arsenic at low dose and states that a threshold for arsenic may exist. The Marcus and Rispin paper is cited as justification. (Threshold Carcinogenicity Using Arsenic as an Example", "Advances in Modern Toxicology, 15:133–158, 1988.)

Response: There are no adequate data on whether arsenic exerts the same effects at low doses that it does at higher doses. To extrapolate to low dose effects, the EPA uses the linearized multistage model. At the present time, there is no substantial database which demonstrates that arsenic has a threshold for adverse effects. Marcus and Rispin theorized that there is a threshold for arsenic. However, there is no adequate proof that such a threshold exists. In addition, it should be noted that there is not an adequate epidemiology study on U.S. populations. Accordingly, at the present time, there is no way to establish the presence or absence of a threshold level for arsenic.

73. *Comment:* Arsenic causes skin cancer, and not all forms of skin cancer are equally lethal.

Response: The EPA knows that the form of skin cancer induced by Arsenic is treatable and agrees with the commenter that not all forms of cancer are equally lethal. However, the EPA is aware of data showing that arsenic can cause internal cancer and is reluctant to change the risk assessment based on skin cancer until the recent data can be evaluated (the Taiwan data).

74. *Comment:* EPA assumes that all forms of arsenic are equally carcinogenic and therefore the proposed criteria are overly conservative.

Response: The Agency does not consider all forms of arsenic to be equally cancinogenic and has clarified this issue by adding footnote "b" to the matrix in this rule.

75. *Comment:* Several commenters stated that the exposure assumptions or models used to generate ambient water quality criteria are extremely conservative for the following reasons: (1) 6.5 g/d reflects consumption of both contaminated and non-contaminated fish, (2) given the mobility of the population, drinking water from the same source over an average lifetime is extremely remote, (3) the supposition that a person will be drinking water from a surface stream in the first place is questionable, and (4) criteria assume that the same person would actually be consuming "contaminated" water which should have been prohibited under the Safe Drinking Water Act.

Response: The EPA exposure model was based on estimates or measures of national averages (Seafood consumption data analysis, U.S. EPA, 1980—see Guidelines, page 79356). Data indicate that fish consumption rates for recreational and subsistence anglers can exceed 6.5 g/day. EPA has suggested that States select more appropriate fish and other aquatic life consumption rates for local populations. Some States have done so. (See TSD, p.37.) The commenter is correct that the 6.5 grams data reflects consumption of both contaminated and non-contaminated fish. The 6.5 grams is the quantitative daily aquatic life consumption used by EPA. However, EPA's methodology assumes that the 6.5 grams per day of aquatic life were taken from waters meeting the criteria level (see 1980 Guidelines, Section A, page 79343).

In EPA's view, the assumption that an individual may drink from the same surface water for their lifetime is reasonable and meets the goal of the CWA. Drinking water directly from surface supplies is not always regulated under the SDWA: There are many circumstances which are not regulated by the SDWA. SDWA regulations are only applicable to public water supplies serving populations of 25 people or more or in which there are 15 or more service connections.

76. *Comment:* Several commenters questioned the fish and water consumption rates of humans as related to the dioxin criteria.

Response: The Agency is reviewing the scientific basis for the human fish consumption factor used in the derivation of dioxin criteria. (56 FR 50983; October 9, 1991.) When these reviews are completed and the findings critically evaluated, the Agency will initiate a process to determine whether the criteria for dioxin should be revised.

77. *Comment:* Bioconcentration factors (BCFs) should be based on the proportion and type of organisms that would be non-migratory and likely to be caught and consumed by recreational fishermen.

Commenters disagreed with the way the BCF's were derived for 8 chemicals:

Antimony
Arsenic
Beryllium
Cadmium
Chromium
Mercury
Selenium
Thallium

Response: BCFs for all of the criteria, including the above cited metals were supplied by EPA's Duluth laboratory and were used to calculate the promulgated criteria (i.e., from the list above, antimony, arsenic, mercury and thallium which are still in today's rule. The other four metals have been deleted. See comment number 57). (See 1980 Guidelines, pp. 79348–49.) EPA has suggested that States may select more appropriate fish species such as non-migratory and recreational species in developing BCF values which would more appropriately reflect local conditions and aquatic species (see response to comment earlier regarding BCFs and the Technical Support Document for Water Quality-based Toxics Control, EPA/505/2–90–001; March, 1991 at pp. 36–41.) Some States have chosen to do so.

78. *Comment:* A commenter stated that EPA utilized a high degree of overprotection in developing criteria for antimony. The commenter requested EPA to update the IRIS and Health Effects Assessment Summary Tables by using available data to provide toxicity information for various antimony compounds that more appropriately reflects such factors as differences in gastrointestinal absorption rates.

Response: In developing a criteria for antimony the Agency relied upon the available data which is very limited for antimony compounds. The greatest volume of information in terms of chronic exposures to antimony salts was for potassium antimony tartrate. This compound is also the most toxic antimony compound tested. In order to be protective of antimony in all its possible forms, organic and inorganic, the Agency relied upon data from potassium antimony tartrate. Therefore, the IRIS-listed reference dose (RfD) for antimony tartrate is used in the criteria development.

It is true that this criterion may be conservative in some cases. EPA is promulgating this antimony criterion because the criteria must protect human health and it has not been established which antimony compounds may be produced under natural conditions in ambient waters.

79. *Comment:* A commenter stated that EPA should establish seperate criteria for the less soluble and commercially more important antimony oxides. The IRIS database indicates a much higher NOAEL for antimony trioxide than for antimony tartrate.

Response: As stated above, the Agency is setting criteria which would result in protection from all soluble forms of antimony, not just the most common forms. It is true that antimony oxide is much less toxic than potassium antimony tartrate. However, the Agency is taking a conservative approach and assuming that there is the potential for toxic organic antimony compounds, such as the tartrate compound, to form under ambient water conditions. For this reason, the Agency chose the more stringent of the two RfDs listed on IRIS for antimony compounds. (See 1980 Guidelines discussion, p. 79355.)

80. *Comment*: A commenter stated that EPA should use a less conservative application of uncertainty factors in developing the RfD for antimony.

Response: The RfD for antimony, based on the lifetime rat study by Schroeder et al. cited in IRIS (1992), includes an uncertainty factor of 1000 since the study resulted in a Lowest Observed Adverse Effect Level (LOAEL). A No Observed Adverse Effect Level (NOAEL) could not be determined from this study. It is Agency policy to assign an uncertainty factor of 1000 to a LOAEL from an animal study of lifetime duration. If there had been a higher degree of certainty that this LOAEL was indeed close to an observed NOAEL, then the uncertainty factor assigned may have been reduced. However, given the paucity of data on antimony, the Agency assigned the full 1000 uncertainty factor in developing an RfD. (See discussion in the 1980 Guidelines, pp. 79353–54.)

81. *Comment*: A commenter stated that EPA should use the revised bioconcentration factor (BCF) of 0.5 recently developed by EPA for antimony instead of the outdated BCF (1.0) used in calculating the criteria.

Response: It is not true that the BCF for antimony has been officially revised since the 1980 ambient water quality criteria (AWQC) was developed. There are draft updated BCFs under development by the Agency. However, the Agency has not provided the public an opportunity for comment on the new BCF as it has for the revised RfD values which were derived from IRIS. Information on IRIS is considered public information, easily accessed and open to public review. The Agency decided it would be unfair to include revised BCF values into this rulemaking without giving all interested parties a chance to comment on them. For this reason the Agency has presented criteria with 1980 BCF values. EPA will revise the criteria for human health once a revised methodology is developed. At that time we will also include all updated BCF values.

82. *Comment*: Several commenters stated that the polychlorinated biphenyls (PCBs) criteria needed revisions. These included: (1) Revising the cancer potency factor estimated by EPA, (2) setting criteria for each of the Aroclor mixtures separately rather than for a single Aroclor mixture, (3) translating the animal evidence of carcinogenicity into human risk values.

In support of their argument concerning the cancer potency of PCBs, the commenters cited from the report, "Reassessment of Liver Findings in PCB Studies in Rats by Pathology Working Group" prepared by the Institute for Evaluating Health Risk (IEHR). The report reviewed five chronic studies in rats using Aroclor 1260, Aroclor 1254, Clophen A–60 and Clophen A–30. PCBs with chlorine content of less than 60% i.e., Aroclor 1254 and Clophen A–30 had little or no evidence of carcinogenicity. With respect to Aroclor 1260 study, the commenter recommended that the EPA should use a cancer potency factor of either 5.1 or 1.8 $(mg/kg/day)^{-1}$. The EPA potency factor of Aroclor 1260 is 7.7 $(mg/kg/day)^{-1}$. The cancer potency factor of 5.1 $(mg/kg/day)^{-1}$ was calculated from the same study (Norback and Wellman) as used by the EPA. Use of geometric means of all the studies with chlorine content of 60% resulted in the cancer potency factor of 1.9 $(mg/kg/day)^{-1}$.

The commenter argues since there is no evidence that the PCBs with chlorine content of less than 60%, are carcinogenic, the Agency should set a separate criterion for each of the mixtures i.e., Aroclor 1242, Aroclor 1254, etc.

Response: EPA disagrees with the commenter concerning the cancer potency calculations using geometric means of several studies resulting in value of 1.9 $(mg/kg/day)^{-1}$. Utilization of a geometric means approach for the calculation of potency estimates from the available studies is not reasonable because different animal strains and age levels were used in these studies. In addition, the study of Norback and Wellman, cited in IRIS (1992), from which EPA calculated its potency factor of 7.7 $(mg/kg/day)^{-1}$, was much superior in its design and conduct than the other studies. Therefore, the Norback and Wellman study is expected to provide a more precise criterion. The re-examination of slides from the Norback and Wellman study by a group of private pathologists and the use of the revised data is alleged to a yield cancer potency factor of 5.1 $(mg/kg/day)^{-1}$. This potency factor is not very different from that calculated by the Agency.

The Agency believes that it is not reasonable to develop a criterion for each of the PCB Aroclor mixtures. PCBs are mixtures of chlorinated biphenyls. Each mixture may contain up to 209 possible individual compounds. These mixtures are prepared by treating biphenyls and chlorine under alkaline conditions and are characterized by the chlorine contents of the mixtures. For example Aroclor 1242, 1254 and 1260 contain 42, 54 and 60 percent chlorine contents respectively. These mixtures are not characterized by the occurrence of each possible compound in the mixture. Each of the mixtures would be expected to contain all combinations of chlorinated compounds even though some of them in small or trace amounts. In summation, all the Aroclors are expected to contain chlorinated carcinogenic PCB isomers. Besides expecting carcinogenic compounds in each mixture, these mixtures cannot adequately be analyzed with commonly available methods.

The Agency believes that the evidence of carcinogenicity observed in animals can be used to estimate risk values. The Agency has used this approach in this regulation based on the existing Agency 1980 Guidelines (51 FR 33992).

83. *Comment:* One commenter noted that there is a marked range of carcinogenic potencies between the various nitrosamines with some nitrosamines exhibiting no carcinogenic activity. The commenter argued that reliance on structural similarity methodology could therefore result in misclassification errors as to whether specific compounds should be treated as carcinogens.

Response: EPA agrees that there is a marked range of carcinogenic potencies between the various nitrosoamines with some nitrosoamines exhibiting no carcinogenic activity. If there are adequate data available for a specific nitrosoamine, EPA uses such data in evaluating the health risks that such a chemical may present. However, such data are often not available. As a consequence, EPA must, as a practical matter, infer the toxicity of one compound from the toxicity of a chemically similar analogue.

84. *Comment:* A commenter submitted a document entitled, "Biological Risk Assessment of N-Nitrosodimethylamine." While this document does not recommend a specific human health criteria for N-nitrosodimethylamine (NDMA), it does conclude that: 0.0044 µg NDMA/kg/day will present the public with a lifetime 10^{-5} risk level of cancer.

Response: It is not at all clear how the author(s) of "Biological Risk Assessment

of N-Nitrosodimethylamine" arrived at the 0.0044 µg NDMA/kg/day with 10^{-5} risk level. Assuming the ingestion of 2 L of water/day by a 70 kg adult, 0.0044 µg NDMA/kg/day is equivalent to a level of NDMA in drinking water of 0.28 µg NDMA/L. Based on the same data, IRIS concluded that the 10^{-5} risk level for NDMA in drinking water is 0.007 µg/L (i.e, 1/40 the value of "Biological Risk Assessment of N-Nitrosodimethylamine"). Thus, EPA disagrees with the comment since inadequate data and analysis were provided.

85. *Comment:* A commenter noted that the human health criteria presented in the table (in parentheses) are for pollutants which had no health based criteria in the 1980 criteria documents (45 FR 79318). The commenter urged EPA to not include these criteria in the final rulemaking.

Response: The proposed rule indicated these values presented with parentheses in the matrix were *not* being proposed as regulatory criteria but were presented as notice for inclusion in future State triennial reviews. So as not to confuse these values with the criteria being promulgated today, those values were deleted from the matrix and presented below.

Compound	Water and organisms (µ/L)	Organisms only (µg/L)
Copper	1300	
1,2-Dichloropropane	0.52	39
1,2-Trans-Dichloroethylene	700	
2-Chlorophenol	120	400
2,4-Dimethylphenol	540	2300
Acenaphtene	1200	2700
Butyl Benzene Phthalate	3000	5200
2-Chloronaphthalene	1700	4300
n-Nitrosodi-n-Propylamide	0.005	1.4

3. Economics

86. *Comment:* Many commenters objected to the Agency's decisions not to develop detailed cost estimates and not to conduct a comprehensive Regulatory Impact Analysis. The objections were presented in terms of (a) EPA's obligation pursuant to Executive Order 12291 to conduct an analysis; (b) the need to use benefit-cost analysis to make effective public policy decisions, and (c) EPA's error in relying on the difficulty of the task as a reason for not conducting the analysis.

Response: EPA's decision not to provide detailed cost estimates was based on the unusually complex characteristics of this rule with respect to projecting the burden on dischargers. Section J of this preamble includes a discussion of EPA's effort to estimate costs for the rule. As a very brief summary, cost estimates for compliance with water quality-based permits would be based on numerous assumptions; results are sensitive to these assumptions; and consequently, the results would not provide meaningful information to the rulemaking process.

For the final rule, the Agency has undertaken a cost assessment to express a range of compliance costs for several combinations of industries and pollutants. The Agency has also estimated and/or described a range of health and ecological benefits for the rule. While this information about costs and benefits does not constitute a comprehensive Regulatory Impact Analysis, the assessment provides descriptive information about the types of costs that might be incurred as new water quality standards are translated into specific NPDES permits. Also, the ranges illustrate the uncertainties inherent in any estimate of costs.

In addition to the compliance costs to dischargers, other types of cost impacts may occur as a result of EPA-imposed numeric criteria in State water quality standards. For example, nonpoint sources of pollution may incur costs to the extent that best management practices need to be modified to meet water quality standards. In addition, States may incur increased monitoring costs, but only if there is some reasonable expectation that the pollutants are manufactured or actually used in the State.

Several commenters, representing the interests of industrial and municipal dischargers, provided cost estimates; others provided cost data for various compliance strategies. These cost estimates cannot form the basis of an economic impact analysis. Insufficient information is presented in the comments to determine whether these costs reflect the most cost-effective means of achieving the required pollutant reductions. Similarly, EPA cannot confirm whether the cost estimates reflect the incremental cost to comply with water quality-based standards beyond the cost to comply with technology-based regulations. It is the incremental costs that are relevant to this assessment. In addition, the information supplied in the comments is not sufficient to measure the impact of these costs on the financial condition of the dischargers (whether industrial or households).

Due to the uncertainties, a Regulatory Impact Analysis would not alter the Agency's decision to fulfill its statutory responsibilities and promulgate numeric criteria for toxic pollutants. The same conclusion applies to detailed compliance cost estimates.

U.S. Government Standard Form 83, Request for OMB Review, includes a section for OMB to waive the requirements to conduct a Regulatory Impact Analysis, so OMB does have such authority.

87. *Comment:* Several commenters asserted that EPA has not demonstrated that the costs and operating inefficiencies of complying with federal criteria are commensurate with environmental benefits.

Response: The provisions in the Clean Water Act covering water quality standards and specifically, establishing numeric water quality criteria for toxic pollutants, do not include consideration of costs or benefit-cost comparisons. As explained above in section J, economic factors are considered at some points in the process (such as establishing water body use classifications), but not as a component of adopting water quality criteria. The statutory requirements covering water quality criteria focus instead of protection of human health and the environment.

EPA has considered the ability and value of estimating the benefits associated with revised water quality criteria. A summary of the human health and ecological benefits is included in Section J of this preamble.

Briefly, the Agency finds that reduced pollutant discharges are feasible at reasonable costs for several examples. In addition, the national toxics rule has the potential to reduce excess cancer cases. Other ecological benefits, such as protection of wildlife and aquatic organisms, are also projected as an outcome of States adopting numeric pollutant criteria in their water quality standards.

88. *Comment:* Several commenters argued that EPA should conduct a Regulatory Flexibility Analysis because not to do so is a violation of the Regulatory Flexibility Act, and an agency cannot abrogate its statutory duty by pleading hardship.

Response: EPA finds that meaningful results from extensive cost and regulatory impact analyses for this rule are unlikely to be achieved. The same conclusion applies to a detailed analysis conducted in response to the Regulatory Flexibility Act. Briefly, the numerous assumptions and analytical difficulties that are inherent to this rulemaking yield information about the scope of costs, but not detailed cost estimates for specific groups of dischargers, such as small entities. Nonetheless, as described above, EPA's evaluation does not find that there will be a significant impact on a substantial number of small entities; therefore, a final Regulatory Flexibility Analysis is not required.

89. *Comment:* Several commenters asserted that EPA should consider current economic conditions in determining whether to promulgate Federal criteria.

Response: While EPA acknowledges that prevailing economic conditions affect individual business decisions concerning investment in pollution control, Congress clearly intended the Agency to move expeditiously when Federal action is warranted. In compliance with congressional intent, EPA is promulgating these criteria at this time.

In addition, it is not clear which "current economic conditions" should be taken into account in establishing federal criteria. The limitation of toxic discharges is intended to be a continuing process, with this rule a part of the on-going control process. Since the criteria will be in effect during all phases of business cycles, current conditions cannot be the sole determinant of economic conditions when analyzing the economic impact of a regulation. Likewise, the impact of this rule will not be incurred immediately because the criteria will be written into new discharge permits as the current permits expire.

90. *Comment:* Several commenters, representing industrial and municipal dischargers, asserted that the economic impacts of complying with EPA-imposed criteria will be substantial and will be burdensome.

Response: While it is likely that some dischargers will incur compliance costs when the EPA-imposed numeric toxic pollutant criteria are translated into specific NPDES permits, it is not certain that such costs or their impacts will be unreasonable. For several industries, as described in the Agency's cost assessment, large segments of the discharging community will not be affected by this rule because, for example, costs to comply are very small, or technology-based limitations are a sufficient basis for effluent control that will also control pollutants to the level needed to comply with in-stream water quality criteria.

91. *Comment:* Commenters representing municipal interests stated that EPA is incorrect in the assumption that industrial sources are the primary source of toxics discharges by POTWs.

Response: EPA recognizes that there are several sources of toxic pollutant contributions to POTWs. Industrial indirect dischargers, while not the only source, are often the primary source, and the toxic influent from these sources can often be controlled through pretreatment programs.

92. *Comment:* Several commenters stated that promulgation of Federal criteria removes the flexibility to reduce impacts that States would have had by adopting their own standards. Further, they argue, EPA is incorrect in its assumption that impacts are no different than what would occur if States had acted to adopt their own standards.

Response: States continue to have the opportunity to adopt their own standards that include numeric criteria for toxic pollutants. As they adopt and EPA approves their water quality standards, the flexibility provided in the standards-implementation and permit-writing phases of the standards process will return to the States. For a discussion of the effect of this promulgation on various implementation questions, including flexibility, see subsection 4 of this section.

In the cost assessment, EPA has investigated the potential incremental effects of EPA setting standards instead of States. Briefly, EPA finds that for certain dischargers, incremental costs may be incurred in States where toxic pollutant criteria are adopted at EPA's levels. If a State were to adopt less stringent criteria, it is possible that the impacts would be reduced. It is important to consider that in some of the examples, EPA's criteria did not result in incremental costs.

As discussed elsewhere in this preamble, EPA encourages States to adopt their own standards and make use of site-specific criteria as appropriate.

4. Implementation

93. *Comment:* The Agency received substantial comment on 40 CFR 131.36(c) which described the proposed implementation procedures for priority toxic pollutant criteria. Comments divided on whether such factors should be included or left to the discretion of the States.

