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40 CFR Part 131

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL–6587–9]

RIN 2040–AC44

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This final rule promulgates: numeric aquatic life criteria for 23 priority toxic pollutants; numeric human health criteria for 57 priority toxic pollutants; and a compliance schedule provision which authorizes the State to issue schedules of compliance for new or revised National Pollutant Discharge Elimination System permit limits based on the federal criteria when certain conditions are met.

EPA is promulgating this rule based on the Administrator's determination that numeric criteria are necessary in the State of California to protect human health and the environment. The Clean Water Act requires States to adopt numeric water quality criteria for priority toxic pollutants for which EPA has issued criteria guidance, the presence or discharge of which could reasonably be expected to interfere with maintaining designated uses.

EPA is promulgating this rule to fill a gap in California water quality standards that was created in 1994 when a State court overturned the State's water quality control plans which contained water quality criteria for priority toxic pollutants. Thus, the State of California has been without numeric water quality criteria for many priority toxic pollutants as required by the Clean Water Act, necessitating this action by EPA. These Federal criteria are legally applicable in the State of California for inland surface waters, enclosed bays and estuaries for all purposes and programs under the Clean Water Act.

EFFECTIVE DATE: This rule shall be effective May 18, 2000.

ADDRESSES: The administrative record for today's final rule is available for public inspection at the U.S. Environmental Protection Agency, Region 9, Water Division, 75 Hawthorne Street, San Francisco, California 94105, between the hours of 8:00 a.m. and 4:30 p.m. For access to the administrative record, call Diane E. Fleck, P.E., Esq. at 415 744–1984 for an appointment. A reasonable fee will be charged for photocopies.

FOR FURTHER INFORMATION CONTACT: Diane E. Fleck, P.E., Esq. or Philip Woods, U.S. Environmental Protection Agency, Region 9, Water Division, 75 Hawthorne Street, San Francisco, California 94105, 415–744–1984 or 415–744–1997, respectively.

SUPPLEMENTARY INFORMATION: This preamble is organized according to the following outline:

A. Potentially Affected Entities

Citizens concerned with water quality in California may be interested in this rulemaking. Entities discharging pollutants to waters of the United States in California could be affected by this rulemaking since water quality criteria are used by the State in developing National Pollutant Discharge Elimination System (NPDES) permit limits. Categories and entities that ultimately may be affected include:

Category	Examples of potentially affected entities
Industry	Industries discharging pollutants to surface waters in California or to publicly-owned treatment works.
Municipalities	Publicly-owned treatment works discharging pollutants to surface waters in California

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by listed in the table could also be affected. To determine whether your facility might be affected by this action, you should carefully examine the applicability criteria in § 131.38(c). If you have questions regarding the particular entity, consult the persons listed in the preceding FOR FURTHER INFORMATION CONTACT section.

B. Introduction and Overview

1. Introduction

This section introduces the topics which are addressed in the preamble and provides a brief overview of EPA's basis and rationale for promulgating Federal criteria for the State of California. Section C briefly describes the evolution of the efforts to control toxic pollutants; these efforts include the changes enacted in the 1987 CWA Amendments, which are the basis for this rule. Section D summarizes California's efforts since 1987 to implement the requirements of CWA section 303(c)(2)(B) and describes EPA's procedure and actions for determining whether California has fully implemented CWA section 303(c)(2)(B). Section E provides the rationale and approach for developing this final rule, including a discussion of EPA's legal basis for this final rule. Section F describes the development of the criteria included in this rule. Section G summarizes the provisions of the final rule and discusses implementation issues. Sections H, I, J, K, L, M, N, O, P, and Q briefly address the requirements of Executive Order 12866, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility Act, the Paperwork Reduction Act, the Endangered Species Act, the Congressional Review Act, Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, the National Technology Transfer and Advancement Act, and Executive Order 13132, Federalism, respectively.

The proposal for this rulemaking was published in the Federal Register on August 5, 1997. Changes from the proposal are generally addressed in the body of this preamble and specifically addressed in the response to comments document included in the administrative record for this rulemaking. EPA responded to all comments on the proposed rule, including comments received after the September 26, 1997, deadline. Although EPA is under no legal obligation to respond to late comments, EPA made a policy decision to respond to all comments.