Response: For reasons stated in the preamble to the proposed rule (56 FR 58437, section 3, Applicability), EPA believes that baseline application conditions must be included in order to provide the intended environmental and human health protection of the criteria. These criteria consist of more than quantitative concentrations. EPA's section 304(a) criteria methodology clearly presents the criteria as criteria maximum concentrations (CMC) and criteria continuous concentrations (CCC) which contain averaging periods and return frequencies. The implementing hydrological conditions merely provide minimum conditions to meet these definitions. The salinity conditions delineating when and where the freshwater and saltwater criteria apply are also necessary. EPA must specify where each of these sets of criteria apply. Likewise the hardness limitations for applying the metals criteria. Each of these paragraphs will be discussed in more detail below but are mentioned here to demonstrate their necessity for implementation of the criteria. Without these generic application conditions NPDES permit writers, the principal users of the criteria, would be unable to develop conditions and limits for inclusion in NPDES permits within the requisite ranges of consistency and predictability.

94. *Comment:* The ability of States to develop site-specific criteria and to grant variances and exceptions to standards received several comments generally indicating that EPA should not constrain the ability of States to use such implementation procedures.

Response: The development of site-specific criteria and the use of variances to standards are optional procedures made available to States that adopt State criteria (40 CFR 131.11(b)(ii) and 131.13). It is neither a statutory nor a regulatory requirement to develop site-specific criteria or to issue variances.

The preamble language to this final rule clarifies EPA's statement on this subject in the proposal. Since the criteria in this rule are Federal criteria applicable to the State, a State cannot unilaterally establish site-specific criteria or grant variances to the Federal rule. That is what EPA meant in the proposal when we indicated that actions pursuant to State law for Federally promulgated criteria are precluded. Such procedures are still available to the State, but are much more cumbersome as it requires the State to meet all the regulatory requirements for developing such procedures, but then EPA would need to undertake a Federal rulemaking process in order to effectuate changes to the Federal rule in accordance with the requirements of the Administrative Procedures Act. EPA continues to emphasize that this is another strong reason for States to act to adopt their own standards even after Federal promulgation action is taken.

95. *Comment:* One EPA Region questioned whether the specification of the applicable hydrological baseline mandated the use of steady state models and eliminated the use of dynamic models for wasteload allocations.

Response: The proposed rule did *not* intend to eliminate the use of dynamic models for wasteload allocations and total maximum daily load determinations. Generally the low flows specified explicitly contain duration and frequency of occurrence which

represent certain probabilities of occurrence. Likewise the criteria for the priority toxic pollutants are defined with duration and frequency components. Dynamic modeling techniques explicitly predict the effects of variability in receiving water, effluent flow, and pollutant concentration. EPA has recommended and described three dynamic modeling techniques for performing waste load allocations in section 4.5 of the 1991 Technical Support Document: Continuous simulation, Monte Carlo simulation and lognormal probability modeling. These procedures allow for calculating wasteload allocations that meet the criteria for priority toxic pollutants without using a single, worst-case concentration based on a critical condition.

Thus, EPA believes that either dynamic modeling or steady State modeling can be used to implement the criteria adopted today.

96. *Comment:* Several commenters in addressing implementation conditions argued that EPA should defer entirely to State discretion including the applicable design flows. Other commenters urged removal of design flows from the rule and rely on the guidance in the TSD and/or other EPA guidance. Another commenter agreed that flow requirements were necessary but that the harmonic mean flow requirement was flawed.

Response. As noted in the preamble to the proposed rule, implementation requirements that include limitations on flow values are required in order to achieve the intended environmental and human health protection. The applicable discussion of this issue is found in the preamble to the proposed rule on pages 58437–58438 and footnotes 1 and 2. The hydrological or biological basis for the proposed low flows were taken directly from EPA's Technical Support Document for Water-Quality-based Toxics Control. (See TSD, Appendix D for aquatic life and section 4.6 for human health.)

The argument by the commenter on the harmonic mean flow was in reality a disagreement on EPA's assumed long-term dose assumption for toxics. The commenter believes short-term effects are more relevant, and therefore requires a different flow, especially for bioaccumulative pollutants. However, EPA continues to support the human health protocol used in the proposed rulemaking and notes that it explicitly accounts for bioaccumulation in the criteria development protocols. For such long-term human assumed consumption of water and aquatic life from such waters containing a pollutant, EPA's best scientific judgment is that the harmonic mean flow is the correct flow to apply in order to correctly estimate the exposure dosage of the average exposed individual.

97. *Comment:* One commenter questioned the applicability of the specified design flows in waters downstream from impoundments which have minimum release rates specified, as for example hydroelectric dams.

Response: EPA's proposed rule in § 131.36(c)(2)(ii) specifies that the low flows are applicable to "waters suitable for the establishment of low flow return frequencies." Thus, free flowing streams and rivers were the types of receiving waters contemplated. In cases where legally specified low flows exist, as for example under FERC licenses, these become the applicable minimum flows. In future State water quality standards reviews, EPA encourages the States to take into account these specified flows and adjust the criteria appropriately to provide equivalent protection of human health and the environment to that applied in today's rule.

98. *Comment:* One commenter noted that "rules" 5(a) and (b) are inconsistent with "rule" 8 in the "Assumptions and Rules Followed by EPA in Writing the proposed § 131.36(d) Requirements for All Jurisdictions." (See the appendix at page 58451 in the proposed rulemaking package.)

Response: "Rules 5(a), 5(b) and rule 8" as stated in the appendix are correct. An incorrect statement of "rule 8" is contained in the preamble to the proposed rule at page 58432. Briefly stated, these rules provide:

- Rule 5(a) applies appropriate human health criteria to all waters in a State classified for either public water supply or for minimal aquatic life protection;
- Rule 5(b) provides that where a State has determined the specific segments where aquatic life are caught and consumed, the human health fish consumption only criteria (Column D2) are being applied to those specific segments;
- Rule 8 provides that where drinking water uses are designated, and even though the State has determined that no potential fish consumption uses exist, the human health criteria for "water + fish" in column D1 are applied. EPA applies these criteria because no "water only" column is available in the section 304(a) criteria methodology and drinking water uses must be protected.

99. *Comment:* Several commenters claimed that EPA was applying the criteria too broadly; that is, to waters where aquatic life propagation or public water supply uses were either not designated or did not constitute existing uses. In contrast, another commenter urged EPA to apply the criteria to all waters of the State where an EPA-approved use attainability analysis did not exist.

Response: Water quality standards contain both a designated use and the criteria necessary to support those designated uses. In this rulemaking EPA is not addressing the designated use component at all, but only the criteria component for the priority toxic pollutants. EPA has relied entirely on the existing State water quality standards to determine the waters to which the criteria apply. In § 131.36(d) EPA refers to all waters within particular designated use classifications.

Because EPA is not addressing the State designated uses here, EPA has not attempted to review State application of designated use classification through use attainability analyses or the other requirements of 40 CFR 131.10. Any identified deficiencies will be handled during the State triennial water quality standard review process with any necessary Federal actions being taken on a State by State basis.

100. *Comment:* One commenter objected to EPA specifying that EPA-approved State mixing zone regulations could be applied to the priority toxic pollutant criteria promulgated today. Others stated that EPA should include procedures to define appropriate mixing zones, that EPA should allow mixing zones in all States and that EPA should require mixing zones in all States.

Response: Mixing zones are one of the general discretionary policies specifically authorized for State adoption by EPA's water quality standards regulation at 40 CFR 131.13. Mixing zones have most recently been defined by EPA in the revised TSD (see page "xx") as "an area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient waterbody. A mixing zone is an allocated impact zone where water quality criteria can be exceeded as long as acutely toxic conditions are prevented." Although mixing zones are discretionary for the States, they are part of the State's water quality standards and therefore subject to EPA review and approval pursuant to CWA section 303(c) and 40 CFR 131.

Mixing zones recognize ambient water dilution and therefore larger mixing zones generally would reduce the stringency of discharge permit limits established to meet ambient water quality criteria. It would be inconsistent with CWA section 501 (33 U.S.C. 1370)

for EPA to impose a less stringent mixing zone policy in a State than is currently authorized. Therefore, in this rulemaking EPA recognizes State mixing zones and provides for their application in implementing the criteria promulgated by this rule. However it does not impose mixing zone requirements on States which do not have such policies.

101. *Comment:* Comments were received that the Federal toxics criteria are not viable because they have never been subject to public comment and review and that the criteria should be subject to continuing peer review and study in order to ensure technical viability. Commenters stated that it is improper to require development of permit limitations on the basis of technically flawed criteria which may not be relaxed in the future due to the anti-backsliding requirements of the CWA and regulations, and that EPA must find that criteria changes which result from peer reviews constitute new information which qualify as an exemption from the anti-backsliding requirements.

Response: We disagree with the premise of this comment that provision for public review and comment on the federal toxics criteria has been inadequate. The criteria methodology and documents were the subject of public review when issued. See the discussion of this issue in the preamble to the proposed rule as well as discussion of EPA's plans to revise criteria guidelines in the future and solicit public comment, 56 FR at 58433. (See also Section F of this preamble.) To the extent we received specific information concerning the criteria in this rulemaking, we have reviewed and responded to that information. Indeed, certain of the promulgated criteria have been changed to reflect public comments. EPA rejects the assertion that the criteria are "technically flawed." EPA believes the criteria are scientifically defensible and would not promulgate criteria that were technically flawed regardless of the anti-backsliding implications. With respect to the comment that revised criteria resulting from peer reviews should constitute "new information" which is exempt from the anti-backsliding requirements, that is not an issue to be decided in this rulemaking. EPA is developing proposed amendments to the NPDES regulations that will interpret and implement the provisions of section 402(o). The commenter's concerns can be addressed in that rulemaking or possibly in a prior permit proceeding if the issue is relevant.

102. *Comment:* One commenter argued that the rule will adversely affect implementation of the NPDES program by diverting resources to deal with permitting and enforcement issues arising from the use of unscientific water quality criteria. It is argued further that no discharger will accept permit conditions that are unreasonable, have no scientific basis, and do not reflect the naturally occurring environmental conditions in the receiving water.

Response: Federally promulgated water quality criteria will be implemented in NPDES permits issued by EPA Regional Offices or authorized States. Dischargers are free to challenge requirements implementing federally promulgated criteria contained in modified, reopened, or reissued permits according to established NPDES permit appeal procedures and as permitted by law. EPA, however, disagrees that the federally promulgated criteria lack a scientific basis and has explained in the preamble to this rule and elsewhere in response to comments why promulgation of the criteria as provided in this rule is necessary to meet the requirements of section 303(c)(2)(B). We anticipate that many dischargers will accept permit requirements based upon the federally promulgated criteria. Dischargers may be permitted to backslide from water-quality based permit limitations where revised criteria are developed if they meet the requirements of CWA sections 402(o) or 303(d)(4) for allowing backsliding in attained and non-attained waters.

103. *Comment:* Comments were received that either the proposed Federal or State standards should provide for a schedule of compliance so that permittees affected by the new federal criteria could have sufficient time to come into compliance.

Response: The proposed rule did not directly provide for a schedule of compliance, however, it also did not change existing applicable State and EPA provisions related to permit issuance or reissuance. EPA agrees with the commenters that some compliance implementation time may, in certain situations, be necessary and appropriate for permittees to meet new permit limits based on the new standards. EPA has not removed this flexibility in the permitting process by this rulemaking. Under the Administrator's April 16, 1990 decision in an NPDES appeal (Star-Kist Caribe Inc., NPDES Appeal No. 88-5), the Administrator stated that the only basis in which a permittee may delay compliance after July 1, 1977 (for a post July 1977 standard), is pursuant to a schedule of compliance established in the permit which is authorized by the State in the water quality standard itself or in other State implementing regulations. (This decision did not affect compliance schedules in individual control strategies issued under section 304(e) of the CWA.)

Standards are made applicable to individual dischargers through NPDES permits which reflect the applicable Federal or State water quality standards. When a permit is issued, a schedule of compliance for water quality-based limitations may be included, as necessary, and EPA assumes this is the case for permits issued to meet these new Federal criteria where States do not have existing statutes, regulations or policy prohibiting compliance schedules. EPA notes that some permits contain a "reopener" clause which may be exercised by the permitting agency on a case-by-case basis to control toxics earlier than the normal re-issuance cycle. However, EPA does not generally contemplate nor does it intend to ask States to undertake permit reissuance related to these new criteria for toxics through anything other than the normal permit reissuance cycle, except in rare instances.

104. *Comment:* EPA's section 304(a) criteria may not be appropriate when applied to non-conventional discharge situations such as stormwater discharges and discharge to ephemeral streams.

Response: EPA's criteria for priority toxic pollutants were developed to protect beneficial designated uses. The criteria are independent of considerations about kinds of dischargers whether point or nonpoint sources. If a State finds that the criteria for the current ambient water designated uses are inappropriate, then EPA's water quality standards regulations provide for a use attainability analysis and establishment of appropriate designated uses. Thus the commenter's concerns are misplaced and focus on the wrong part of the water quality standard.

105. *Comment:* Two comments addressed the salinity and effects on determining which criteria apply at particular locations in estuaries. One commenter, a State agency, supported the concept of clarifying the salinity ranges within which the various freshwater and marine water criteria apply. The State was concerned because the salinity ranges selected by EPA were different from those the State had recently placed in sediment standards. The second commenter asserted that the proposed rule created an untenable situation where fresh and salt waters mix. This commenter suggested that rather than using the more stringent of

the fresh or saltwater criteria, EPA should interpolate between the two on the basis of salinity.

Response: The range of salinities incorporated into this rule at 40 CFR 131.36(c)(3) are appropriate, especially in light of the guidance for the applications of the metals criteria addressed elsewhere in this package.

EPA's proposed rulemaking on salinity, however, was silent on the percentage of the time that the proposed salinity limits could be exceeded but the respective fresh or saltwater criteria still apply. It could be inferred that EPA intended 100% of the time as the appropriate limit. It is EPA's position that a reasonable exceedence should be specified or otherwise the intermediate brackish water zone becomes unnecessarily large. It is EPA's judgment that a factor of 95% of the time provides reasonable cut off points. Thus, for the freshwater criteria to apply, the salinity should be less than 1 ppt 95% of the time. Likewise for the marine water criteria to apply the salinity should be greater than 10 ppt 95% of the time.

EPA recognizes that judgment is required in providing guidance on the appropriateness of freshwater and saltwater water quality criteria across a salinity gradient. This is because a fundamental understanding is lacking of metals form, bioavailability and toxicity along with the relative sensitivities at appropriate salinities of species that occupy this gradient. EPA's recommendations are reasonable given that (1) the database for most metals includes tests with saltwater and freshwater species that tolerate these salinities; (2) that salinities at a particular location change daily with tide and wind and seasonally; and (3) that at low salinities, freshwater and saltwater species mix. It is reasonable that the presence of both types of species in this transition zone require application of both freshwater and saltwater water quality criteria. Given the temporal variability of salinity in both the short and long term and the judgmental basis for EPA's recommendations, knowledge of the kinds of organisms at a site of concern will be particularly helpful in being confident that the appropriate criterion has been applied to the site.

The second commenter's suggestion is not supported by data or professional experience of EPA's scientists. For many metals, toxicity to saltwater species increases at low salinities. Therefore, underprotection would result from the use of an interpolation approach that would result in higher criteria at low or intermediate salinities.

5. Timing and Process

106. *Comment:* EPA should delay Federal promulgation until current State efforts to adopt water quality standards have been completed.

Response: Without sufficiently protective and defensible water quality standards, EPA and the States cannot effectively control discharges of toxic pollutants. While the Clean Water Act clearly gives primary authority for adopting water quality standards to the States, Congress clearly signaled its frustration with State delays in adopting criteria for toxics in the 1987 Clean Water Act amendments. Since the 1987 amendments, the States have had over five years to meet the statute's requirements for adopting water quality standards for toxic pollutants. Further delay is unacceptable. It is now time for EPA to exercise its oversight authority to ensure that human health and the environment are adequately protected.

107. *Comment:* Several comments were received relating to the general subject of State action during or subsequent to this rulemaking and on the processes EPA would use to withdraw Federal criteria applicable to a State. A related comment was that EPA should clarify that partial withdrawals are possible. Another comment questioned which criteria would apply in a situation where EPA approves State standards subsequent to the Federal promulgation.

Response: EPA is fully aware that several States are actively involved in reviewing and possibly revising their standards to meet the requirements of the Act simultaneously with the Agency's action to promulgate Federal standards. It is an objective of the Federal action to spur State action to complete their own administrative procedures so as to obviate the need for Federal promulgation. However, for the reasons stated earlier in the preamble as the basis for this rulemaking, EPA believes States have already had more than adequate time to respond to the statutory requirement and that EPA has a responsibility to act to put standards in place to serve as a basis for environmental control programs. Nevertheless, EPA encourages States to continue to adopt their own standards and thereby enabling themselves to make use of the flexibility inherent in the program through use of the various implementation processes even if such action will not be completed until after promulgation of this rule. EPA is committed to timely withdrawal of the Federal standards after State adoption and EPA approval of State standards.

The assertion that upon adoption of standards by the State, EPA's Federal criteria are no longer applicable within the State is not correct. The Federal criteria will continue to be the applicable water quality standards until withdrawn. Where the State standards are less stringent than the Federal standards, the Federal standards will be controlling until final action is taken to withdraw the Federal standards. In this situation, the permitting agency must use the more stringent standards in issuing permits. As a practical matter, it is assumed that permit holders would seek a stay of permit requirements pending the final decision of the Federal standards. While there may be a period in which there are both State and Federal standards in effect, the most stringent standards (either the State's or EPA's) would be controlling.

As described earlier in the preamble, EPA will act to withdraw this rule as applicable to a State, if the State completes action on adopting standards that adequately protect their waterbodies from toxic contamination and EPA approves those standards. The standards do not necessarily have to be exactly as those promulgated by EPA but they must meet the requirements of the Act and 40 CFR 131.11.

Many comments were received that EPA should not be required to receive comment and execute a rulemaking in order to withdraw State-adopted and EPA-approved standards that are less stringent than those promulgated by EPA. As described in Section E-3 of this preamble, EPA withdrawal action differs depending upon whether the State standards are equal to or more or less stringent than those promulgated in this rule.

While it would be administratively less cumbersome not to provide notice and comment in withdrawing a more stringent Federal water quality standard, EPA, however, is constrained by the provisions of the Administrative Procedures Act, 5 U.S.C. Section 551 (4) and (5) which we believe preclude the Agency from withdrawing a rule as suggested by the commenters. EPA will take timely action to withdraw the Federal rule in these cases. EPA has had experience in withdrawing the Federal rule covering each situation, i.e. standards equal to or more or less stringent than the Federal rule (51 FR 11581, April 4, 1986; 47 FR 53372, November 26, 1982; 56 FR 13592, April 3, 1991). It has not proven to be a practical problem. Consistent with the water quality standards guidance and historical operating policies, EPA confirms that partial approval of State standards and partial withdrawal of the

Federal rule is allowable. (See generally, Chapter 2, Water Quality Standards Handbook, December 1983)

There is an exception to this process. If a State adopts a 10^{-5} risk level when EPA promulgated 10^{-6}, the rule can be withdrawn without notice and comment because we raised the possibility of different risk levels in the proposal and we have accepted both risk levels as meeting the requirements of the Act.

108. *Comment:* EPA received comment that there is no procedural necessity for this rule because Congress did not set a specific deadline for State action to comply with section 303(c)(2)(B).

Response: For the reasons set forth elsewhere in this preamble, EPA has the requisite statutory authority to promulgate these criteria and that such criteria are necessary as a basis for water quality-based control programs designed to protect the public health and the environment.

Section 303(c)(2)(B) of the Act requires States action to address toxic pollutants "whenever a State reviews water quality standards pursuant to paragraph (1) of this subsection * * *". Paragraph (1) refers to the requirements to review and revise, if necessary, standards at least once each three year period—the triennial review cycle for standards.

Notwithstanding arguments concerning timeliness of EPA and State actions, the Agency has made a decision that toxics criteria for priority toxic pollutants should be in place. The Administrator's action has started the process described in CWA section 303(c)(4) for Federal promulgation. Thus, because of the Agency's action, the comment at this point is moot.

109. *Comment:* EPA received numerous comments concerning the 30-day public comment period. Some industries and municipalities expressed concern that the rulemaking was too extensive to allow meaningful comment within 30 days. Some commenters requested extensions up to six additional months. Several commenters noted that EPA had never before promulgated a final water quality standards rule within 90 days of proposal.

Response: EPA appreciates that 30 days is a short comment period but believes that it is fully consistent with section 303(c)(4) (33 U.S.C. 1313(c)(4)) which requires EPA to promulgate a final regulation within 90 days of proposal. The fact that EPA only met this requirement once in its nine final promulgation actions does not change the statutory requirement.

In most of those previous cases (and in 2 cases today) the Agency was in fact superseding a State rule. Pursuant to the Agency's regulation at 40 CFR 131.21(c) the State rule stayed in effect until EPA's final rule took effect. Today's action is different. Here, by and large, there are no State criteria for priority toxic pollutant in place and EPA is acting to fill that void. This EPA action has a greater sense of urgency and justifies the Agency's effort to meet the 90 day statutory time schedule in CWA section 303(c)(4).

The addition of section 303(c)(2)(B) to the Clean Water Act was a clear and unequivocal signal from Congress that it was dissatisfied with the slow pace at which States were adopting numeric criteria for toxic pollutants. This intent is made clear in the legislative history of that provision. It is the only time in the 26-year history of the program that Congress explicitly directed the States to address certain pollutants in their standards. Moreover, section 303(c)(4), which authorizes Federal promulgation has explicit deadlines and Congressional directives to act promptly. The intent of the Federal promulgation section of the Act is to accelerate human health and ecological protection by establishing water quality standards as a basis for pollution control programs. To achieve these objectives and meet the statutory deadline, we need sufficient time to review public comments and make any necessary revisions.

Although the State and pollutant coverage of this final rule is large, the issues involved are neither new nor numerous. The primary focus of this rule is the narrow issue of whether a State has adopted sufficient water quality criteria for toxic pollutants in State standards as necessary to support water quality-based control programs.

EPA alerted the public to its intentions and the planned contents of the proposal on April 19, 1990, in an announcement in the Federal Register. In addition, we notified the administrators of the State agencies responsible for the water quality standards program of each potentially affected State of our plans on April 9, 1990. In the April 19, 1990, notice, EPA described what would be in the proposal, including: Which pollutants, which States, the cancer risk level, and EPA's intention to update criteria using publicly available information in the Integrated Risk Information System. Since that notice, EPA has apprised the public of its intentions and status of its action through State and Regional meetings and quarterly newsletters on the criteria and standards program. EPA, through both its Headquarters and Regional Offices have met with the States, and the regulated community individual and public meetings and public hearings to discuss EPA's plans and progress. This lengthy lead time has allowed potential commenters to prepare for the proposal and should have facilitated preparation and submission of meaningful comments within the 30-day public comment period.

As discussed previously in this preamble and the preamble to the proposed rule, the methodology used to develop the criteria and the criteria themselves have previously undergone scientific peer and public review and comment and were revised as appropriate. Some human health criteria were updated by recalculating the criteria using revised reference dose information contained and publicly available in the Agency's Integrated Risk Information System. Information in this system was peer reviewed within EPA and, as a matter of policy, is the information which was recommended to the States for their use. Most of these reviews occurred before 1987. Congress acted to amend the Act with full knowledge of the EPA process for developing criteria and the Agency's recommendations under section 304(a). EPA believes it is consistent with Congressional intent to rely on existing criteria rather than engage in a time-consuming reevaluation of the underlying basis for water quality criteria. At some point in the standards setting process the States and EPA must act recognizing that scientific research leading to improved water quality information is an ongoing process. In the case of this rulemaking, EPA affirms that in addition to all the environmental, programmatic, and statutory factors supporting the rule, the basic criteria methodologies are scientifically sound as are the resulting criteria.

In the five years since the February 1987 enactment of section 303(c)(2)(B), most States have worked extensively to adopt water quality standards for toxics pollutants. The issues in this proposal are the same ones that States, dischargers, public interest groups, and EPA have discussed and debated in-depth during those deliberations. The comments prepared for State and EPA meetings and hearings are to a great extent the same as those to be made on this Federal action and made it easier for the commenters to prepare submissions on this rule. The arguments presented in the public comments that EPA's action is new or that the States are not in compliance because they are

carefully reviewing their standards all tend to ignore the fact that many of the criteria were available as early as 1980. Because of a lack of State action, EPA made it a priority emphasis in the revision to the water quality standards regulation in 1983 and, most importantly of all, that section 303(c)(2)(B) was not the start of the process but the signal from Congress that delays had to cease. It is now eleven years after the criteria were first made available to the States, five years after Congress specifically directed the States to Act. Given this background, 30 days was sufficient for commenters to prepare and submit meaningful comments. The extensive nature of the comments submitted support this position. Further delay in the process is totally unwarranted for all of the above programmatic, health, ecological, and statutory reasons.

110. *Comment:* EPA should promulgate criteria only for those pollutants clearly shown to be interfering with designated uses.

Response: The record supporting this proposal contains extensive data on the toxic pollutant problem in each State. It shows the presence of numerous toxics in State waterbodies and it also contains information on impaired waterbodies. Earlier in this preamble, in section E-2 of this preamble, we described that rationale for why EPA could not undertake extensive studies in each State.

In responses to previous comments earlier in this section, we described EPA's legal authority to undertake this promulgation action including why it is not necessary for EPA to promulgate standards pollutant-by-pollutant, waterbody-by-waterbody. In summary: (1) EPA has sufficient data to indicate the widespread presence of toxic pollutants, (2) administratively, given the statutory schedule for promulgation, Congress clearly never intended EPA to conduct in-depth State analysis, (3) EPA, in its December 1983 guidance on options to meet the statutory requirement of section 303(c)(2)(B) indicated a policy position that "* * * the presence or potential construction of facilities that manufacture or use priority toxic pollutants or other information indicating that such pollutants are or may be discharged strongly suggests that States should set standards since such pollutants have the potential to or could be interfering with attaining designated uses", (4) neither the Act nor EPA's regulation limits the establishment of standards to a waterbody-by-waterbody, pollutant-by-pollutant approach, (5) as a matter of public policy to protect human health and the environment, it is the Agency's position that a more conservative approach is warranted, and (6) actual dischargers of such pollutants should expect to have control limits placed in their permits for such pollutants while other dischargers will not be affected.

111. *Comment:* Since EPA published a range of risk levels in its water quality criteria documents, it should allow a range in this rule or allow States to select the appropriate risk level.

Response: EPA's publication of a range of risk levels in individual water quality criteria documents was simply an illustration of how the criteria recommendations would be affected by adopting various risk levels. It was not intended to nor did it, in fact, establish a policy on risk levels.

Consistent with recognizing the primary authority of States to adopt water quality standards and that Agency policy allows States to select an appropriate risk level within the general range of 10^{-4} to 10^{-6}, EPA modified this final rule to apply the human health criteria at the risk level adopted or proposed by the State for all or a majority of toxic pollutants under applicable State water quality standards regulations, or in the case of Idaho, Nevada, and Rhode Island, on an expression of State preference. EPA notes that in a majority of cases, the 10^{-6} risk level is the one adopted by the States. In order for the human health criteria to be implemented in water quality programs, a single risk level must be chosen so that a specific numeric limit is established for a pollutant. The rationale for EPA's choice of a risk level for each State in this rule is contained in section G-1 of this preamble.

Any State adopting its own standards that meet the requirements of the Act may adopt a risk level other than that used by EPA in this rule. The ability of a State to select an alternative risk level is one of the reasons EPA encourages each State to adopt its own water quality standards rather than rely on Federal promulgation.

6. State Issues

Alaska, Washington, and Idaho

112. *Comment:* Alaska, Washington and Idaho have noted errors in the proposed rules. In some cases these errors were improper citations, or the inclusion of, or failure to include, certain criteria.

Response: EPA sought comments on the interpretation it had made of the various State water quality standards that were potentially affected by the proposed rulemaking. EPA expected and received comments on the appropriateness of the individual criteria groups applied to the State beneficial use designations.

In deciding which changes it can make to the proposed rules EPA notes that the preamble to the proposed rule laid out the intent and purposes of this action extensively. Beginning on page 58431 of the preamble to the proposed rule, EPA described the 12 "rules" or logic used to derive the criteria applicable to States judged not in compliance with CWA section 303(c)(2)(B). The gist of this rationale was for EPA to apply aquatic life criteria to State-defined designated uses providing even minimal support to aquatic life survival; and human health criteria to State-defined designated uses providing for public water supply and/or aquatic life consumption. Moreover, EPA provided in the matrix in proposed 40 CFR 131.36(b) all of the numeric levels that it proposed for application to the designated uses. Thus, EPA believes that sufficient notice was provided as to the purpose of the proposed rule, the types of affected State designated uses and the identification and stringency of the section 304(a) criteria to provide the Agency some latitude in deleting and adding criteria, especially when these changes are made because of comments made by the affected States and are necessary to correct unintended mistakes.

After discussing this comment with the State of Alaska, it was agreed that the following changes to the rule were necessary. These changes occur in 40 CFR 131.36(d)(16)(ii).

The State's current water quality standards (WQS) reference "Gold Book" criteria for all uses included in the rule except secondary contact recreation. Because the promulgated numbers are, in essence, revised Gold Book criteria, to be consistent with State WQS, EPA applied aquatic life and human health numbers to all uses except secondary contact. Secondary contact recreation is included because it is defined in the State's standards as including fishing. D1 criteria are applied to the drinking water use. D2 criteria are applied to all uses except drinking water for both fresh and marine waters. All acute aquatic life criteria are included in this rule. (See correspondence between the State and EPA in the record.) Also, all human health criteria for carcinogens based on the fact that the State has not adopted a risk level and therefore, cannot calculate or apply appropriate criteria for carcinogens. The chronic aquatic life criterion for selenium as it has been updated since publication of the Gold Book and made more stringent.

The seafood processing use (2)(A)(ii) was deleted from rule because it is an industrial use category to which the criteria promulgated today do not appropriately apply.

Additionally, in 40 CFR 131.36(13)(iii), the risk level for carcinogens was changed to 10^{-5} to reflect the State's July 1992, proposal to amend its water quality standards and to reflect an indication of State policy preference received on November 16, 1992.

The following changes were made with respect to the State of Washington. After discussion with the State, EPA has assigned appropriate criteria to use categories rather than to classes. The rule was revised as follows (see 40 CFR 131.36(d)(17)):

(22)(i) Fish and Shellfish
Fish
Water Supply (domestic)
Recreation
(22)(ii) Fish and Shellfish; Fish
B1 and B2—#2, 10
C1—#2, 10
C2—#2, 6, 10, 14
Water supply (domestic)
D1—All
Recreation
D2—All marine waters
D2—freshwaters not protected for domestic water supply

The following changes were made with respect to the State of Idaho. After discussion with the State, EPA renumbered the use classifications to reflect the reorganization of the State standards and made the following changes in the criteria assigned (see 40 CFR 131.36(d)(18)):

1.b Domestic Water Supplies
Remove cyanide and asbestos
3.a Primary Contact Recreation
Remove B1—All
Remove B2—All
Add D1—All
3.b Secondary Contact Recreation
Remove B1—All
Remove B2—All

Alaska

113. *Comment:* EPA has incorrectly included CMC (acute) aquatic life criteria for freshwater and saltwater for Alaska in the proposed rule.

Response: EPA's inclusion of CMC aquatic life criteria in the rule is appropriate. Alaska's water quality standards state that, "Substances shall not * * * exceed criteria cited in EPA, Quality Criteria for Water." Whether or not the State has adopted both acute and chronic criteria by reference is ambiguous and requires clarification through this rulemaking, especially in light of language included in the following three documents issued by the State:

1. The State's Water Quality Standards Workbook, published in July 1991, and widely distributed in order to "understand what water quality standards and criteria are, how to interpret the Alaska water quality standards regulation * * *", states that, "* * * EPA has developed a two-number criterion for acute and chronic conditions. The state adopts only the chronic criterion."

In the same state WQS workbook, Table 1, "Alaska's Water Quality Criteria for Toxic Substances in Freshwater and Saltwater", is said to "represent the toxic substances criteria adopted by reference in the AWQS." This table does not include any acute values for the priority toxic pollutants.

2. An August 30, 1991 letter from John A. Sandor, Commissioner of ADEC, to Harold Geren, Chief of EPA Region 10's Water Permits and Compliance Branch, states, "The Department affirms its decision to continue to use "Gold Book" *chronic* criteria to establish receiving water criteria and effluent limits in NPDES permits." (emphasis added)

114. *Comment:* Alaska was not informed of EPA's intention to include acute criteria in this rulemaking.

Response: On November 4, 1991, EPA Region 10's Water Division Director sent via fax and hard copy, a letter to ADEC's Chief of Water Quality Management, notifying the State of EPA's intention to include acute criteria in this rulemaking. The letter stated, "These letters affirm Alaska's use of "Gold Book" chronic criteria for freshwater and marine systems and have convinced us that Alaska is in compliance * * * with the following exceptions: * * * Acute aquatic life criteria for all pollutants * * *."

115. *Comment:* The statement included in the rule that, "Alaska is included in today's proposal because although the State had previously adopted all section 304(a) criteria by reference, the State Attorney General has decided that the adoption by reference is invalid", is in error and should be deleted from the final rule.

Response: EPA concurs that the statement was in error and no such statement is included in this final rule.

Arkansas

116. *Comment:* Any promulgation of human health criteria for the State of Arkansas should be withdrawn from the rulemaking because the state has adopted such criteria.

Response: A State's standard must be reviewed and approved by EPA before the State can be removed from the rule. Arkansas formally submitted their water quality standards containing human health criteria to EPA on December 17, 1991. EPA's review found that the human health criteria were supportive of designated uses and therefore no human health criteria are promulgated in this rule. The State's criteria to protect human health were approved by EPA on January 24, 1992. EPA also disapproved Arkansas' water quality standards for failing to adopt the criteria for priority pollutants to protect aquatic life as required by section 303(c)(2)(B). Necessary aquatic life criteria are promulgated today and include the following: Cadmium, chromium, copper, lead, mercury, nickel, selenium, silver, zinc, and cyanide.

117. *Comment:* Arkansas is not required by the Act to adopt numeric criteria for metals because it has not been established that the metals listed "could reasonably be expected to interfere with those designated uses adopted by the State."

Response: EPA's policy is that the presence of any Section 307(a) pollutants raises an issue as whether they could reasonably be expected to interfere with designated uses. The presence in ambient waters and the discharge of metals is documented in several databases, including the Toxic Release Inventory, STORET, and discharge monitoring reports. The State could have submitted supporting documentation that demonstrates that the presence or discharge of these metals is not expected to interfere with designated uses. The State submitted no such information. In the absence of any demonstration to the contrary, EPA must conclude that the metals can reasonably be expected to interfere with designated uses.

118. *Comment:* The documentation on which EPA based its assertion that designated uses "could reasonably be expected to be interfered with" should be provided under this rulemaking process.

Response: The documentation that showed the widespread occurrence of metals in Arkansas' waters in concentrations exceeding EPA's recommended levels was part of the record for this rulemaking and was available for review at the Region 6 office as well as at EPA headquarters.

119. *Comment:* All pertinent data developed by EPA under the 304(1) process should be made available without special request to ensure its availability to potentially affected parties.

Response: The material developed by the States with respect to section 304(l)

was publicly available at the time the list was compiled. A complete discussion of the relationship between the 304(l) list and today's rule is included earlier in this section. Moreover, because EPA did not rely on the State's section 304(l) materials for this rulemaking, it was unnecessary to place such materials in the record.

California

120. *Comment:* A commenter urged that the national rule should clarify that no criterion continuous concentration for selenium less stringent than 5 µg/l will be allowed in California's San Francisco Bay. Commenters suggested that the National Rule should direct Region IX to develop site-specific criteria for selenium in San Francisco Bay. It was further suggested that the National Rule should state that the 5 µg/l selenium criterion (B2) applies only to fish and aquatic invertebrates, not to more sensitive uses such as wildlife. The narrative standards should govern for the more sensitive uses.

Response: This rule promulgates EPA's freshwater criteria for selenium of a CCC of 5 µg/l (4 day average) and a CMC of 20 µg/l (1 hour average) for San Francisco Bay and Delta. In EPA's November 6, 1991 approval letter on California's Enclosed Bays and Estuaries Plan, EPA approved California's decision to allow regional water quality control boards (Regional Boards) to determine where in an estuary it is appropriate to apply freshwater or saltwater criteria. Although most Regional Boards have not yet specified the appropriate standard, EPA generally agrees with this process. However, the EPA standards approval letter specifically found that utilization of the saltwater criteria for selenium in the San Francisco Bay/Delta would be inappropriate. This finding is based on substantial scientific evidence that there are high levels of selenium bioaccumulation in San Francisco Bay and the saltwater criteria fails to account for food chain effects. Accordingly, in the absence of Regional Board action consistent with EPA's approval letter, EPA is promulgating the freshwater criteria for selenium for the San Francisco Bay/Delta. EPA's criteria for selenium in freshwater are derived from laboratory and field data on the effects of selenium on aquatic vertebrates, invertebrates and plants and should be protective of aquatic organisms under most conditions. The selenium criteria were not developed with the intent to address protection of wildlife such as waterfowl. EPA is in the process of developing wildlife criteria for selenium. Recent studies and analyses have enhanced our understanding of avian exposure to selenium in the field and have clarified the importance of food chain biomagnification and low level toxic effects on avian reproduction. Such information is, for the most part, new information available after the Water Quality Criteria for Selenium was published in 1987. EPA supports the efforts of the State to develop selenium criteria based upon food chain biomagnification. However, in the absence of a final wildlife criteria document, or other sufficient information, EPA is unable to promulgate a criterion more stringent than 5 µg/l as part of this rulemaking. The purpose of this rule is to establish Federal criteria for all waters that do not have EPA-approved state criteria. It is not appropriate to use this Federal rule as a mechanism for directing promulgation efforts of a region. Further, EPA's regulations, guidance documents, and the Preamble to the Federal rule clearly specify the steps to be taken when a state wishes to adopt site specific criteria. EPA believes that it is already clear that both the numeric and the narrative standards apply in all cases. This information is contained in EPA's guidance documents and does need not be reiterated in this rulemaking.

121. *Comment:* EPA should promulgate freshwater selenium criteria in California for the Sacramento-San Joaquin Delta, the inland surface waters including the San Joaquin River, and the Central Valley Wildlife refuges.

Response: The draft rulemaking proposed the national selenium criteria for all water bodies in California and included those listed above. On November 6, 1991, EPA approved California's Inland Surface Waters Plan which adopted EPA's selenium criteria for freshwater bodies with the exception of Salt Slough, Mud Slough, and the upper San Joaquin River. EPA approved the State's selenium criteria but did not approve these exceptions. Accordingly, the final national rule promulgates the EPA freshwater criteria for selenium for Salt Slough, Mud Slough, and the upper San Joaquin River. The State's freshwater selenium criteria will apply elsewhere in the Sacramento-San Joaquin Delta and San Joaquin River. The California Inland Surface Waters Plan also included a selenium criterion of 2 ppb for the inflow to Grasslands Area Wildlife Refuge in the Central Valley that is more protective than EPA's criteria. This selenium criterion was approved by EPA and, therefore, today's promulgation will not apply to the inflow to Grasslands Valley Wildlife Refuge.

122. *Comment:* Several commenters asserted that: (1) Past efforts to develop site specific objectives for San Francisco Bay demonstrate the technical difficulties, costs, and uncertainty of developing site specific criteria and; (2) those difficulties make site-specific criteria ineffective in amending inappropriate national criteria.

Response: EPA approved the water quality criteria adopted by California in the Enclosed Bays and Estuaries Plan on November 6, 1991. EPA has revised today's rule so that it does not include pollutants covered by those state-adopted, EPA-approved criteria, except for selenium as described in the previous comment and response. The San Francisco Bay is a highly complex estuarine system. In such cases, developing site specific criteria may be difficult. In October 1991, EPA made technical comments on the site specific objectives proposed for San Francisco Bay. The site specific criteria for San Francisco Bay have not yet been adopted by the State and, therefore, it is premature to evaluate their effectiveness. EPA has approved site specific criteria in several States and recommends that site specific criteria be developed where physical or chemical characteristics of the site alter the biological availability of the chemical or where species at the site are more or less sensitive than those species used in the development of national criteria. Please see Science and Implementation under general comments.

123. *Comment:* A commenter indicated that Region IX has placed impediments on the adoption of site-specific criteria which make future adoption of site-specific criteria an unrealistic alternative.

Response: There is no indication what "impediments" the commenter refers to, or the action by which Region 9 allegedly created such impediments. Please see Implementation under general comments about requirements for site-specific criteria.

124. *Comment:* EPA also received comments that the proposed rule would establish inappropriate and technically unsupported criteria for copper, nickel, lead, and mercury for South San Francisco Bay.

Response: The final rule has been amended to reflect EPA's November 6, 1991 action on California's Enclosed Bays and Estuaries Plan and does not include criteria for copper, nickel, mercury or lead for San Francisco Bay. EPA generally approved California's approach directing regional boards to choose between two sets of criteria

(freshwater or saltwater) in an estuary. California's saltwater and freshwater criteria are approved by EPA. At this point, EPA does not have sufficient information to conclude that this approach of allowing Regional Boards to choose between the two sets of criteria is inappropriate for copper, nickel, lead, and mercury in the South Bay. Therefore, criteria for these metals are not included in this final rule.