Since detailed information concerning many of the topics in this preamble was published previously in the Federal Register in preambles for this and other rulemakings, references are frequently made to those preambles. Those rulemakings include: Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule, 62 FR 42159, August 5, 1997 (referred to as the "proposed CTR"); Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants, 57 FR 60848, December 22, 1992 (referred to as the "National Toxics Rule" or "NTR"); and the NTR as amended by Administrative Stay of Federal Water Quality Criteria for Metals and Interim Final Rule, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance—Revision of Metals Criteria, 60 FR 22228, May 4, 1995 (referred to as the "National Toxics Rule [NTR] as amended"). The NTR, as amended, is codified at 40 CFR 131.36. A copy of the proposed CTR and its preamble, and the NTR, as amended, and its preambles are contained in the administrative record for this rulemaking.

EPA is making this final rule effective upon publication. Under the Administrative Procedure Act, 5 U.S.C. 553(d)(3), agencies must generally publish a rule no more than 30 days prior to the effective date of the rule except as otherwise provided for by the Agency for good cause. The purpose of the 30-day waiting period is to give affected parties a reasonable time to adjust their behavior before the final rule takes effect. See *Omnipoint Corp. v. F.C.C.*, 78 F.3d 620, 630–631 (D.C. Cir. 1996); *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1485 (9th Cir. 1992).

In this instance, EPA finds good cause to make the final rule effective upon publication. In order to find good cause, an Agency needs to find that the 30-day period would be: (1) Impracticable, (2) unnecessary, or (3) contrary to the public interest. Here EPA is relying on the second reason to support its finding of good cause. EPA also notes that the State has requested EPA to make the rule immediately effective.

EPA finds that in this instance, waiting 30 days to make the rule effective is unnecessary. As explained in further detail elsewhere in this preamble, this rule is not self implementing; rather it establishes ambient conditions that the State of California will implement in future permit proceedings. These permit proceedings will, by regulation, take longer than 30 days to complete. This means that although the rule is immediately effective, no discharger's conduct would be altered under the rule in less than 30 days, and therefore the 30-day period is unnecessary.

2. Overview

This final rule establishes ambient water quality criteria for priority toxic pollutants in the State of California. The criteria in this final rule will supplement the water quality criteria promulgated for California in the NTR, as amended. In 1991, EPA approved a number of water quality criteria (discussed in section D), for the State of California. Since EPA had approved these criteria, it was not necessary to include them in the 1992 NTR for these criteria. However, the EPA-approved criteria were subsequently invalidated in State litigation. Thus, this final rule contains criteria to fill the gap created by the State litigation.

This final rule does not change or supersede any criteria previously promulgated for the State of California in the NTR, as amended. Criteria which EPA promulgated for California in the NTR, as amended, are footnoted in the final table at 131.38(b)(1), so that readers may see the criteria promulgated in the NTR, as amended, for California and the criteria promulgated through this rulemaking for California in the same table. This final rule is not intended to apply to waters within Indian Country. EPA recognizes that there are possibly waters located wholly or partly in Indian Country that are included in the State's basin plans. EPA will work with the State and Tribes to identify any such waters and determine whether further action to protect water quality in Indian Country is necessary.

This rule is important for several environmental, programmatic and legal reasons. Control of toxic pollutants in surface waters is necessary to achieve the CWA's goals and objectives. Many of California's monitored river miles, lake acres, and estuarine waters have elevated levels of toxic pollutants. Recent studies on California water bodies indicate that elevated levels of toxic pollutants exist in fish tissue which result in fishing advisories or bans. These toxic pollutants can be attributed to, among other sources, industrial and municipal discharges.

Water quality standards for toxic pollutants are important to State and EPA efforts to address water quality problems. Clearly established water quality goals enhance the effectiveness of many of the State's and EPA's water programs including permitting, coastal water quality improvement, fish tissue quality protection, nonpoint source controls, drinking water quality protection, and ecological protection. Numeric criteria for toxic pollutants allow the State and EPA to evaluate the adequacy of existing and potential control measures to protect aquatic ecosystems and human health. Numeric criteria also provide a more precise basis for deriving water quality-based effluent limitations (WQBELs) in

National Pollutant Discharge Elimination System (NPDES) permits and wasteload allocations for total maximum daily loads (TMDLs) to control toxic pollutant discharges. Congress recognized these issues when it enacted section 303(c)(2)(B) to the CWA.

While California recognizes the need for applicable water quality standards for toxic pollutants, its adoption efforts have been stymied by a variety of factors. The Administrator has decided to exercise her CWA authorities to move forward the toxic control program, consistent with the CWA and with the State of California's water quality standards program.