125. *Comment:* Several commenters questioned the appropriateness of promulgating EPA criteria for special water bodies such as ephemeral streams, constructed agricultural drains, effluent-dominated streams, irrigation-flow dominated streams, or evaporation ponds.

Response: The criteria contained in this rule apply to all "waters of the United States" as defined in the Clean Water Act and implementing regulations except where State-adopted/EPA-approved criteria apply. Waters of the U.S. may include human-constructed water bodies. Waters of the U.S. does not include waters that fall under EPA's waste treatment system exemption. California deferred adopting water quality standards for certain effluent-dominated streams and irrigation-flow dominated streams. This deferral was disapproved by EPA in its letter dated November 6, 1991 on the basis that it did not protect the water bodies from toxics that are reasonably expected to interfere with designated uses. EPA Region IX agrees with California that site specific criteria would be appropriate for many waters in these categories. If California adopts and EPA approves site-specific criteria that protect the designated uses, criteria for those waters will be removed from this final rule.

126. *Comment:* Several commenters found it impossible to comment on the proposed rule in the short comment period provided. Specifically, commenters noted that the thirty-day comment period is unreasonable and unfair for California given Region IX's delay in acting on California's own water quality standards.

Response: Commenters had more than five weeks to review Region IX's November 6, 1991 action, including thirty days to compare it to the proposed Federal rule. Also, please see general comments under Timing and Process.

127. *Comment:* EPA was not mandated to propose standards for California at this time, especially in light of Region IX's November 6, 1991 action on California's standards. The Clean Water Act contains no specific deadline for EPA to propose standards and does not require standards to be proposed for the entire nation at once. California could be separated from other states in order to allow reasonable time to evaluate both actions.

Response: On November 6, 1991, Region IX disapproved California's failure to adopt numerical criteria for all 307(a) pollutants for all "waters of the U.S." in California. According to EPA's water quality standards regulations (40 CFR part 131), the State has a 90-day opportunity to correct any deficiencies and EPA may then approve adequate corrections. If the State does not adopt the necessary corrections (or additions) within that period, then EPA must "promptly" propose and promulgate Federal standards in place of those deficient State standards. (Clean Water Act, section 303(c)(4)(A); 40 CFR 131.22.) In this instance, Federal promulgation occurred more than 90 days after November 6, 1991, and took into account any and all changes adopted by the State during those ninety days. To further delay promulgation for California when EPA is prepared to act on California's standards concurrent with other States is unnecessary. As to the adequacy of time to evaluate both actions, see response to preceding comment.

128. *Comment:* California commenters stated that it is unclear whether Federal or State criteria would apply to waters which California exempted, since EPA disapproved this exemption.

Response: California, by exempting certain waters from its 303(c)(2)(B) criteria, failed to adopt such criteria for those waters. EPA's disapproval of the exemptions did not bring about an adoption which the State never made. With this rulemaking, EPA adopts criteria for all 307(a) priority pollutants for those exempted waters which are Waters of the U.S. See additional comments below.

129. *Comment:* It is unclear which of California's use classifications are considered aquatic life or human health classifications. The proposed rule equates aquatic life protection with aquatic life consumption and states that waters with any aquatic life designation must meet human health criteria. A commenter indicated that assigning fish consumption for any aquatic life segment is equivalent to Federal promulgation of new designated uses and should not be done in this rulemaking.

Response: California's basin plans identify specific aquatic life and human health uses that are to be protected in a particular waterbody. EPA has no intention of changing designated uses in this rulemaking. As stated in the proposed rulemaking, States may remove the human health use classification for waters which have aquatic life but no existing aquatic life consumption uses. California, however, applies human health protection for fish consumption statewide to all navigable waters through the Inland Surface Waters Plan, Enclosed Bays and Estuaries Plan, and Ocean Plan. Therefore, the Federal rule is based on the presumption that, for all navigable waters of the State, aquatic life is present, fish or other aquatic life are being caught and consumed, and human health protection for fish consumption is necessary. It is consistent with EPA's established water quality standard regulations to require States to include all uses identified in Section 101(a) of the Act for all waters unless removed through an approved use attainability analysis. (See 40 CFR 131.10(j)). In this rulemaking EPA has not included the human health criteria (based on fish consumption) for any segments for which a State has conducted, and EPA has approved, a use attainability analysis to remove fish consumption as a use. Please see Legal Authority under general comments.

130. *Comment:* EPA's claim on 56 FR 58422 at p. 58431 that comprehensive Federal promulgation of standards place "no undue or inappropriate burden on States or dischargers" is unsubstantiated and believed to be untrue in California. The economic impacts of complying with Federal criteria are believed to be enormous particularly for publicly owned treatment works (POTWs) and are likely to discourage water reclamation projects.

Response: The commenter provides no explanation as to why complying with Federal criteria will discourage water reclamation projects. EPA is unconvinced that this would be the case. Please see Economics under general comments in response to economic impact concerns.

131. *Comment:* The commenter is concerned about the use of 10^{-6} risk level criteria as opposed to MCLs for protection of drinking water.

Response: California does not have any water bodies where drinking water is the sole exposure pathway. Therefore, MCLs may not be sufficient to protect human health from exposure to toxics from combined drinking water and fish consumption pathways. See section F-5 for a more detailed discussion of risk levels included in this rule.

132. *Comment:* The commenter is concerned that State schedules of compliance will not apply to Federal criteria.

Response: Federal criteria will be implemented in accordance with existing state adopted compliance schedules. For a detailed discussion of this subject see a response to comment in subsection 4 of this section.

133. *Comment:* A commenter asserted that EPA did not do enough to educate the State early on of the 303(c)(2)(B) requirements and that EPA's final 303(c)(2)(B) guidance was not transmitted to the States until December 12, 1988, almost two years after the 1987 amendments. This delay left California with inadequate time to adopt criteria on a pollutant-by-pollutant and water body-specific basis, and consider the scientific uncertainties relating to the Federal data and methodologies.

Response: As stated in the Preamble to the proposed rule, the December, 1988 guidance was not substantially different from earlier drafts which were available for review by the states. That guidance proposed a pollutant-by pollutant and waterbody specific approach as an acceptable option. While recommending certain approaches, the guidance also made it clear that States retained flexibility to implement their own preferred approaches. Please see Science and Timing and Process under general comments.

134. *Comment:* One commenter stated that Region IX's requirement that California adopt criteria for all priority pollutants is erroneously based on statements in California's Functional Equivalent Documents and is inconsistent with national guidance. Another commenter stated that this requirement was unfounded.

Response: Region IX has consistently advised California that it must adopt criteria for all pollutants for which EPA has section 304(a) criteria recommendations, with the exception of any pollutants which cannot reasonably be expected to interfere with designated uses. Omission of any such pollutant must be based on evidence concerning the presence and effect of that pollutant in any given waterbody. This policy is consistent with national guidance, the history of which is set forth in Part B2 of the Preamble of November 19, 1991. None of the guidance options has ever allowed the exclusion of any such pollutant from the requirements of section 303(c)(2)(B) without a factual scientific basis. In the absence of such scientific basis, EPA relied on California's draft Functional Equivalent Document which stated that "it is likely that priority pollutants not covered in this plan will be found [in the State] in a more extensive analytical survey." This statement is sufficient basis for EPA to have determined that all priority pollutants would reasonably be expected to interfere with designated uses in all waters of the State.

135. *Comment:* The Federal criteria are more stringent than necessary for some water bodies in California.

Response: Without specific information about which pollutants and which water bodies the commenter is referencing, EPA has difficulty responding to this comment. In the absence of such specific information, EPA determined that it was appropriate to adopt EPA's section 304(a) criteria for all "waters of the U.S." that lack State-adopted, EPA-approved criteria. If, based on further scientific information, the State adopts site-specific criteria which are less stringent than the Federal criteria but, in EPA's judgment, fully meet the requirements of the Act, EPA will undertake a rulemaking to remove the affected pollutants from the Federal rule. For additional information, please see Science under general comments.

136. *Comment:* Major wastewater dischargers in California have filed a petition in State court to restrain the State from utilizing its section 303(c)(2)(B) standards for inland waters, bays, and estuaries. They filed the petition out of concern over significant economic impacts caused by blanket imposition of the [EPA] criteria. The filing of the petition illustrates the concerns of many public agencies over use of EPA criteria as national standards.

Response: The petition referred to in this comment is a challenge to section 304(a) criteria which have been adopted by the State. It is a pending proceeding in State court and does not affect today's rulemaking. The commenter states that this matter reflects a widespread concern over adoption of section 304(a) criteria as national standards. That concern is apparent in the comments received from several entities, particularly in California, and they are addressed in the Economics under general comments.

137. *Comment:* A commenter stated that "only marine criteria should be selected for enclosed bays in California since these are, by definition, indentations along the coast which enclose an area of oceanic water. It is not appropriate to apply freshwater criteria to these water bodies." The commenter also indicated that States should be given the discretion to determine when freshwater or salt water criteria should apply in an estuary.

Response: State standards in California's Inland Surface Waters and Enclosed Bays and Estuaries Plans have been approved for most of the priority toxic pollutants. These standards include both freshwater and saltwater uses and leave the selection of appropriate criteria to the regional boards. EPA approved the two sets of criteria on November 6, 1991. The Federal rule has been amended to reflect this approval. The final Federal rule applies to those parameters and also to water bodies where State standards are lacking or not protective. The regional boards shall determine for both State and Federal criteria whether freshwater or saltwater criteria are appropriate at the confluence of the water bodies with different water quality objectives.

District of Columbia

138. *Comment:* The adequacy of new human health criteria has not been proven to be germane to the District of Columbia.

Response: As a general proposition, EPA is applying criteria for all priority toxic pollutants not addressed by approved State criteria for those States not in full compliance with section 303(c) of CWA. EPA's reasoning behind this approach (and the exceptions) are discussed fully in the preamble. However, two reasons deserve repeating here. First, existing data sources indicate the discharge, potential discharge or presence of substantial numbers of priority toxic pollutants in most States. With the failure of some States to adopt toxic criteria in a timely fashion, coupled with the evidence of the discharge or potential presence of priority toxic pollutants for which the State has failed to adopt criteria, the Agency believes there is a need for numeric criteria for most priority toxic pollutants in most States. Second, the support of each criterion on a state-by-state and waterbody-by-waterbody basis by EPA would be an enormous administrative burden on EPA and would be contrary to the statutory scheme and Congressional directive for swift action. Congress directed EPA to accomplish the promulgation within 90 days and EPA has made every effort to expedite this rulemaking. Providing the adequacy for all criteria for all States would take years and would be counter to the directive of swift action.

Florida

139. *Comment:* One commenter stated that, since the State of Florida adopted numeric criteria on December 7, 1990 based on Option II of EPA's section 303(c)(2)(B) guidance, the Federal rule should not include criteria for all priority toxic pollutants.

Response: Since the time that the proposed rulemaking was published, Florida formally requested EPA's review of the criteria adopted by the State on

December 7, 1990. EPA approved these criteria, with the exception of the absence of criteria for 2,3,7,8 TCDD (i.e., dioxin) on February 25, 1992. Therefore, EPA has only included criteria for 2,3,7,8 TCDD for the State of Florida in the final rulemaking.

Kentucky

140. *Comment:* One commenter stated that Kentucky has proposed and adopted a revision to 401 KAR 5:031 which deletes the previously adopted numeric human health criteria for dioxin. A request was made by the commenter that EPA's determination of full compliance for Kentucky for the section 303(c)(2)(B) requirement be considered and a Federal water quality criteria be promulgated through this Federal rulemaking. Alternatively, a request was made that such criteria be established as an interim final rule in a separate rulemaking.

Response: At the time EPA published the proposed rulemaking, the State-adopted criteria for 2,3,7,8, TCDD for the State of Kentucky was in effect as part of 401 KAR 5:031 (Surface water standards). EPA is aware that the proposed deletion of 2,3,7,8 TCDD criteria was put into effect on January 29, 1992. EPA's position on Kentucky's proposed deletion of the State-adopted dioxin criteria was transmitted to Kentucky by letter dated November 21, 1991. In that letter, EPA's Region IV Water Management Division Director stated, "Should the State complete adoption of the proposed amendment without replacing the adopted dioxin criteria with approvable criteria values, I will recommend to the Regional Administrator that the dioxin criteria, or absence of dioxin criteria, be disapproved by EPA. If the State does not adopt criteria within 90 days of EPA's disapproval action, EPA will initiate a promulgation of Federal water quality criteria for dioxin for the State." This continues to be EPA's position on this issue.

Louisiana

141. *Comment:* EPA should not promulgate dioxin standards for Louisiana.

Response: Louisiana submitted to EPA criteria to protect human health for dioxin on December 18, 1991. EPA's review found that the criteria adopted by the State were scientifically defensible and supported the designated uses. EPA approved the State standard on January 24, 1992. Therefore, Louisiana is not included in today's rule.

Nevada

142. *Comment:* A Nevada commenter suggested that Column D1 criteria should apply only at the point of intake of any municipal or domestic supply.

Response: Column D1 criteria are to apply to all waters designated by the State of Nevada for municipal or domestic supply. In the case of Lake Mead, that is the entire lake except for the segment at the end of Las Vegas Bay recognizing that Las Vegas Wash enters there. All of Lake Mead is subject to human consumption of water either directly from the lake or downstream.

143. *Comment:* It was stated that the State of Nevada has already considered and rejected criteria similar to the proposed amendments, and Nevada's decision is not contrary to the requirements of the Clean Water Act.

Response: The State excluded criteria similar to those in the proposed rulemaking from the water quality standard amendments considered for adoption by the Nevada State Environmental Commission (SEC). The State did not provide an adequate justification for this exclusion; therefore, on January 16, 1991, EPA disapproved this portion of the SEC action as being inconsistent with section 303(c)(2)(B). Without substantive justification (such as evidence of lack of presence of particular pollutants in waters of the State) for excluding any of the priority pollutants from State standards, all of them must be added.

144. *Comment:* A Nevada commenter stated that Las Vegas Wash should be excluded from any human health protection for consumption of aquatic organisms under the Federal rule.

Response: The general issue of the applicability of column D2 (consumption of aquatic organisms) criteria is discussed in the preamble and in the Science portion of general comments. Human health protection is required where a fishery, or other aquatic life that can be consumed, is present. Las Vegas Wash has been designed by the State for the use of "Propagation of aquatic life, excluding fish." State regulations clarify that this designation does not preclude the establishment of a fishery. Although the commenter offers anecdotal information that no one fishes in (or eats any kind of aquatic organism from) Las Vegas Wash, no evidence is provided supporting that anecdotal information. No use attainability analysis has been conducted to justify removal or amendment of this use. Also, the State has already adopted (and EPA approved) standards for protection of aquatic life in Las Vegas Wash. Because of the existing aquatic life use and the potential for consumption of aquatic organisms, EPA has applied column D2 criteria to Las Vegas Wash.

145. *Comment:* A Nevada commenter stated that the proposed rule does not provide sufficient notice as to why certain criteria were included and others excluded from the proposed rulemaking for Nevada.

Response: The rulemaking includes criteria only for parameters that Nevada did not adopt, or, if the State did adopt criteria for a parameter, for parameters that were specifically disapproved. This information was all part of the administrative record associated with Nevada's adoption of numeric standards for toxics in May 1990 and EPA's approval/disapproval on January 16, 1991 and was available to the public prior to the notice of EPA's proposed rule, and during the public comment period for the proposed rule.

New Jersey

146. *Comment:* A commenter argues that New Jersey is in compliance with section 303(c)(2)(B) of the Clean Water Act because the State incorporates section 304(a) criteria, by reference, in their Water Quality Standards Regulation for actions involving the development of water quality based effluent limitations for point sources.

Response: While the State Water Quality Standards Regulation does incorporate section 304(a) criteria by reference, the standards do not specify the application factors necessary to implement criteria (e.g., a risk level for carcinogens). Further, the reference in the water quality standards regulation limits application of these criteria to actions involving the development of water quality-based controls for point sources while water quality standards must serve as the basis for controls on all sources, point and nonpoint.

147. *Comment:* A commenter noted that water quality criteria were not proposed in the promulgation for New Jersey waters classified as PL (Pinelands), or as mainstem Delaware River and Delaware Bay (zones 1C-6).

Response: EPA agrees that, due to EPA oversight, criteria were not proposed in the promulgation for New Jersey waters classified as PL (Pinelands) or as mainstem Delaware River and Delaware Bay (zones 1C-6).

Appropriate criteria for New Jersey waters classified as PL (Pinelands), and as mainstem Delaware River and Delaware Bay (zones 1C-6) are now included in this final rule.

Puerto Rico

148. *Comment:* A commenter stated that EPA's proposed rule presents serious problems regarding its implementation, specifically in determining the waters to which such criteria would be applicable in the Commonwealth of Puerto Rico.

Response: The Puerto Rico Water Quality Standards Regulations is clear regarding the designated uses of all waters of the Commonwealth of Puerto Rico. EPA is assigning necessary and appropriate criteria to support those uses in order to satisfy the requirements of section 303(c)(2)(B) of the Clean Water Act.

149. *Comment:* A commenter stated that the Puerto Rico Water Quality Standards Regulation, which establishes the classifications and designated uses, does not comply with the Federal Water Quality Standards Regulation in terms of the adoption of subcategories of uses, the need to conduct use attainability analyses when standards are exceeded, the adoption of a variety of uses for a single waterbody, and in considering the social and economic needs of the Commonwealth.

Response: While the Federal Water Quality Standards Regulation authorizes the adoption of subcategories of uses, States are not required to adopt subcategories of uses in the establishment of standards. States are not required to complete use attainability analyses (UAAs) when designated uses are not met. Section 131.10(j) of the water quality standards regulation requires that States must complete UAAs when removing designated uses that are not existing uses, or when specifying uses inconsistent with the goals of the Clean Water Act. States may not remove designated uses if they are existing uses. In the establishment of water quality standards and water body classifications, including requisite public participation, Puerto Rico has taken social and economic needs of the Commonwealth into consideration, as well as the inherent differences in levels of protection and water quality required by the various designated uses. Notwithstanding this discussion, the rule only addresses appropriate criteria for priority toxic pollutants. Other elements of State water quality standards are not addressed.

150. *Comment:* It was commented that the Puerto Rico Water Quality Standards Regulation does not recognize the uses of waterbodies that are actually attained.

Response: Designated uses of waterbodies are not required to only reflect those uses that are actually attained. While the Puerto Rico Water Quality Standards Regulation defines Class SD waters as surface waters intended for use as a raw water source for public water supply and the preservation and propagation of desirable species, not all Class SD waters presently meet these goals. Designated uses need not be existing uses. Consolidation of various uses (i.e., fishing and swimming) into one classification is an acceptable approach for designating uses of waterbodies, and a necessary one in order to meet the goal of the Clean Water Act. Federal regulations require that waters have designated uses that provide for fishable/swimmable water quality where attainable. When establishing criteria to protect these various designated uses, criteria may be specified to protect each use.

Washington

151. *Comment:* The term "water supplies" should be deleted from the Class AA listing in (22)(i) because it is incorrect.

Response: EPA concurs, it was a misprint.

152. *Comment:* Comments were received that EPA should not promulgate criteria for dioxin in the State of Washington. The commenters expressed concerns that EPA's actions would be disruptive and unnecessarily interfere with ongoing State administrative and judicial actions involving Department of Ecology's decisions in establishing effluent limitations in permits issued to numerous pulp and paper mills. The Department of Ecology had established the permit effluent limitations based on the State's existing narrative water quality criterion. The commenters urged EPA to defer action pending the conclusion of the ongoing State actions challenging the State's authority to establish permit limitations based on its narrative criterion. In addition commenters said that the current State regulations met the requirements of section 303(c)(2)(B) and that the State's regulations were equivalent to another State's water quality standards that an EPA region had approved as being in compliance with section 303(c)(2)(B).

Response: EPA carefully considered the comments on this issue and has decided to exercise its discretionary authority under section 303(c)(4)(B) to promulgate human health criteria for dioxin and the other toxic pollutants to be applicable to waters in the State of Washington. This action will ensure that there are numeric water quality criteria applicable in the State as required by section 303(c)(2)(B).

EPA's review of the current Washington water quality standards for toxic pollutants indicates that those standards do not include the necessary water quality criteria to satisfy the requirements of section 303(c)(2)(B). While WAC 173-201-047(1) includes numeric aquatic life criteria, protection of human health is only addressed through a narrative criterion that provides that toxic substances not be introduced at levels which "adversely affect public health, as determined by the department * * *." WAC 173-201-047(4). EPA believes that this limited narrative criterion does not satisfy the requirements of section 303(c)(2)(B).

EPA acknowledges that the Department of Ecology relied upon its narrative criterion to establish effluent limitations for dioxin in State NPDES permits. EPA supported the Department's reliance in its narrative criterion in developing necessary effluent limitations for the control of discharge of dioxin. EPA encourages all States to have narrative criteria for protection of aquatic life, wildlife and human health in instances when the State does not have an applicable numeric criterion. However, section 303(c)(2)(B) is clear in its directive that States adopt numeric criteria for toxic pollutants if EPA has issued section 304(a) guidance and the discharge or presence of such pollutants could reasonably be expected to interfere with designated uses in the State.

In the notice of proposed rulemaking, EPA discussed the basis for its decision to include Washington in the rule. 56 FR at 58477. The absence of any numeric criteria for human health and the acknowledged discharge and presence of toxic pollutants being expected to interfere with designated used supported inclusion of Washington in the rule. With respect to dioxin, the issuance of permits with discharge limitations was further evidence that the discharge or presence of dioxin could reasonably be expected to interfere with designated basis.

EPA does not believe that promulgation of numeric criteria for the State of Washington should be delayed pending resolution of the ongoing litigation challenging the Department of Ecology's authority to establish effluent limitations based on the State's narrative criterion. The State's narrative criterion, while it may be the basis for deriving effluent limitations, is not adequate to satisfy the requirements of Section 303(c)(2)(B). Some commenters argued that Washington had in effect incorporated by reference EPA's Section 304(a) water quality criteria guidance as the basis for interpreting and

implementing the State's narrative criterion. The Washington water quality standards, however, merely provide that for toxic substances not listed in the standards, concentrations shall be determined "in consideration of USEPA's Quality Criteria for Water, 1986, and as revised, and other relevant information." WAC 173-201-047(3). The State standards neither require use of EPA's criteria nor limit the State's decision to use of such criteria. Therefore, even a decision by the Washington Supreme Court that the Department of Ecology is authorized to use its narrative criterion to develop permit effluent limitations would not address the specific requirement of section 303(c)(2)(B) that the State adopt numeric criteria.

In response to the comments that the current Washington regulations are equivalent to regulations adopted by the Commonwealth of Massachusetts which is not included in today's rulemaking, EPA believes there is a important difference between the two State regulations. The Massachusetts regulations provide that in deriving criteria for unlisted pollutants, the State "shall use the recommended limit published by EPA pursuant to section 304(a) * * *." Code of Massachusetts Regulations, Title 314, section 4.05(5)(e). Pursuant to an Implementation Policy adopted on February 23, 1990, Massachusetts stated that it would use a risk management goal of 10^{-6} for individual chemicals and 10^{-5} for mixtures of chemicals in deriving criteria for carcinogens. The regulations contain a specificity regarding what the applicable criteria will be that is not present in the Washington regulations. EPA's Region I determined that the Massachusetts regulations complied with section 303(c)(2)(B) and approved those regulations on December 20, 1990. See 56 FR 58452.

EPA's decision to promulgate appropriate human health criteria for the State of Washington is consistent with the Agency's prior statements regarding the status of Washington's compliance with Section 303(c)(2)(B). In the Federal Register notice of April 17, 1990, EPA identified Washington as not being in compliance with section 303(c)(2)(B). 55 FR 14350. By letter dated March 27, 1990, from the Department of Ecology to EPA, the Department listed the adoption of human health criteria as an action for its triennial review that had been requested by EPA. By letter dated March 21, 1991, from EPA to the Department of Ecology, EPA explained that the State would remain in noncompliance under section 303(c)(2)(B) for human health criteria even if the State proceeded to adopt aquatic life criteria and a human health risk level. These documents are in the record of this rulemaking.

Executive Order 12291

1. Introduction and Rationale for Estimating Costs

Executive Order 12291 requires EPA to prepare a Regulatory Impact Analysis for major regulations, which are defined by certain levels of costs or impacts. For example, the Executive Order specifies that a regulation imposing an annual cost to the economy of $100 million or more is considered major. According to the Executive Order, the Regulatory Impact Analysis should contain descriptions of both potential costs and benefits. While the Executive Order calls for an estimate of costs, the Statute mandating today's rule does not allow cost to be a consideration in setting water quality criteria. The following discussion describes the Agency's consideration of costs in the rulemaking and decision process even though cost considerations are not included in the development of numeric criteria for toxic pollutants.

In developing the proposed rule, EPA considered various perspectives regarding the potential incremental costs that might be incurred as a result of the Agency promulgating numeric criteria for individual States. The Agency concluded that the costs incurred by individual dischargers as a result of complying with water quality-based permits might be large enough to designate the rule as "major," according to the definitions included in Executive Order 12291. The Agency did not include a quantitative estimate of the costs due to the uncertainties of such an estimate, but instead, described the types of costs that were expected.

There are certain characteristics of the rule that make the estimation of costs particularly complicated and difficult. Since the rule imposes requirements only until the State submits, and EPA approves, the State's own numeric standards, the cost estimates should be calculated on a per State and per pollutant basis, so that State/pollutant combinations can be removed as numeric standards are approved. Additionally, an analysis of the incremental costs attributed to the rule should reflect information on specific impaired stream segments and the dischargers on those segments.

Because a detailed analysis of all affected stream segments is not practical given the available resources, the development of compliance cost estimates for this rule would require numerous assumptions about pollutant loadings, impacts of technology-based regulations on loadings, combinations of pollutants handled by a given treatment approach, and the costs of each treatment train. The many sources of uncertainty associated with estimating the costs would produce an estimate with limited value for evaluating the merits of the rule. In addition, the rule does not remove the responsibility of States to adopt numeric criteria for toxic pollutants. As the remaining States submit their own standards and EPA approves those standards, the costs attributed to the rule will decline. Hence, EPA, with the concurrence of OMB, proceeded with the proposed rulemaking without a quantitative estimate of compliance costs.

2. Overview of Projected Costs

EPA acknowledges that there will be a cost to some dischargers for complying with new water quality standards as those standards are translated into specific NPDES permit limits. The addition of Federally promulgated criteria for toxic pollutants could affect the wasteload allocations developed for each waterbody segment in affected States to the extent the pollutant is discharged into the stream. Revised wasteload allocations may result in adjustments to individual NPDES permit limits for point source dischargers, and these adjustments could result in increased wastewater treatment costs or other pollution control activities such as recycling or process changes. The magnitude of these costs depends on the types of treatment or other pollution control, the number and type of pollutants being treated, and the level of control that can be achieved by technology-based effluent limits for each industry.

Similar sources of costs and the variables affecting costs may also apply to indirect industrial dischargers to the extent that the industrial discharger is a source of toxic pollutants discharged by the POTW. The POTW may incur costs for expansion, operational changes, additional treatment, modified pretreatment programs, and increased operator training.

Nonpoint sources of toxic pollutants may also incur increased costs to the extent that best management practices need to be modified or applied to more sources to reflect the revised water quality standards. Although there is no Federal permit program for nonpoint sources comparable to that for point sources, there are State regulatory programs to control nonpoint source discharges.

Monitoring programs are another source of potential incremental costs to dischargers and States. Monitoring programs to generate information on the existing quality of water and the types and amount of pollutants being discharged are potentially affected by the imposition of EPA criteria. The addition of Federal criteria for toxic pollutants does not require the State to engage in a program to monitor ambient waters for such pollutants. Unless there is some reasonable expectation that the pollutants are manufactured or actually used in the State with the likelihood that those pollutants will be discharged into surface waters, NPDES permittees also would not have to monitor for these pollutants.

3. Comments and EPA's Response

EPA received numerous comments regarding the potential cost impacts of the rule; most of these comments contend that a Regulatory Impact Analysis is required. Specifically, many commenters asserted that EPA should estimate the costs that dischargers would incur and include such cost estimates in all decision-making aspects of the rule. Some of these comments argued the qualitative discussion of costs did not fulfill the requirements of E.O. 12291.

EPA does not concede that its rationale for *not* estimating costs was flawed. Rather than appear nonresponsive, however, the Agency recognizes that further discussion is warranted and has undertaken an assessment of potential costs that might be incurred for several types of dischargers.

This cost assessment is not a Regulatory Impact Analysis, nor is it a comprehensive cost analysis. The following discussion is intended to describe the scope and range of costs that might occur. Many analytical assumptions were necessary to conduct this cost assessment, which is presented in the form of four examples. Each example was conducted independently with no common data sources. The examples are not intended to represent an estimate of the total costs of the rule.

The Agency maintains that a comprehensive analysis of costs would not provide enough additional information to assist Agency management with decisions concerning the rule. A complete analysis of costs for this rule would likely include differential costs to comply with various levels of regulatory control. Similarly, an RIA would likely evaluate alternative options for structuring the rule, where the options might reflect various level of stringency. Due to the complexities of analyzing the impacts of this rule, however, a meaningful cost estimate would be extremely difficult and costly, and it is uncertain whether an RIA would lend reliable information to the decision-making process.

4. Scope of Cost Impacts

Since this rule directly affects only those States that have not adopted their own numeric criteria for toxic pollutants, the cost impacts are limited to dischargers in those States. The cost impacts are further limited by several other factors. First, the potential impact of the rule is limited to treating discharges of only those pollutants included in the rulemaking for each State. In other words, if today's rule imposes criteria for only one pollutant (assuming criteria were adopted and approved for all other pollutants—a situation which occurs for several States), the number of dischargers in that State that might incur compliance costs are limited to dischargers for which that single pollutant drives the treatment needed to comply with their NPDES permit. This situation significantly reduces the number of dischargers with a cost impact. The number of pollutants that could be the basis for additional treatment may be reduced from the number actually included in the rule due to the overlap of controls for groups of pollutants. For example, discharges of several of the metals can be reduced by a single treatment system (generally lime precipitation and clarification) without additional treatment for each additional pollutant in that group.

In some cases, the controls in place—whether installed to comply with technology-based limitations or to comply with a discharge permit issued pursuant to section 304(l) of the Clean Water Act—may be sufficient to provide compliance with water quality criteria. In other cases, controls implemented to meet whole effluent toxicity permit requirements may preclude the need to implement additional controls to reduce a toxic pollutant discharge covered by the rule.

Finally, flow levels, receiving stream conditions, and wasteload allocations are likely to cause variation in the need to install additional treatment technology. For all of these reasons, the Agency believes that the number of dischargers with potential incremental costs is significantly lower than the total number of dischargers in the controlled States.

An estimate of the number of point sources that could be affected begins with the major dischargers from the 14 States included in today's rule.[8] The focus on major dischargers (where the term "major" refers to the distinction used in the NPDES program for facilities with the potential for a significant impact on water quality) is consistent with the rulemaking's focus on toxic pollutants. Any point source with a significant discharge of toxic pollutants is likely to be included in this category.

The number of major facilities for the 18 States is 2,055. (See Footnote 5.) This is a subset of the approximately 7,000 major dischargers in the entire country (3,000 industrial, 4,000 municipal). Of these, 229 facilities already have Individual Control Strategies (ICS) that were established in response to section 304(l) of the Clean Water Act. These facilities have effluent limitations for toxic pollutants sufficient to achieve water quality standards in the receiving water. Thus, the number of major facilities that potentially could be subject to incremental requirements is 1,826. The exact number is likely to be lower because of the number of regulated pollutants in each State and the current discharges of the facilities.

All of the analytical difficulties described above, such as estimating pollutant loadings and compliance costs, would need resolution to accurately estimate the cost impacts for this group of dischargers. In place of attempting to estimate total costs, the following four examples illustrate the range of costs likely to be incurred in specific situations, and some of the problems involved in developing potential compliance costs for this rule.

5. Example: Regulating Dioxin for the Pulp and Paper Industry

As an example of the range of costs that could be associated with the imposition of EPA's numeric criteria, we considered the pulp and paper industry and the pollutant dioxin.

Dioxin (i.e., 2,3,7,8-TCDD, listed as Compound #16 at § 131.35(b) of the proposed rule) is a likely by-product from chlorine bleaching of chemically-pulped wood. Chlorine bleaching is used by approximately 100 pulp mills in the United States. Of those bleach mills, 22 are located in States that had not adopted human health criteria for dioxin as of the date of the proposed

[8] When this assessment was prepared, the Agency contemplated that 18 States would be included in the rule. Thus, the estimated costs described in this preamble are based on a "universe" of 18 States. Since then, four States have adopted and EPA has approved priority toxic pollutant criteria. In the examples that follow, the assessment has not been revised from 18 States to 14 States because the objective of the assessment—to describe the scope and range of impacts—is met even with the higher number of States.

rule. (See Footnote 5.) Thus, this rule could potentially serve as the basis for establishing dioxin limitations in the NPDES permits for those facilities. Of the 22 bleach mills in "unapproved" States, however, 13 already have dioxin limitations in their discharge permits, established in response to section 304(l) of the Clean Water Act. Only for the remaining nine facilities, then, will this rule be a potential reason for establishing dioxin limitations in the discharge permits.

For those nine facilities, however, the effluent levels of dioxin, as reported by the facilities, are all equal to or less than 10 parts per quadrillion (ppq).[6] This effluent data has important implications for projecting costs and impacts. Today's rule will result in water quality standards that contain EPA's human health criteria of 0.013 ppq for dioxin at a 10^{-6} incremental risk level (or 0.13 ppq for States that have expressed a preference for a 10^{-5} incremental risk level). This value would then be reflected in the permits for the facilities that discharge dioxin, after conducting a wasteload allocation and accounting for stream dilution. If the resulting permit limitation is less than 10 ppq, compliance with the permit is likely to be determined at 10 ppq, because that is level of detection for dioxin for the EPA analytical method.

The practical interpretation of the effluent data for these nine facilities is that promulgation of this rule is unlikely to affect the need for treatment and thus, the costs of compliance for water quality-based permits.

These conclusions are very much a function of the laboratory analytical methods and their levels of detection for dioxin. If more precise and reliable measurement becomes available and is incorporated into the monitoring requirements in the permits for these facilities, the small differences between their effluent levels and the more stringent water quality-based limitations could present the need for additional treatment or revised production processes.

The Agency has collected extensive information about the pulp industry's efforts to reduce dioxin discharges from chlorine-bleaching facilities. The industry has responded to the need to reduce dioxin (and related chemicals) discharges with a variety of technological advancements. These include process refinements, such as changing input chemicals or altering the bleaching process. These types of changes are not necessarily prohibitive in terms of investment cost or operating costs. Substantial dioxin reductions have been achieved at little or no incremental compliance costs by changing certain process chemicals. For example, a change to dioxin precursor-free brownstock defoamers has been successful in reducing dioxin discharges at virtually no change in chemical cost and with no additional equipment. Other process chemical changes, however, can result in increased costs. For example, increased chlorine dioxide substitution, which is often accompanied by increased chlorine dioxide generation on-site, has been adopted by various facilities at on investment cost of approximately $20 million each. At the costly extreme, dioxin discharge reductions at other facilities reflect major renovations, not only to reduce dioxin discharges, but to modernize or otherwise restructure the facility. For example, a facility might choose to rebuild its bleach plant and adopt an entirely new bleaching process. Costs for this type of rebuilding may reach $100 million.

In summary, the costs associated with meeting an EPA-imposed dioxin limit can be estimated only with information on the bleaching process currently used at each facility, its wastewater characteristics, the characteristics of the receiving stream, and the level of control mandated by a new water quality-based permit. Based on reported effluent levels, however, this rule is unlikely to be the basis for any incremental compliance costs for Pulp and Paper mills to reduce dioxin discharges.

6. Example: Regulating Copper in the Metal Finishing Industry

As a second example of the range of costs that might be incurred as a result of complying with water quality-based permits issued in response to the imposition of EPA's criteria for toxic pollutants, we considered the metal finishing category for the control of the pollutant copper.

Effluent guidelines limitations and standards, which are technology-based regulations developed by the Agency pursuant to section 304 of the Clean Water Act, were promulgated for this industry in July 1983. Briefly, the effluent guidelines for the metal finishing industry set national standards for all dischargers to surface waters and to wastewater treatment plants (sometimes called publicly-owned treatment works, or POTW). The effluent guidelines for the metal finishing industry include numeric limitations for copper, based on the Best Available Technology Economically Achievable (BAT), for direct dischargers. The limitations for copper, as promulgated, are a daily maximum of 3.38 mg/l and a monthly average of 2.07 mg/l. The technology basis for these limitations is generally lime precipitation and clarification.

When the Agency promulgated effluent guidelines for this industry, the estimated number of direct dischargers subject to the regulation was approximately 2,900. In the Agency's permit compliance database, which reflects a more recent assessment, there are approximately 4,000 metal finishing direct dischargers. The higher, and more conservative number (in terms of projecting the number of affected facilities) is used in this assessment.

Of the 18 States included in this assessment, only six will receive EPA's aquatic criteria for copper; the remainder have already adopted aquatic criteria for copper in their standards.[7] (See Footnote 5.) Approximately 530 of the direct dischargers are located in these six States (where two States account for 93 percent of the facilities).

The number of potentially affected facilities is further reduced for several reasons. First, the number of facilities that would actually be considered for water quality-based permits could be lower, after subtracting any facilities that have individual control strategies (ICSs) to control the discharge of copper. In addition, the Agency has provided a formula in today's rule to allow the permitting authority to determine a water-effect ratio to account for metals speciation. The practical result is that, where determined, the water quality criteria for copper in certain waterbodies is likely to increase. This adjustment will have the effect of bringing the water quality-based limitation closer to the BAT limitation; for some facilities, this water-effect adjustment could eliminate the need for incremental treatment.

Finally, depending on site-specific conditions at each facility, such as the actual discharge concentration of copper, treatment-in-place, and the dilution provided by the receiving stream, complying with the in-stream concentration specified in the rule could be achieved by merely complying with BAT limitations. Alternatively,

[6] U.S. Environmental Protection Agency, Engineering and Analysis Division, "1990 National Census of Pulp, Paper, and Paperboard Manufacturing Facilities—Preliminary Summary Report of Questionnaire Responses for Mills Which Bleach Chemical Pulps," October 31, 1991.

[7] For metal pollutants, such as copper, the aquatic criteria tend to be more stringent than the criteria based on protecting human health. For purposes of this assessment, EPA is estimating impacts related to the aquatic life protection criteria because those criteria are more relevant for establishing water quality standards.

since the in-stream water quality criteria is more stringent than the discharge limitation established by BAT, it is possible that a facility complying with BAT would need additional treatment to comply with a water quality-based limitation.

For purposes of this assessment, EPA investigated whether BAT would be sufficient to meet water quality criteria. Many simplifying assumptions are incorporated into the following discussion. The investigation focused on metal finishing facilities with water releases of the metal pollutants (including, but not limited to copper) as reported in the Toxic Release Inventory.[8] The facilities included in this assessment were limited to those for which plant and stream flow data were readily accessible. While the number of facilities meeting all of these criteria was small, the results were indicative of both scenarios described above. In Connecticut (which is used for illustrative purposes only because it is not included in the final rule), EPA has identified a facility for which BAT will be sufficient for controlling discharges of copper to the level needed to comply with a water quality-based limitation for copper, assuming EPA's criteria level. At that site, the stream dilution is such that meeting the BAT limitation at the discharge point will also likely meet the water quality criteria within the stream. We have also identified another facility in Connecticut for which BAT will not be sufficient—that is, the effluent levels needed to comply with the water quality criteria in the stream are lower than the level that BAT will provide. Thus, additional treatment controls, and incremental compliance costs, are potentially needed for the second facility.

Without a detailed water quality and stream dilution analysis for all dischargers, the number of facilities where BAT will be sufficient to also meet water quality criteria is unknown. For purposes of this assessment, the distribution of facilities where additional treatment may be necessary is assumed to be between 25 and 75 percent. Additionally, the distribution of facility and stream characteristics for metal finishers in Connecticut is assumed to be representative of the distribution of characteristics in the other States. Using these simplifying assumptions, EPA estimates that 130 to 400 facilities are potentially subject to additional treatment requirements.

During the development of the effluent guidelines for this industry, EPA considered several treatment technologies that control pollutant discharges. In addition to the precipitation and clarification technology that was used as the basis for effluent limitations, EPA investigated and published information about effluent filtration, which provides more stringent control of copper discharges.[9] Filtration was not selected as the basis for BAT because of its high cost when considered on a nationwide basis.[10] The removal efficiency for filtration is substantially higher than that for precipitation and clarification. Based on engineering judgment, if filtration were installed at a facility in addition to the technology used as the basis for BAT, meeting the in-stream water quality criteria for copper would be technologically feasible. Hence, the incremental costs for filtration are used here to estimate the range of costs that might be attributable to this rule.

During development of BAT, the Agency estimated total annual costs to add filtration to precipitation and clarification for various sizes of facilities. The incremental cost estimates used here reflect one of several combinations of manufacturing processes and conditions. The costs are likely to be an overestimate because they reflect the upper bound of each flow size range. The potential incremental total annual costs used to estimate the compliance burden for meeting a water quality-based permit are approximately $20,000 for small plants, $43,000 for medium plants, and $146,000 for large plants. To estimate the costs that might be incurred by the dischargers potentially affected by the rule, we assume that the distribution of facility sizes for those dischargers is the same as the distribution used for BAT development. While specific cost estimates depend on many site-specific factors, the range of costs that could be expected for 130 to 400 facilities are approximately $7 million to $20 million.