Today'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/or the environment. The CWA allows some flexibility and differences among States in their adopted and approved water quality standards, but it should be implemented in a manner that ensures a level playing field among States. Although California has made important progress toward satisfying CWA requirements, it has not satisfied CWA section 303(c)(2)(B) by adopting numeric water quality criteria for toxic pollutants. This section was added to the CWA by Congress in 1987. Prior to today, the State of California had been the only State in the Nation for which CWA section 303(c)(2)(B) had remained substantially unimplemented after EPA's promulgation of the NTR in December of 1992. Section 303(c)(4) of the CWA authorizes the EPA Administrator to promulgate standards where necessary to meet the requirements of the Act. The Administrator determined that this rule was a necessary and important component for the implementation of CWA section 303(c)(2)(B) in California.

EPA acknowledges that the State of California is working to satisfy CWA section 303(c)(2)(B). When the State formally adopts, and EPA approves, criteria consistent with statutory requirements, as envisioned by Congress in the CWA, EPA intends to stay this rule. If within the applicable time frame for judicial review, the States' standards are challenged, EPA will withdraw this rule after such judicial review is complete and the State standards are sustained.

C. Statutory and Regulatory Background

The preamble to the August 5, 1997, proposed rule provided a general discussion of the statutory and regulatory background for the proposed rule. 62 FR 42160–42163. EPA is including that discussion in the record for the final rule. Commenters questioned EPA's authority to promulgate certain aspects of the proposal. EPA is responding to those comments in the appropriate sections of this preamble, and in the response to comments document included in the administrative record for this rulemaking. Where appropriate, EPA's responses expand upon the discussion of statutory and regulatory authority found in the proposal.

D. California Water Quality Standards Actions

1. California Regional Water Quality Control Board Basin Plans, and the Inland Surface Waters Plan (ISWP) and the Enclosed Bays and Estuaries Plan (EBEP) of April 1991

The State of California regulates water quality through its State Water Resources Control Board (SWRCB) and through nine Regional Water Quality Control Boards (RWQCBs). Each of the nine RWQCBs represents a different geographic area; area boundaries are generally along watershed boundaries. Each RWQCB maintains a Basin Plan which contains the designated uses of the water bodies within its respective geographic area within California. These designated uses (or "beneficial uses" under State law) together with legally-adopted criteria (or "objectives" under State law), comprise water quality standards for the water bodies within each of the Basin areas. Each of the nine RWQCBs undergoes a triennial basin planning review process, in compliance with CWA section 303. The SWRCB provides assistance to the RWQCBs.

Most of the Basin Plans contain conventional pollutant objectives such as dissolved oxygen. None of the Basin Plans contains a comprehensive list of priority toxic pollutant criteria to satisfy CWA section 303(c)(2)(B). The nine RWQCBs and the SWRCB had intended that the priority toxic pollutant criteria contained in the three SWRCB statewide plans, the Inland Surface Waters Plan (ISWP), the Enclosed Bays and Estuaries Plan (EBEP), and the Ocean Plan, apply to all basins and satisfy CWA section 303(c)(2)(B).

On April 11, 1991, the SWRCB adopted two statewide water quality control plans, the ISWP and the EBEP. These statewide plans contained narrative and numeric water quality criteria for toxic pollutants, in part to satisfy CWA section 303(c)(2)(B). The water quality criteria contained in the designated uses in each of the Basin Plans, created a set of water quality standards for waters within the State of California.

Specifically, the two plans established water quality criteria or objectives for all fresh waters, bays and estuaries in the State. The plans contained water quality criteria for some priority toxic pollutants, provisions relating to whole effluent toxicity, implementation procedures for point and nonpoint sources, and authorizing compliance schedule provisions. The plans also included special provisions affecting waters dominated by reclaimed water (labeled as Category (a) waters), and waters dominated by agricultural drainage and constructed agricultural drains (labeled as Category (b) and (c) waters, respectively).

2. EPA's Review of California Water Quality Standards for Priority Toxic Pollutants in the ISWP and EBEP, and the National Toxics Rule

The EPA Administrator has delegated the responsibility and authority for review and approval or disapproval of all new or revised State water quality standards to the EPA Regional Administrators (see 40 CFR 131.21). Thus, State actions under CWA section 303(c)(2)(B) are submitted to the appropriate EPA Regional Administrator for review and approval.

In mid-April 1991, the SWRCB submitted to EPA for review and approval the two statewide water quality control plans, the ISWP and the EBEP. On November 6, 1991, EPA Region 9 formally concluded its review of the SWRCB's plans. EPA approved the narrative water quality criterion and the toxicity criterion in each of the plans. EPA also approved the numeric water quality criteria contained in both plans, finding them to be consistent with the requirements of section 303(c)(2)(B) of the CWA and with EPA's national criteria guidance published pursuant to section 304(a) of the CWA.