It is likely that the assessment presented here for copper will include meeting aquatic criteria for other metals due to the similarity in treatment technology. Thus, the cost impacts estimated here will likely provide sufficient treatment to comply with the aquatic criteria for most of the metals.

Another means of considering the potential costs is to evaluate the cost-effectiveness of the additional treatment, where cost-effectiveness is defined by the ratio of incremental cost to incremental pollutant removal. The cost-effectiveness of filtration for those facilities projected to need additional treatment is based on the cost estimates shown above and the pollutant removals for not only copper, but five additional metals that will be removed by filtration. Cost-effectiveness ratios are expressed as "dollars per pound-equivalent removed," where a pound-equivalent is a pound of pollutant weighted by the relative toxicity of that pollutant. The cost-effectiveness of filtration for these facilities is $22 per pound-equivalent removed. This result suggests that filtration is a cost-effective technology.

In summary, the actual burden to dischargers in the metal finishing industry ranges from no impact, where BAT is sufficient to protect the receiving stream, to an incremental cost impact of 5 to 13 percent above the cost of BAT, where filtration is needed. In addition, treatment to comply with more stringent standards appears to be cost-effective.

7. Example: Regulating Priority Pollutants in the Organic Chemicals, Synthetic Fibers, and Plastics Industry

A third example of the range of costs that might be incurred as a result of complying with EPA's criteria for toxic pollutants is based on several segments of the organic chemicals manufacturing industry, where EPA considered the control of all priority pollutant discharges.

Technology-base effluent limitations guidelines and standards were promulgated for this industry in November 1987. The Agency is still engaged in rulemaking activities for this industry in response to litigation and court remands. The following discussion is based on the regulation and supporting documentation from the 1987 final rulemaking.[11]

[8] U.S. Environmental Protection Agency, Toxic Release Inventory, 1989. A search of the inventory for direct dischargers in the metal finishing industry in the six States yielded 41 facilities. Two of the six States have zero facilities matching that description. The comparisons of BAT and water quality criteria are drawn from that subset of the inventory.

[9] U.S. Environmental Protection Agency, Effluent Guidelines Division, Development Document for Effluent Limitations Guidelines and Standards for the Metal Finishing Point Source Category, June 1983.

[10] When establishing BAT, the Clean Water Act requires specific consideration of cost and economic achievability; such consideration is not required when establishing water quality standards. This is not to say that economic considerations are completely outside of the water quality standards process, but that such factors are considered at other points in the process, such as establishing waterbody use classifications. Here, the focus is adopting water quality criteria that are protective of human health and the environment.

[11] U.S. Environmental Protection Agency, Industrial Technology Division, Development Document for Effluent Guidelines and Standards for the Organic Chemicals, Plastics and Synthetic Fibers Point Source Category, Volume I, EPA 440/1-87-009, October 1987.

During development of the effluent guidelines for the organic chemicals industry, the Agency considered the potential for pollutant discharges from all of the priority pollutants. Approximately half of the priority pollutants were detected in effluents from chemical manufacturing facilities, and the effluent guidelines for this industry include limitations for most of these pollutants. The technology basis for establishing BAT varies by pollutant and by industry subcategory, but for many subcategory/pollutant combinations is steam stripping and/or biological treatment.

The promulgated effluent guidelines for the organic chemicals industry were expected to control discharges from more than 700 facilities. Of these, 275 are located in the 18 States used in this assessment to analyze the economic impacts of EPA's human health criteria. (See Footnote 5.) The human health criteria are likely to be the more significant values (compared to aquatic life criteria) for purposes of controlling organic pollutant discharges. The number of direct dischargers in the 18 States is estimated to be 90, based on the total industry proportion of direct dischargers. These dischargers are potentially subject to incremental requirements as a result of today's rule.

The key question for estimating the effect of the rule is whether BAT is sufficient to protect water quality to the levels that would be mandated by imposition of the criteria promulgated today. Water quality modelling results suggest very few exceedances of the water quality criteria, after the imposition of BAT requirements.

The level of control provided by the effluent guideline reflects the analytical laboratory level of detection for nearly half of the regulated pollutants. While the maximum monthly average expressed in the effluent guidelines may be higher than the detection limit (to account for variability), the level of detection corresponds to the long-term average of the treatment's removal efficiency. No water quality exceedances were projected among the pollutants that are regulated at levels higher than the detection limit.

The practical effect of the BAT limitations, combined with levels of detection and water quality assessments, is that this rule is unlikely to affect the behavior of chemical manufacturers in terms of pollution control investments. By complying with BAT limitations, the facilities are likely to also comply with more stringent, water quality-based limitations. Even though EPA's human health criteria suggest that permit requirements for some dischargers will be lower than the level of detection, a facility that cannot demonstrate compliance with the lower permit value is unlikely to add treatment or change processes in response to the revised permit.

In summary, BAT requirements for this industry control nearly half of the regulated pollutants to the level of detection for each pollutant. It is unlikely that the rule will result in incremental economic impacts for direct dischargers in the organic chemicals, plastics, and synthetic fibers industry.

8. Example: Regulating Priority Pollutant for POTWs

The final example of the range of costs that might be incurred as a result of EPA-imposed numeric criteria is for POTWs. An important aspect of regulatory impact for sewage treatment plants is that increases in investment and operating costs are often passed on to consumers in the form of user fees or taxes. For purposes of this assessment, however, we have not extended the cost impacts to household burden.

For POTWs, the choice of treatment technology is dependent on many factors; one of the most important is the pollutant (or group of pollutants) of concern and the source of that pollutant. For example, different technologies are recommended if the pollutants of concern are dissolved organic compounds as opposed to suspended solids. For this assessment, we relied on summary cost information presented in comments the Agency received during development of the Great Lakes Water Quality Initiative and on summary information from a rulemaking that focused on the incremental cost for POTWs to upgrade wastewater treatment.[12] The pollutants of concern and levels of control in those sources are similar to the additional controls that might be imposed by compliance with water quality standards following adoption of EPA's numeric criteria for priority toxic pollutants.

Several comments to the proposed rule contended that reverse osmosis is needed to comply with EPA's criteria for metals. According to commenters, this technology is likely to be very expensive when applied to the high flows found at many POTWs. EPA believes that POTWs often have alternatives to installing this type of treatment technology. These alternatives may be attractive from an overall water quality perspective because they prevent pollution at the source. For example, it may be less expensive for a small number of indirect dischargers to reduce their metals contribution to the POTW's wastestream than for the POTW to treat all of its effluent.

Copper discharges are another potential source of difficulty for POTWs in meeting water quality criteria. Many drinking water systems use copper to control algae growth. The copper is then discharged to the POTW and then to the receiving stream. Other algae controls, such as potassium permanganate, may be effective for some drinking water systems. This example of an alternative would reduce the copper loading to the POTW's receiving stream without requiring expensive treatment such as reverse osmosis at the POTW. Reverse osmosis was not used in either of the cost sources noted above; nor is it used here. The pollution control technology selected for a POTW depends on various engineering judgments and site-specific conditions. The incremental costs used in this assessment are based on activated carbon for some POTWs and on polymer addition for others. Engineering judgment suggests that many of the organic and metal compounds of concern will be removed in the final effluent with these types of treatment technologies.

The following cost assessment is likely to be an overestimate due to the simplifying assumptions used in this procedure. The number of POTWs that possibly could be subject to incremental costs that are attributable to this rule is first limited to POTWs in those States that had not adopted their own numeric criteria by the time of the proposed rulemaking. A total of 18 States was used to project the number of POTWs (See Footnote 5.) Of the approximately 15,000 POTWs in the U.S., 3,942 are identified as "majors" in the Permit Compliance System. Of these, 952 are located in the 18 States. Even as of the proposed rule, however, this number of POTWs is an overestimate of the number that might incur increased costs because it includes *all* States projected to receive *any* pollutant criteria. In fact, many of the 18 states need only a limited number of pollutant criteria (for some States, as few as one).

The number of POTWs that might be subject to new or more stringent permit requirements is further reduced because some portion of those permits already include limitations for some of the pollutants of concern. Such permit limitations and the ICSs were established in response to section 304(l) of the Clean Water Act. Another factor that may eliminate the need for additional treatment by the POTW is the use of whole effluent toxicity limits,

[12] Best Conventional Pollutant Control Technology; Effluent Limitations Guidelines; Final Rule, 51 FR 24974, July 9, 1986.

which are possibly already controlling toxic discharges. In addition, existing treatment and pretreatment may obviate the need for more stringent permit requirements. Other site-specific analyses, such as wasteload allocations and dilution studies are likely to affect the reasonable expectation that a pollutant is discharged. Also, as mentioned earlier, the water-effect ratio calculation is likely to eliminate the need for incremental treatment in certain waterbodies.

For purposes of this assessment, the number of POTWs that will need additional treatment has been estimated by focusing on the results of section 304(l) reviews. During each State's review of dischargers to identify sources that were discharging toxic pollutants at a level that could potentially cause water quality impairments, less than 5 percent of the major municipal dischargers were listed. Applying this proportion to the number of municipal dischargers covered by today's rule yields an estimated 46 POTWs that could potentially cause water quality criteria violations. The provisions of section 304(l) required States to respond to these projected violations by developing Individual Compliance Strategies and permit limitations for toxic pollutants.

The Agency acknowledges that the discharger reviews conducted in response to section 304(l) were not comprehensive and probably undercounted the number of dischargers, including POTWs, that were discharging toxic pollutants. Some of the reasons for undercounting include the lack of monitoring information, quickly-conducted reviews, varying methodologies among States, and out-of-date discharge information. For purposes of this assessment, the number of sources that potentially cause water quality criteria problems is assumed to be three times the number actually listed; in other words, the number of POTWs subject to additional controls is conservatively estimated to be triple the 46 actually identified, or 138 POTWs.

As mentioned, there are various alternatives that an individual POTW might undertake to comply with more stringent permit requirements. While the most costly alternatives involve additional pollution control equipment to the POTW, there are other mechanisms to improve the quality of the POTW's effluent. For example, a pretreatment program could require an industrial discharger to reduce or eliminate its contribution of toxic pollutants to the POTW's wastestream. Alternatively, nonpoint sources could undertake better management practices to reduce runoff. Many of these alternatives have little or no incremental cost impact to the POTW. While some of the alternatives involve a shift in costs, the overall effect is likely to be a lower cost than if incurred solely by the POTW. Even with the availability of alternatives for compliance, this assessment assumes that half of the POTWs will install additional treatment. Hence, 50 percent, or 69, of the potentially affected POTWs are assumed to incur additional compliance costs.

The costs of additional pollution controls are derived from the two sources mentioned above. The cost calculations for activated carbon include capital costs, O&M costs, source controls, and studies (such as mixing zone demonstrations, toxicity testing, monitoring, and fish bio-uptake tests). For purposes of this assessment, simplifying assumptions were then applied to those cost calculations to estimate total annual costs for various sizes of POTWs. The incremental total annual costs for activated carbon are estimated to be $0.4 million for a small POTW, $1.4 million for a medium POTW, and $12.8 million for a large POTW. The cost estimates for improved secondary treatment by polymer addition include annualized capital costs and O&M expenses. The incremental total annual costs for this technology are estimated to be less than $0.1 million for a small POTW, $0.4 million for a medium POTW, and $1.5 million for a large POTW.

Based on engineering judgment, 75 percent of the POTWs are assumed to rely on chemical addition to meet permit limits. The remaining 25 percent are assumed to rely on activated carbon adsorption. To estimate costs for each group of POTWs, the facilities are categorized according to flow groups, assuming that the size distribution of the POTWs in the affected States is the same as those used in each cost source. Then, the incremental costs for each type of treatment are applied to the number of POTWs in each size category. This procedure results in an incremental cost estimate of approximately $30 million.

To summarize, some POTWs may be subject to additional treatment requirements as a result of this rule. The number of POTWs and the types of treatment are dependent on many site-specific conditions and on the pollutants included in today's rule. For many of the POTWs that are major discharges in the States that will need to adopt new water quality standards, there is likely to be no incremental cost. Using a conservative estimate of the remaining POTWs, the upper bound of an incremental cost estimate is approximately $30 million for POTWs to comply with new discharge permit requirements.

9. Conclusions of EPA's Cost Assessment

Today's rule establishes a legal minimum standard where States have failed to comply with the statutory mandate to adopt numeric criteria for toxic pollutants. The impacts to dischargers are difficult to estimate because of the numerous assumptions and unknowns. While the Agency acknowledges that some dischargers may incur compliance costs due to new water quality standards, a meaningful cost estimate that covers the entire rule is not feasible.

In the absence of a cost estimate, per se, the Agency has described the types of costs that may be incurred by various types of dischargers. In addition, this cost assessment includes four examples of potential compliance cost scenarios: reducing dioxin discharges from pulp mills, reducing copper discharges for metal finishing, controlling priority pollutant discharges for organic chemical manufacturing, and reducing discharges from POTWs.

EPA finds that the costs to comply with toxic pollutant criteria may be less than anticipated at the time the rule was proposed. Many States have adopted their own numeric criteria and are therefore excluded from today's rulemaking. In addition, for some point source categories, where technology-based controls have been established, more stringent water quality-based controls will result in no incremental compliance costs. Further, EPA concludes that additional analysis is not warranted because the uncertainty of such an analyses would not provide enough reliable information to assist decision-makers in evaluating the regulatory strategy for this statutorily-mandated rule.

10. Introduction to Benefits Assessment

The numeric criteria for toxic pollutants promulgated in today's rule are essential in implementing toxics controls and protecting human health and aquatic ecosystems. Under this Rule, a total of 15 States and Territories will receive criteria for human health and aquatic life (14 for human health and 13 for aquatic life). The adopted standards will result in decreased toxic pollutant loading discharges which will result in improved protection of human health and aquatic life.

The Agency did not include a quantitative estimate of the benefits in the proposed rule for reasons similar to those cited above for not including a detailed cost estimate. The environmental benefits associated with this promulgation are difficult to assess and quantify. A comprehensive analysis of human health and ecological benefits is not practical given the available resources and inherent limitations such as (1) assuming a linear relationship between pollutant loading reductions and benefits attributed to the clean-up of surface waters; (2) underestimating the benefits or reducing toxics due to the complexity of assessing impacts on aquatic ecosystems; and (3) the uncertainty in estimating the magnitude of intermedia transfers of pollutants. Such uncertainties limit the value of using such estimates to evaluate the net benefits of this rule. However, the Agency has undertaken a preliminary assessment of potential human health and ecological benefits that might be accrued through promulgation of the rule.

11. Human Health Assessment Scope

The potential benefits to human health of establishing toxic criteria include: (1) Reducing the potential health risks to persons eating fish contaminated with toxic pollutants, (2) reducing the potential health risks to persons drinking contaminated drinking water, and (3) reducing the potential health risks to swimmers from dermal exposure to contaminated surface waters. EPA's qualitative assessment is limited to assessing (1) potential benefits from reducing pollutant levels in fish that may be caught by sport and subsistence fishermen and subsequently consumed by them and their families; and (2) potential benefits that may also result from lowering pollutant levels in commercially caught fish consumed by the general population. This assessment is limited to assessing only the potential reduction in cancer risk; no attempt has been made to assess potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects.

12. Ecological Assessment Scope

Some of the ecological benefits are difficult to assess due to the complexity of ecological interactions, the limited amount of ecological risk information available, and the lack of an established methodology for evaluating ecological benefits. In addition, difficulties arise in estimating the exposure of aquatic ecosystems due to the large size of ecosystems, wide geographical distribution, heterogeneous characteristics and the wide range of populations with differing sensitivities to impacts. While the benefits of promulgating this rule were not quantified due to such uncertainties and limitations, the potential benefits of establishing toxic criteria for the protection of aquatic life can be described qualitatively.

The most recent National Water Quality Inventory indicates that one-third of monitored river miles, lake acres, and coastal waters have elevated levels of toxic pollutants. After evaluating these data, the Agency concluded that the data most likely understate the presence or discharge of toxic pollutants because of the limited amount of monitoring data for some States and inconsistencies among the States in how the data were generated. Thus, it is likely that significant portions of water bodies in some States exceed water quality criteria for the protection of aquatic life. These criteria were developed to protect most aquatic organisms, as well as wildlife that consume aquatic organisms, from acute and chronic toxic effects that adversely affect survival, growth or reproduction. These effects will vary due to the diversity of species with differing sensitivities to impacts. For example, lead exposure can cause spinal deformities in rainbow trout. Nickel exposure can affect spawning behavior of shrimp. Nickel, mercury, and copper exposure can affect the growth activity of algae. In addition, copper, mercury, and cadmium can be acutely toxic to aquatic life including finfish. These types of ecological effects are expected to be reduced because this rule should reduce ambient pollutant levels. In addition, this rule will reduce continuous discharges of toxics which will allow for a natural recovery of the ecosystems.

13. Qualitative Benefits Assessment

Human health benefits that can be attributed to this rule are expressed in terms of the reduction in cancer risk. The analysis performed was limited to assessing only the potential reduction in cancer risk; no assessment of potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects was conducted. However, given the number of pollutants, there could be: (1) Decreased incidence of systemic toxicity to vital organs such as liver and kidney; (2) decreased extent of learning disability and intellectual impairment due to the exposure to such pollutants as lead; and (3) decreased risk of adverse reproductive effects and genotoxicity.

The ecological benefits that can be expected from today's rule include protection of both fresh and salt water organisms, as well as wildlife that consume aquatic organisms. Today's rule will result in a reduction in the presence and discharge of toxic pollutants in the water bodies of these States thereby protecting those aquatic ecosystems currently under stress, providing the opportunity for the reestablishment of productive ecosystems in damaged water bodies, and protection of resident endangered species.

In addition, the rule would result in the propagation and productivity of fish and other organisms, maintaining fisheries for both commercial and recreational purposes. Recreational activities such as boating, water skiing, and swimming would also be preserved along with the maintenance of an aesthetically pleasing environment. Both recreational and commercial activities contribute, in turn, to the support of local and State economies.

K. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq., Pub. L. 96-354) requires EPA to assess whether its regulations create a disproportionate effect on small entities. Among its provisions, the Act directs EPA to prepare and publish an initial regulatory flexibility analysis at the time a rule is proposed if the rule will have a significant impact on a substantial number of small entities. In the preamble to the proposed rule, EPA discussed the possibility that the rule could result in treatment costs to some dischargers to comply with water quality standards that incorporate new criteria for toxic pollutants. The Agency did not conclude, however, that the rule would have a significant impact on a substantial number of small entities due to the uncertainties associated with estimating total costs and impacts. The difficulties of cost estimation for specific groups of dischargers (such as small businesses or governments) were described in the preamble section that outlined EPA's response to Executive Order 12291. Similarly, in today's final rulemaking, the details of EPA's findings concerning the costs and impacts of this rule are presented in section J, above.

Briefly, the complexities and difficulties associated with estimating costs for purposes of economic or regulatory analysis similarly apply to estimating impacts to small entities. For purposes of this rulemaking, small entities are small dischargers, whether industrial or municipal. Regardless of

the parameters used to define small dischargers (for example, discharge flow, number of employees, population served), EPA's expression of costs and impacts for this rulemaking is limited to the descriptions in section J. EPA does not find that there will be a significant impact on a substantial number of small entities because impacts on specific dischargers cannot be predicted with certainty, and based on several examples in the cost assessment, it appears that potential impacts will not be concentrated among small dischargers.

In addition, EPA again finds that the impacts on small entities are best considered during standards development and implementation when site-specific costs can be estimated, and any resulting impacts can be minimized or alleviated as part of writing the discharge permit. It is not the Agency's intent to ignore the consequences of incorporating toxic pollutant criteria, but instead, that these consequences are more appropriately defined and accounted for in the permit-writing context. The water quality standards regulation provides several means (such as adjusting designated uses, setting site-specific criteria, or granting variances) to consider costs and adjust standards to account for the impacts on small dischargers.

While the imposition of EPA's numeric criteria for toxic pollutants may limit the flexibility that States will have to use these procedures to modify standards, EPA's expectation is that impacts will not be concentrated on small dischargers. Although there can be site-specific cases of water quality violations due to toxic discharges from low-flow point sources, EPA generally finds that priorities for NPDES permits focus on major dischargers. Small entities are less likely to be included in this group.

Other requirements of the Regulatory Flexibility Act are fulfilled in other sections of this preamble. Specifically, the Agency's explanation for taking this action and the legal basis for the rule are found in section E. The number of small entities that will be affected by the rule is not estimated for the reasons expressed above. The projected reporting and recordkeeping requirements are discussed in Section L. There is no anticipated duplication, overlap, or conflict with other Federal rules, except to the extent that technology-based standards (such as BAT) are sufficient to also meet water quality standards. Alternatives to the final rule include any of the opportunities that States had to adopt their own standards, incorporating any of the procedures to limit the compliance burden; these alternatives are discussed in Sections B and C.

The Agency concludes that this rulemaking, *per se*, will not result in a significant impact on a substantial number of small entities, and a final regulatory flexibility analysis is not required.

L. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* These requirements will not be effective until OMB approves them and a technical amendment to that effect is published in the Federal Register. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 0988.04) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM-223Y); Washington, DC 20460 or by calling (202) 260-2740.

Public reporting burden for this collection of information is estimated to average 725 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223Y, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs; Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." Comments must be submitted by January 21, 1993.

List of Subjects in 40 CFR Part 131

Water pollution control, Water quality standards, Toxic pollutants.

Dated: December 1, 1992.

William K. Reilly,

Administrator.

For the reasons set out in the preamble title 40, chapter I, part 131 of the Code of Federal Regulations is amended as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 is revised to read as follows:

Authority: 33 U.S.C. 1251 et seq.

Subpart D—[Amended]

2. Section 131.36 is added to subpart D to read as follows:

§ 131.36 Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B).

(a) *Scope.* This section is not a general promulgation of the section 304(a) criteria for priority toxic pollutants but is restricted to specific pollutants in specific States.

(b)(1) *EPA's Section 304(a) Criteria for Priority Toxic Pollutants.*

BILLING CODE 6560-50-M

A		B		C		D	
		FRESHWATER		SALTWATER		HUMAN HEALTH (10^{-6} risk for carcinogens)	
						For Consumption of:	
(#) COMPOUND	CAS Number	Criterion Maximum Conc. d (ug/L) B1	Criterion Continuous Conc. d (ug/L) B2	Criterion Maximum Conc. d (ug/L) C1	Criterion Continuous Conc. d (ug/L) C2	Water & Organisms (ug/L) D1	Organisms Only (ug/L) D2
1 Antimony	7440360					14 a	4300 a
2 Arsenic	7440382	360 m	190 m	69 m	36 m	0.018 a,b,c	0.14 a,b,c
3 Beryllium	7440417					n	n
4 Cadmium	7440439	3.9 e,m	1.1 e,m	43 m	9.3 m	n	n
5a Chromium (III)	16065831	1700 e,m	210 e,m			n	n
b Chromium (VI)	18540299	16 m	11 m	1100 m	50 m	n	n
6 Copper	7440508	18 e,m	12 e,m	2.9 m	2.9 m		
7 Lead	7439921	82 e,m	3.2 e,m	220 m	8.5 m	n	n
8 Mercury	7439976	2.4 m	0.012 i	2.1 m	0.025 i	0.14	0.15
9 Nickel	7440020	1400 e,m	160 e,m	75 m	8.3 m	610 a	4600 a
10 Selenium	7782492	20	5	300 m	71 m	n	n
11 Silver	7440224	4.1 e,m		2.3 m			
12 Thallium	7440280					1.7 a	6.3 a
13 Zinc	7440666	120 e,m	110 e,m	95 m	86 m		
14 Cyanide	57125	22	5.2	1	1	700 a	220000 a,j
15 Asbestos	1332214					7,000,000 fibers/L k	
16 2,3,7,8-TCDD (Dioxin)	1746016					0.000000013 c	0.000000014 c
17 Acrolein	107028					320	780
18 Acrylonitrile	107131					0.059 a,c	0.66 a,c
19 Benzene	71432					1.2 a,c	71 a,c
20 Bromoform	75252					4.3 a,c	360 a,c
21 Carbon Tetrachloride	56235					0.25 a,c	4.4 a,c
22 Chlorobenzene	108907					680 a	21000 a,j
23 Chlorodibromomethane	124481					0.41 a,c	34 a,c
24 Chloroethane	75003						
25 2-Chloroethylvinyl Ether	110758						
26 Chloroform	67663					5.7 a,c	470 a,c
27 Dichlorobromomethane	75274					0.27 a,c	22 a,c

(#) COMPOUND	CAS Number	B FRESHWATER Criterion Maximum Conc. d (ug/L) B1	B FRESHWATER Criterion Continuous Conc. d (ug/L) B2	C SALTWATER Criterion Maximum Conc. d (ug/L) C1	C SALTWATER Criterion Continuous Conc. d (ug/L) C2	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Water & Organisms (ug/L) D1	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Organisms Only (ug/L) D2
28 1,1-Dichloroethane	75343						
29 1,2-Dichloroethane	107062					0.38 a,c	99 a,c
30 1,1-Dichloroethylene	75354					0.057 a,c	3.2 a,c
31 1,2-Dichloropropane	78875						
32 1,3-Dichloropropylene	542756					10 a	1700 a
33 Ethylbenzene	100414					3100 a	29000 a
34 Methyl Bromide	74839					48 a	4000 a
35 Methyl Chloride	74873					n	n
36 Methylene Chloride	75092					4.7 a,c	1600 a,c
37 1,1,2,2-Tetrachloroethane	79345					0.17 a,c	11 a,c
38 Tetrachloroethylene	127184					0.8 c	8.85 c
39 Toluene	108883					6800 a	200000 a
40 1,2-Trans-Dichloroethylene	156605						
41 1,1,1-Trichloroethane	71556					n	n
42 1,1,2-Trichloroethane	79005					0.60 a,c	42 a,c
43 Trichloroethylene	79016					2.7 c	81 c
44 Vinyl Chloride	75014					2 c	525 c
45 2-Chlorophenol	95578						
46 2,4-Dichlorophenol	120832					93 a	790 a,j
47 2,4-Dimethylphenol	105679						
48 2-Methyl-4,6-Dinitrophenol	534521					13.4	765
49 2,4-Dinitrophenol	51285					70 a	14000 a
50 2-Nitrophenol	88755						
51 4-Nitrophenol	100027						
52 3-Methyl-4-Chlorophenol	59507						
53 Pentachlorophenol	87865	20 f	13 f	13	7.9	0.28 a,c	8.2 a,c,j
54 Phenol	108952					21000 a	4600000 a,j
55 2,4,6-Trichlorophenol	88062					2.1 a,c	6.5 a,c
56 Acenaphthene	83329						

A		B		C		D	
		FRESHWATER		SALTWATER		HUMAN HEALTH (10^{-6} risk for carcinogens)	
#) COMPOUND	CAS Number	Criterion Maximum Conc. d (ug/L) B1	Criterion Continuous Conc. d (ug/L) B2	Criterion Maximum Conc. d (ug/L) C1	Criterion Continuous Conc. d (ug/L) C2	For Consumption of: Water & Organisms (ug/L) D1	Organisms Only (ug/L) D2
57 Acenaphthylene	208968						
58 Anthracene	120127					9600 a	110000 a
59 Benzidine	92875					0.00012 a,c	0.00054 a,c
60 Benzo(a)Anthracene	56553					0.0028 c	0.031 c
61 Benzo(a)Pyrene	50328					0.0028 c	0.031 c
62 Benzo(b)Fluoranthene	205992					0.0028 c	0.031 c
63 Benzo(ghi)Perylene	191242						
64 Benzo(k)Fluoranthene	207089					0.0028 c	0.031 c
65 Bis(2-Chloroethoxy)Methane	111911						
66 Bis(2-Chloroethyl)Ether	111444					0.031 a,c	1.4 a,c
67 Bis(2-Chloroisopropyl)Ether	108601					1400 a	170000 a
68 Bis(2-Ethylhexyl)Phthalate	117817					1.8 a,c	5.9 a,c
69 4-Bromophenyl Phenyl Ether	101553						
70 Butylbenzyl Phthalate	85687						
71 2-Chloronaphthalene	91587						
72 4-Chlorophenyl Phenyl Ether	7005723						
73 Chrysene	218019					0.0028 c	0.031 c
74 Dibenzo(a,h)Anthracene	53703					0.0028 c	0.031 c
75 1,2-Dichlorobenzene	95501					2700 a	17000 a
76 1,3-Dichlorobenzene	541731					400	2600
77 1,4-Dichlorobenzene	106467					400	2600
78 3,3'-Dichlorobenzidine	91941					0.04 a,c	0.077 a,c
79 Diethyl Phthalate	84662					23000 a	120000 a
80 Dimethyl Phthalate	131113					313000	2900000
81 Di-n-Butyl Phthalate	84742					2700 a	12000 a
82 2,4-Dinitrotoluene	121142					0.11 c	9.1 c
83 2,6-Dinitrotoluene	606202						
84 Di-n-Octyl Phthalate	117840						
85 1,2-Diphenylhydrazine	122667					0.040 a,c	0.54 a,c

A		B		C		D	
		FRESHWATER		SALTWATER		HUMAN HEALTH (10^{-6} risk for carcinogens)	
						For Consumption of:	
(#) COMPOUND	CAS Number	Criterion Maximum Conc. d (ug/L) B1	Criterion Continuous Conc. d (ug/L) B2	Criterion Maximum Conc. d (ug/L) C1	Criterion Continuous Conc. d (ug/L) C2	Water & Organisms (ug/L) D1	Organisms Only (ug/L) D2
86 Fluoranthene	206440					300 a	370 a
87 Fluorene	86737					1300 a	14000 a
88 Hexachlorobenzene	118741					0.00075 a,c	0.00077 a,c
89 Hexachlorobutadiene	87683					0.44 a,c	50 a,c
90 Hexachlorocyclopentadiene	77474					240 a	17000 a,j
91 Hexachloroethane	67721					1.9 a,c	8.9 a,c
92 Indeno(1,2,3-cd)Pyrene	193395					0.0028 c	0.031 c
93 Isophorone	78591					8.4 a,c	600 a,c
94 Naphthalene	91203						
95 Nitrobenzene	98953					17 a	1900 a,j
96 N-Nitrosodimethylamine	62759					0.00069 a,c	8.1 a,c
97 N-Nitrosodi-n-Propylamine	621647						
98 N-Nitrosodiphenylamine	86306					5.0 a,c	16 a,c
99 Phenanthrene	85018						
100 Pyrene	129000					960 a	11000 a
101 1,2,4-Trichlorobenzene	120821						
102 Aldrin	309002	3 g		1.3 g		0.00013 a,c	0.00014 a,c
103 alpha-BHC	319846					0.0039 a,c	0.013 a,c
104 beta-BHC	319857					0.014 a,c	0.046 a,c
105 gamma-BHC	58899	2 g	0.08 g	0.16 g		0.019 c	0.063 c
106 delta-BHC	319868						
107 Chlordane	57749	2.4 g	0.0043 g	0.09 g	0.004 g	0.00057 a,c	0.00059 a,c
108 4-4'-DDT	50293	1.1 g	0.001 g	0.13 g	0.001 g	0.00059 a,c	0.00059 a,c
109 4,4'-DDE	72559					0.00059 a,c	0.00059 a,c
110 4,4'-DDD	72548					0.00083 a,c	0.00084 a,c
111 Dieldrin	60571	2.5 g	0.0019 g	0.71 g	0.0019 g	0.00014 a,c	0.00014 a,c
112 alpha-Endosulfan	959988	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a
113 beta-Endosulfan	33213659	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a

A		B		C		D	
		FRESHWATER		SALTWATER		HUMAN HEALTH (10^{-6} risk for carcinogens)	
						For Consumption of:	
(#) COMPOUND	CAS Number	Criterion Maximum Conc. d (ug/L) B1	Criterion Continuous Conc. d (ug/L) B2	Criterion Maximum Conc. d (ug/L) C1	Criterion Continuous Conc. d (ug/L) C2	Water & Organisms (ug/L) D1	Organisms Only (ug/L) D2
114 Endosulfan Sulfate	1031078					0.93 a	2.0 a
115 Endrin	72208	0.18 g	0.0023 g	0.037 g	0.0023 g	0.76 a	0.81 a,i
116 Endrin Aldehyde	7421934					0.76 a	0.81 a,i
117 Heptachlor	76448	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00021 a,c	0.00021 a,c
118 Heptachlor Epoxide	1024573	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00010 a,c	0.00011 a,c
119 PCB-1242	53469219		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
120 PCB-1254	11097691		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
121 PCB-1221	11104282		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
122 PCB-1232	11141165		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
123 PCB-1248	12672296		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
124 PCB-1260	11096825		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
125 PCB-1016	12674112		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
126 Toxaphene	8001352	0.73	0.0002	0.21	0.0002	0.00073 a,c	0.00075 a,c
Total No. of Criteria (h) =		24	29	23	27	91	98

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Footnotes:

a. Criteria revised to reflect current agency q_1^* or RfD, as contained in the Integrated Risk Information System (IRIS). The fish tissue bioconcentration factor (BCF) from the 1980 criteria documents was retained in all cases.

b. The criteria refers to the inorganic form only.

c. Criteria in the matrix based on carcinogenicity (10^{-6} risk). For a risk level of 10^{-5}, move the decimal point in the matrix value one place to the right.

d. Criteria Maximum Concentration (CMC) = the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time (1-hour average) without deleterious effects. Criteria Continuous Concentration (CCC) = the highest concentration of a pollutant to which aquatic life can be exposed for an extended period of time (4 days) without deleterious effects. ug/L = micrograms per liter

e. Freshwater aquatic life criteria for these metals are expressed as a function of total hardness (mg/L), and as a function of the pollutant's water effect ratio, WER, as defined in § 131.36(c). The equations are provided in matrix at § 131.36(b)(2). Values displayed above in the matrix correspond to a total hardness of 100 mg/L and a water effect ratio of 1.0.

f. Freshwater aquatic life criteria for pentachlorophenol are expressed as a function of pH, and are calculated as follows. Values displayed above in the matrix correspond to a pH of 7.8.

$CMC = \exp\{1.005(pH) - 4.830\}$ $CCC = \exp\{1.005(pH) - 5.290\}$

g. Aquatic life criteria for these compounds were issued in 1980 utilizing the 1980 Guidelines for criteria development. The acute values shown are final acute values (FAV) which by the 1980 Guidelines are instantaneous values as contrasted with a CMC which is a one-hour average.

h. These totals simply sum the criteria in each column. For aquatic life, there are 30 priority toxic pollutants with some type of freshwater or saltwater, acute or chronic criteria. For human health, there are 91 priority toxic pollutants with either "water + fish" or "fish only" criteria. Note that these totals count chromium as one pollutant even though EPA has developed criteria based on two valence states. In the matrix, EPA has assigned numbers 5a and 5b to the criteria for chromium to reflect the fact that the list of 126 priority toxic pollutants includes only a single listing for chromium.

i. If the CCC for total mercury exceeds 0.012 ug/L more than once in a 3-year period in the ambient water, the edible portion of aquatic species of concern must be analyzed to determine whether the concentration of methyl mercury exceeds the FDA action level (1.0 mg/kg). If the FDA action level is exceeded, the State must notify the appropriate EPA Regional Administrator, initiate a revision of its mercury criterion in its water quality standards so as to protect designated uses, and take other appropriate action such as issuance of a fish consumption advisory for the affected area.

j. No criteria for protection of human health from consumption of aquatic organisms (excluding water) was presented in the 1980 criteria document or in the 1986 Quality Criteria for Water. Nevertheless, sufficient information was presented in the 1980 document to allow a calculation of a criterion, even though the results of such a calculation were not shown in the document.

k. The criterion for asbestos is the MCL (56 FR 3526, January 30, 1991).

l. This letter not used as a footnote.

m. Criteria for these metals are expressed as a function of the water effect ratio, WER, as defined in 40 CFR 131.36(c).

CMC = column B1 or C1 value × WER
CCC = column B2 or C2 value × WER

n. EPA is not promulgating human health criteria for this contaminant. However, permit authorities should address this contaminant in NPDES permit actions using the State's existing narrative criteria for toxics.

General Notes:

1. This chart lists all of EPA's priority toxic pollutants whether or not criteria recommendations are available. Blank spaces indicate the absence of criteria recommendations. Because of variations in chemical nomenclature systems, this listing of toxic pollutants does not duplicate the listing in Appendix A of 40 CFR Part 423. EPA has added the Chemical Abstracts Service (CAS) registry numbers, which provide a unique identification for each chemical.

2. The following chemicals have organoleptic based criteria recommendations that are not included on this chart (for reasons which are discussed in the preamble): copper, zinc, chlorobenzene, 2-chlorophenol, 2,4-dichlorophenol, acenaphthene, 2,4-dimethylphenol, 3-methyl-4-chlorophenol, hexachlorocyclopentadiene, pentachlorophenol, phenol

3. For purposes of this rulemaking, freshwater criteria and saltwater criteria apply as specified in 40 CFR 131.36(c).

(2) *Factors for Calculating Metals Criteria*

$CMC = WER \exp\{m_A[\ln(hardness)] + b_A\}$ $CCC = WER \exp\{m_C[\ln(hardness)] + b_C\}$

	m_A	b_A	m_C	b_C
Cadmium	1.128	−3.828	0.7852	−3.490
Copper	0.9422	−1.464	0.8545	−1.465
Chromium (III)	0.8190	3.688	0.8190	1.561
Lead	1.273	−1.460	1.273	−4.705
Nickel	0.8460	3.3612	0.8460	1.1645
Silver	1.72	−6.52		
Zinc	0.8473	0.8604	0.8473	0.7614

Note: The term "exp" represents the base e exponential function.

(c) *Applicability.* (1) The criteria in paragraph (b) of this section apply to the States' designated uses cited in paragraph (d) of this section and supersede any criteria adopted by the State, except when State regulations contain criteria which are more stringent for a particular use in which case the State's criteria will continue to apply.

(2) The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are the other numeric toxics criteria when applied to the same use classifications including mixing zones, and low flow values below which numeric standards can be exceeded in flowing fresh waters.

(i) For all waters with mixing zone regulations or implementation procedures, the criteria apply at the appropriate locations within or at the boundary of the mixing zones; otherwise the criteria apply throughout the waterbody including at the end of any discharge pipe, canal or other discharge point.

(ii) A State shall not use a low flow value below which numeric standards can be exceeded that is less stringent than the following for waters suitable for the establishment of low flow return frequencies (i.e., streams and rivers):

Aquatic Life

Acute criteria (CMC)	1 Q 10 or 1 B 3
Chronic criteria (CCC)	7 Q 10 or 4 B 3

Human Health

Non-carcinogens	30 Q 5
Carcinogens	Harmonic mean flow

Where:

CMC—criteria maximum concentration—the water quality criteria to protect against acute effects in aquatic life and is the highest instream concentration of a priority toxic pollutant consisting of a one-hour average

not to be exceeded more than once every three years on the average;

CCC—criteria continuous concentration—the water quality criteria to protect against chronic effects in aquatic life is the highest instream concentration of a priority toxic pollutant consisting of a 4-day average not to be exceeded more than once every three years on the average;

1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically;

1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model);

7 Q 10 is the lowest average 7 consecutive day low flow with an average recurrence frequency of once in 10 years determined hydrologically;

4 B 3 is biologically based and indicates an allowable exceedence for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);

30 Q 5 is the lowest average 30 consecutive day low flow with an average recurrence frequency of once in 5 years determined hydrologically; and the harmonic mean flow is a long term mean flow value calculated by dividing the number of daily flows analyzed by the sum of the reciprocals of those daily flows.

(iii) If a State does not have such a low flow value for numeric standards compliance, then none shall apply and the criteria included in paragraph (d) of this section herein apply at all flows.

(3) The aquatic life criteria in the matrix in paragraph (b) of this section apply as follows:

(i) For waters in which the salinity is equal to or less than 1 part per thousand 95% or more of the time, the applicable criteria are the freshwater criteria in Column B;

(ii) For waters in which the salinity is equal to or greater than 10 parts per thousand 95% or more of the time, the applicable criteria are the saltwater criteria in Column C; and

(iii) For waters in which the salinity is between 1 and 10 parts per thousand as defined in paragraphs (c)(3) (i) and (ii) of this section, the applicable criteria are the more stringent of the freshwater or saltwater criteria. However, the Regional Administrator may approve the use of the alternative freshwater or saltwater criteria if scientifically defensible information and data demonstrate that on a site-specific basis the biology of the waterbody is dominated by freshwater aquatic life and that freshwater criteria are more appropriate; or conversely, the biology of the waterbody is dominated by saltwater aquatic life and that saltwater criteria are more appropriate.

(4) *Application of metals criteria.* (i) For purposes of calculating freshwater aquatic life criteria for metals from the equations in paragraph (b)(2) of this section, the minimum hardness allowed for use in those equations shall not be less than 25 mg/l, as calcium carbonate, even if the actual ambient hardness is less than 25 mg/l as calcium carbonate. The maximum hardness value for use in those equations shall not exceed 400 mg/l as calcium carbonate, even if the actual ambient hardness is greater than 400 mg/l as calcium carbonate. The same provisions apply for calculating the metals criteria for the comparisons provided for in paragraph (c)(3)(iii) of this section.

(ii) The hardness values used shall be consistent with the design discharge conditions established in paragraph (c)(2) of this section for flows and mixing zones.

(iii) The criteria for metals (compounds #1–#13 in paragraph (b) of this section) are expressed as total recoverable. For purposes of calculating aquatic life criteria for metals from the equations in footnote M. in the criteria matrix in paragraph (b)(1) of this section and the equations in paragraph (b)(2) of this section, the water-effect ratio is computed as a specific pollutant's acute or chronic toxicity values measured in water from the site covered by the standard, divided by the respective acute or chronic toxicity value in laboratory dilution water. The water-effect ratio shall be assigned a value of 1.0, except where the permitting authority assigns a different value that protects the designated uses of the water body from the toxic effects of the pollutant, and is derived from suitable tests on sampled water representative of conditions in the affected water body, consistent with the design discharge conditions established in paragraph (c)(2) of this section. For purposes of this paragraph, the term acute toxicity value is the toxicity test results, such as the lethal concentration of one-half of the test organisms (i.e., LC50) after 96 hours of exposure (e.g., fish toxicity tests) or the effect concentration to one-half of the test organisms, (i.e., EC50) after 48 hours of exposure (e.g., daphnia toxicity tests). For purposes of this paragraph, the term chronic value is the result from appropriate hypothesis testing or regression analysis of measurements of growth, reproduction, or survival from life cycle, partial life cycle, or early life stage tests. The determination of acute and chronic values shall be according to current standard protocols (e.g., those published by the American Society for Testing Materials (ASTM)) or other comparable methods. For calculation of criteria using site-specific values for both the hardness and the water effect ratio, the hardness used in the equations in paragraph (b)(2) of this section shall be as required in paragraph (c)(4)(ii) of this section. Water hardness shall be calculated from the measured calcium and magnesium ions present, and the ratio of calcium to magnesium shall be approximately the same in standard laboratory toxicity testing water as in the site water.

(d) *Criteria for Specific Jurisdictions*—(1) *Rhode Island, EPA Region 1.* (i) All waters assigned to the following use classifications in the Water Quality Regulations for Water Pollution Control adopted under Chapters 46–12, 42–17.1, and 42–35 of the General Laws of Rhode Island are subject to the criteria in paragraph (d)(1)(ii) of this section, without exception:

6.21 Freshwater	6.22 Saltwater:
Class A	Class SA
Class B	Class SB
Class C	Class SC

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(1)(i) of this section:

Use classification	Applicable criteria
Class A Class B waters where water supply use is designated	These classifications are assigned the criteria in: Column D1—all
Class B waters where water supply use is not designated; Class C; Class SA; Class SB; Class SC	Each of these classifications is assigned the criteria in: Column D2—all

(iii) The human health criteria shall be applied at the 10^{-5} risk level, consistent with the State policy. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(2) *Vermont, EPA Region 1.* (i) All waters assigned to the following use classifications in the Vermont Water Quality Standards adopted under the authority of the Vermont Water Pollution Control Act (10 V.S.A., Chapter 47) are subject to the criteria in paragraph (d)(2)(ii) of this section, without exception:

Class A
Class B
Class C

(ii) The following criteria from the matrix in paragraph (b)(1) of this section

apply to the use classifications identified in paragraph (d)(2)(i) of this section:

Use classification	Applicable criteria
Class A	
Class B waters where water supply use is designated	This classification is assigned the criteria in: Column B1—all Column B2—all Column D1—all
Class B waters where water supply use is not designated	
Class C	These classifications are assigned the criteria in: Column B1—all Column B2—all Column D2—all

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level.

(3) *New Jersey, EPA Region 2.* (i) All waters assigned to the following use classifications in the New Jersey Administrative Code (N.J.A.C.) 7:9–4.1 et seq., Surface Water Quality Standards, are subject to the criteria in paragraph (d)(3)(ii) of this section, without exception.

N.J.A.C. 7:9–4.12(b): Class PL
N.J.A.C. 7:9–4.12(c): Class FW2
N.J.A.C. 7:9–4.12(d): Class SE1
N.J.A.C. 7:9–4.12(e): Class SE2
N.J.A.C. 7:9–4.12(f): Class SE3
N.J.A.C. 7:9–4.12(g): Class SC
N.J.A.C. 7:9–4.13(a): Delaware River Zones 1C, 1D, and 1E
N.J.A.C. 7:9–4.13(b): Delaware River Zone 2
N.J.A.C. 7:9–4.13(c): Delaware River Zone 3
N.J.A.C. 7:9–4.13(d): Delaware River Zone 4
N.J.A.C. 7:9–4.13(e): Delaware River Zone 5
N.J.A.C. 7:9–4.13(f): Delaware River Zone 6

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(3)(i) of this section:

Use classification	Applicable criteria
PL (Freshwater Pinelands), FW2	These classifications are assigned the criteria in: Column B1—all except #102, 105, 107, 108, 111, 112, 113, 115, 117, and 118. Column B2—all except #105, 107, 108, 111, 112, 113, 115, 117, 118, 119, 120, 121, 122, 123, 124, and 125. Column D1—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level. Column D2—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level.
PL (Saline Water Pinelands), SE1, SE2, SE3, SC	These classifications are each assigned the criteria in: Column C1—all except #102, 105, 107, 108, 111, 112, 113, 115, 117, and 118. Column C2—all except #105, 107, 108, 111, 112, 113, 115, 117, 118, 119, 120, 121, 122, 123, 124, and 125. Column D2—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level.
Delaware River zones 1C, 1D, 1E, 2, 3, 4, 5 and Delaware Bay zone 6	These classifications are each assigned the criteria in: Column B1—all. Column B2—all. Column D1—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level. Column D2—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level.
Delaware River zones 3, 4, and 5, and Delaware Bay zone 6	These classifications are each assigned the criteria in: Column C1—all. Column C2—all. Column D2—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level.

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level for EPA rated Class A, B_1, and B_2 carcinogens; EPA rated Class C carcinogens shall be applied at 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c. in the matrix in paragraph (b)(1) of this section.

(4) *Puerto Rico, EPA Region 2.* (i) All waters assigned to the following use classifications in the Puerto Rico Water Quality Standards (promulgated by Resolution Number R–83–5–2) are subject to the criteria in paragraph (d)(4)(ii) of this section, without exception:

Article 2.2.2—Class SB
Article 2.2.3—Class SC
Article 2.2.4—Class SD

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(4)(i) of this section:

Use classification	Applicable criteria
Class SD	This Classification is assigned criteria in: Column B1—all, except: 10, 102, 105, 107, 108, 111, 112, 113, 115, 117, and 126. Column B2—all, except: 105, 107, 108, 112, 113, 115, and 117. Column D1—all, except: 6, 14, 105, 112, 113, and 115. Column D2—all, except: 14, 105, 112, 113, and 115.
Class SB, Class SC	These Classifications are assigned criteria in:

Use classification	Applicable criteria
	Column C1—all, except: 4, 5b, 7, 8, 10, 11, 13, 102, 105, 107, 108, 111, 112, 113, 115, 117, and 126. Column C2—all, except: 4, 5b, 10, 13, 108, 112, 113, 115, and 117. Column D2—all, except: 14, 105, 112, 113, and 115.

(iii) The human health criteria shall be applied at the State-proposed 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c, in the criteria matrix in paragraph (b)(1) of this section.

(5) *District of Columbia, EPA Region 3.*

(i) All waters assigned to the following use classifications in chapter 11 Title 21 DCMR, Water Quality Standards of the District of Columbia are subject to the criteria in paragraph (d)(5)(ii) of this section, without exception:

1101.2 Class C waters

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classification identified in paragraph (d)(5)(i) of this section:

Use classification	Applicable criteria
Class C	This classification is assigned the additional criteria in: Column B2—#10, 118, 126. Column D1—#15, 16, 44, 67, 68, 79, 80, 81, 88, 114, 116, 118. Column D2—all.

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(6) *Florida, EPA Region 4.*

(i) All waters assigned to the following use classifications in Chapter 17–301 of the Florida Administrative Code (i.e., identified in Section 17–302.600) are subject to the criteria in paragraph (d)(6)(ii) of this section, without exception:

Class I
Class II
Class III

(ii) The following criteria from the matrix paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(6)(i) of this section:

Use classification	Applicable criteria
Class I	This classification is assigned the criteria in: Column D1—#16
Class II Class III (marine)	This classification is assigned the criteria in:
Class III (freshwater)	This classification is assigned the criteria in: Column D2—#16

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(7) *Michigan, EPA Region 5.*

(i) All waters assigned to the following use classifications in the Michigan Department of Natural Resources Commission General Rules, R 323.1100 designated uses, as defined at R 323.1043. Definitions; A to N, (i.e., identified in Section (g) "Designated use") are subject to the criteria in paragraph (d)(7)(ii) of this section, without exception:

Agriculture
Navigation
Industrial Water Supply
Public Water Supply at the Point of Water Intake
Warmwater Fish
Other Indigenous Aquatic Life and Wildlife
Partial Body Contact Recreation

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(7)(i) of this section:

Use classification	Applicable criteria
Public Water supply	This classification is assigned the criteria in: Column B1—all, Column B2—all, Column D1—all.
All other designations	These classifications are assigned the criteria in: Column B1—all, Column B2—all, and Column D2—all.

(iii) The human health criteria shall be applied at the State-adopted 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(8) *Arkansas, EPA Region 6.*

(i) All waters assigned to the following use classification in section 4C (Waterbody uses) identified in Arkansas Department of Pollution Control and Ecology's Regulation No. 2 as amended and entitled, "Regulation Establishing Water Quality Standards for Surface Waters of the State of Arkansas" are subject to the criteria in paragraph (d)(8)(ii) of this section, without exception:

Extraordinary Resource Waters
Ecologically Sensitive Waterbody
Natural and Scenic Waterways
Fisheries:
(1) Trout
(2) Lakes and Reservoirs
(3) Streams
(a) Ozark Highlands Ecoregion
(b) Boston Mountains Ecoregion
(c) Arkansas River Valley Ecoregion
(d) Ouachita Mountains Ecoregion
(e) Typical Gulf Coastal Ecoregion
(f) Spring Water-influenced Gulf Coastal Ecoregion
(g) Least-altered Delta Ecoregion
(h) Channel-altered Delta Ecoregion
Domestic Water Supply

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classification identified in paragraph (d)(8)(i) of this section:

Use classification	Applicable criteria
Extraordinary Resource Waters Ecologically Sensitive Waterbody Natural and Scenic Waterways Fisheries: (1) Trout (2) Lakes and Reservoirs (3) Streams (a) Ozark Highlands Ecoregion (b) Boston Mountains Ecoregion (c) Arkansas River Valley Ecoregion (d) Ouachita Mountains Ecoregion (e) Typical Gulf Coastal Ecoregion (f) Spring Water-influenced Gulf Coastal Ecoregion (g) Least-altered Delta Ecoregion (h) Channel-altered Delta Ecoregion	These uses are each assigned the criteria in— Column B1—#4, 5a, 5b, 6, 7, 8, 9, 10, 11, 13, 14 Column B2—#4, 5a, 5b, 6 7, 8, 9, 10, 13, 14

(9) *Kansas, EPA Region 7.*

(i) All waters assigned to the following use classification in the Kansas Department of Health and Environment regulations, K.A.R. 28–16–28b through K.A.R. 28–16–28f, are subject to the criteria in paragraph (d)(9)(ii) of this section, without exception.

Section 28–16–28d
- Section (2)(A)—Special Aquatic Life Use Waters
- Section (2)(B)—Expected Aquatic Life Use Waters
- Section (2)(C)—Restricted Aquatic Life Use Waters
- Section (3)—Domestic Water Supply
- Section (6)(c)—Consumptive Recreation Use.

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(9)(i) of this section:

Use classification	Applicable criteria
Sections (2)(A), (2)(B), (2)(C), (6)(C)	These classifications are each assigned all criteria in: Column B1, all except #9, 11, 13, 102, 105, 107, 108, 111–113, 115, 117, and 126; Column B2, all except #9, 13, 105, 107, 108, 111–113, 115, 117, 119–125, and 126; and Column D2, all except #9, 112, 113, and 115.
Section (3)	This classification is assigned all criteria in: Column D1, all except #9, 12, 112, 113, and 115.

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level.

(10) *California, EPA Region 9.*

(i) All waters assigned any aquatic life or human health use classifications in the Water Quality Control Plans for the various Basins of the State ("Basin Plans"), as amended, adopted by the California State Water Resources Control Board ("SWRCB"), except for ocean waters covered by the Water Quality Control Plan for Ocean Waters of California ("Ocean Plan") adopted by the SWRCB with resolution Number 90–27 on March 22, 1990, are subject to the criteria in paragraph (d)(10)(ii) of this section, without exception. These criteria amend the portions of the existing State standards contained in the Basin Plans. More particularly these criteria amend water quality criteria contained in the Basin Plan Chapters specifying water quality objectives (the State equivalent of federal water quality criteria) for the toxic pollutants identified in paragraph (d)(10)(ii) of this section. Although the State has adopted several use designations for each of these waters, for purposes of this action, the specific standards to be applied in paragraph (d)(10)(ii) of this section are based on the presence in all waters of some aquatic life designation and the presence or absence of the MUN use designation (Municipal and domestic supply). (See Basin Plans for more detailed use definitions.)

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the water and use classifications defined in paragraph (d)(10)(i) of this section and identified below:

Water and use classification	Applicable criteria
Waters of the State defined as bays or estuaries except the Sacramento-San Joaquin Delta and San Francisco Bay	These waters are assigned the criteria in: Column B1—pollutants 5a and 14; Column B2—pollutants 5a and 14; Column C1—pollutant 14; Column C2—pollutant 14; Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
Waters of the Sacramento—San Joaquin Delta and waters of the State defined as inland (i.e., all surface waters of the State not bays or estuaries or ocean) that include a MUN use designation	These waters are assigned the criteria in: Column B1—pollutants 5a and 14; Column B2—pollutants 5a and 14; Column D1—pollutants 1, 12, 15, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–48, 49, 59, 66, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
Waters of the State defined as inland without an MUN use designation	These waters are assigned the criteria in: Column B1—pollutants 5a and 14; Column B2—pollutants 5a and 14; Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
Waters of the San Joaquin River from the mouth of the Merced River to Vernalis	In addition to the criteria assigned to these waters elsewhere in this rule, these waters are assigned the criteria in: Column B2—pollutant 20

Water and use classification	Applicable criteria
Waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to the mouth of the Merced River	In addition to the criteria assigned to these waters elsewhere in this rule, these waters are assigned the criteria in: Column B1—pollutant 10 Column B2—pollutant 10
Waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta	These waters are assigned the criteria in: Column B1—pollutants 5a, 10* and 14 Column B2—pollutants 5a, 10* and 14 Column C1—pollutant 14 Column C2—pollutant 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
All inland waters of the United States or enclosed bays and estuaries that are waters of the United States that include an MUN use designation and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or its Water Quality Control Plan for Enclosed Bays and Estuaries of California, Tables 1 and 2, or has deferred applicability of those tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California or page 6 of its Water Quality Control Plan for Enclosed Bays and Estuaries of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column D1—all pollutants except #2
All inland waters of the United States that do not include an MUN use designation and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or has deferred applicability of these tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column D2—all pollutants except #2
All enclosed bays and estuaries that are waters of the United States and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or its Water Quality Control Plan for Enclosed Bays and Estuaries of California, Tables 1 and 2, or has deferred applicability of those tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California or page 6 of its Water Quality Control Plan for Enclosed Bays and Estuaries of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column C1—all pollutants Column C2—all pollutants Column D2—all pollutants except #2

*The fresh water selenium criteria are included for the San Francisco Bay estuary because high levels of bioaccumulation of selenium in the estuary indicate that the salt water criteria are underprotective for San Francisco Bay.

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(11) *Nevada, EPA Region 9.* (i) All waters assigned the use classifications in Chapter 445 of the Nevada Administrative Code (NAC), Nevada Water Pollution Control Regulations, which are referred to in paragraph (d)(11)(ii) of this section, are subject to the criteria in paragraph (d)(11)(ii) of this section, without exception. These criteria amend the existing State standards contained in the Nevada Water Pollution Control Regulations. More particularly, these criteria amend or supplement the table of numeric standards in NAC 445.1339 for the toxic pollutants identified in paragraph (d)(11)(ii) of this section.

(ii) The following criteria from matrix in paragraph (b)(1) of this section apply to the waters defined in paragraph (d)(11)(i) of this section and identified below:

Water and use classification	Applicable criteria
Waters that the State has included in NAC 445.1339 where Municipal or domestic supply is a designated use	These waters are assigned the criteria in: Column B1—pollutant #118 Column B2—pollutant #118 Column D1—pollutants #15, 16, 18, 19, 20, 21, 23, 26, 27, 29, 30, 34, 37, 38, 42, 43, 55, 58–62, 64, 66, 73, 74, 78, 82, 85, 87–89, 91, 92, 96, 98, 100, 103, 104, 105, 114, 116, 117, 118
Waters that the State has included in NAC 445.1339 where Municipal or domestic supply is not a designated use	These waters are assigned the criteria in: Column B1—pollutant #118 Column B2—pollutant #118 Column D2—all pollutants except #2.

(iii) The human health criteria shall be applied at the 10^{-6} risk level, consistent with State policy. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(12) *Alaska, EPA Region 10.*

(i) All waters assigned to the following use classifications in the Alaska Administrative Code (AAC), Chapter 18 (i.e., identified in 18 AAC 70.020) are subject to the criteria in paragraph (d)(12)(ii) of this section, without exception:

70.020.(1) (A) Fresh Water
70.020.(1) (A) Water Supply
(i) Drinking, culinary, and food processing,
(iii) Aquaculture;
70.020.(1) (B) Water Recreation
(i) Contact recreation,
(ii) Secondary recreation;
70.020.(1) (C) Growth and propagation of fish, shellfish, other aquatic life, and wildlife
70.020.(2) (A) Marine Water
70.020.(2) (A) Water Supply
(i) Aquaculture,
70.020.(2) (B) Water Recreation
(i) contact recreation,
(ii) secondary recreation;
70.020.(2) (C) Growth and propagation of fish, shellfish, other aquatic life, and wildlife;
70.020.(2) (D) Harvesting for consumption of raw mollusks or other raw aquatic life.

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(12)(i) of this section:

Use classification	Applicable criteria
(1)(A) i	Column B1—all Column B2—#10 Column D1 #'s 2, 16, 18–21, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 53, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88, 89, 91–93, 96, 98, 102–105, 107–111, 117–126
(1)(A) iii	Column B1—all Column B2—#10 Column D1 #'s 2, 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126
(1)(B) i, (1)(B) ii, (1)(C)	Column B1—all Column B2—#10 Column D2 #'s 2, 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126
(2)(A) i, (2)(B) i, and (2)(B) ii, (2)(C), (2)(D)	Column C1—all Column C2—#10 Column D2 #s 2, 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126

(iii) The human health criteria shall be applied at the State-proposed risk level of 10^{-5}. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(13) *Idaho, EPA Region 10.*

(i) All waters assigned to the following use classifications in the Idaho Administrative Procedures Act (IDAPA), Chapter 16 (i.e., identified in IDAPA 16.01.2100.02–16.01.2100.07) are subject to the criteria in paragraph (d)(13)(ii) of this section, without exception:

16.01.2100.01.b. Domestic Water Supplies
16.01.2100.02.a. Cold Water Biota
16.01.2100.02.b. Warm Water Biota
16.01.2100.02cc. Salmonid Spawning
16.01.2100.03.a. Primary Contact Recreation
16.01.2100.03.b Secondary Contact Recreation

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(13)(i) of this section:

Use classification	Applicable criteria
01.b	This classification is assigned the criteria in: Column D1—all except #14 and 115
02.a 02.b 02cc	These classifications are assigned the criteria in: Column B1—all Column B2—all Column D2—all
03.a	This classification is assigned the criteria in: Column D2—all
03.b	This classification is assigned the criteria in: Column D2—all

(iii) The human health criteria shall be applied at the 10^{-6} risk level, consistent with State policy.

(14) *Washington, EPA Region 10.*

(i) All waters assigned to the following use classifications in the Washington Administrative Code (WAC), Chapter 173–201 (i.e., identified in WAC 173–201–045) are subject to the criteria in paragraph (d)(14)(ii) of this section, without exception:

173–201–045
Fish and Shellfish
Fish
Water Supply (domestic)
Recreation

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(14)(i) of this section:

Use classification	Applicable criteria
Fish and Shellfish; Fish	These classifications are assigned the criteria in: Column B1 and B(2)—#2, 10 Column C1—#2, 10 Column C2—#2, 6, 10, 14 Column D2—all
Water Supply (domestic)	These classifications are assigned the criteria in: Column D1—all
Recreation	This classification is assigned the criteria in: Column D2—Marine waters and freshwaters not protected for domestic water supply

(iii) The human health criteria shall be applied at the State proposed risk level of 10^{-6}.

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