EPA noted the lack of criteria for some pollutants, and found that, because of the omissions, the plans did not fully satisfy CWA section 303(c)(2)(B). The plans did not contain criteria for all listed pollutants for which EPA had published national criteria guidance. The ISWP contained human health criteria for only 65 pollutants, and the EBEP contained human health criteria for only 61 pollutants for which EPA had issued section 304(a) guidance criteria. Both the ISWP and EBEP contained aquatic life criteria for all pollutants except cyanide and chromium III (freshwater

304(a) criteria guidance. The SWRCB's administrative record stated that all priority pollutants with EPA criteria guidance were likely to be present in California waters. However, the SWRCB's record contained insufficient information to support a finding that the excluded pollutants were not reasonably expected to interfere with designated uses of the waters of the State.

Although EPA approved the statewide selenium objective in the ISWP and EBEP, EPA disapproved the objective for the San Francisco Bay and Delta, because there was clear evidence that the objective would not protect the designated fish and wildlife uses (the California Department of Health Services had issued waterfowl consumption advisories due to selenium concentrations, and scientific studies had documented selenium toxicity to fish and wildlife). EPA restated its commitment to object to National Pollutant Discharge Elimination System (NPDES) permits issued for San Francisco Bay that contained effluent limits based on an objective greater than 5 parts per billion (ppb) [four day average) and 20 ppb (1 hour average), the freshwater criteria. EPA reaffirmed its disapproval of California's site-specific selenium objective for portions of the San Joaquin River, Salt Slough, and Mud Slough. EPA also disapproved of the categorical deferrals and exemptions. These disapprovals included the disapproval of the State's deferral of water quality objectives to effluent dominated streams (Category a) and to streams dominated by agricultural drainage (Category b), and the disapproval of the exemption of water quality objectives to constructed agricultural drains (Category c). EPA found the definitions of the categories imprecise and overly broad which could have led to an incorrect interpretation.

Since EPA had disapproved portions of each of the California statewide plans which were necessary to satisfy CWA section 303(c)(2)(B), certain disapproved aspects of California's water quality standards were included in EPA's promulgation of the National Toxics Rule (NTR) (40 CFR 131.36, 57 FR 60848). EPA promulgated specific criteria for certain water bodies in California.

The NTR was amended, effective April 14, 1995, to stay certain metals criteria which had been promulgated as total recoverable. Effective April 15, 1995, EPA promulgated interim final metals criteria as dissolved concentrations for those metals which had been stayed (Administrative Stay of Federal Water Quality Criteria for Metals and Interim Final Rule, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance—Revision of Metals Criteria; 60 FR 22228, 22229, May 4, 1995] the NTR, as amended]). The stay was in response to a lawsuit against EPA challenging, among other issues, metals criteria expressed as total recoverable concentrations. A partial Settlement Agreement required EPA to stay specific metals criteria in the NTR. EPA then promulgated certain metals criteria in the dissolved form through the use of conversion factors. These factors are listed in the NTR, as amended. A scientific discussion of these criteria is found in a subsequent section of this preamble.

Since certain criteria have already been promulgated for specific water bodies in the State of California in the NTR, as amended, they are not within the scope of today's final rule. However, for clarity in reading a comprehensive rule for the State of California, these criteria are incorporated into 40 CFR 131.38(d)(2). Footnotes to the Table in 40 CFR 131.38(b)(1) and 40 CFR 131.38(d)(3) clarify which criteria (and for which specific water bodies) were promulgated by the NTR, as amended, and are therefore excluded from this final rule. The appropriate (freshwater or saltwater) aquatic life criteria which were promulgated in the NTR, as amended, for all inland surface waters and enclosed bays and estuaries include: chromium III and cyanide. The appropriate (water and organism or organism only) human health criteria which were promulgated in the NTR, as amended, for all inland surface waters and enclosed bays and estuaries include:

antimony
thallium
asbestos
acrolein
acrylonitrile
carbon tetrachloride
chlorobenzene
1,2-dichloroethane
1,1-dichloroethylene
1,3-dichloropropylene
ethylbenzene
1,1,2,2-tetrachloroethane
tetrachloroethylene
1,1,2-trichloroethane
trichloroethylene
vinyl chloride
2,4-dichlorophenol
2-methyl-4,6-dinitrophenol
2,4-dinitrophenol
benzidine
bis(2-chloroethyl)ether
bis(2-ethylhexyl)phthalate
3,3-dichlorobenzidine
diethyl phthalate
dimethyl phthalate
di-n-butyl phthalate
2,4-dinitrotoluene
1,2-diphenylhydrazine
hexachlorobutadiene
hexachlorocyclopentadiene
hexachloroethane
isophorone
nitrobenzene
n-nitrosodimethylamine
n-nitrosodiphenylamine

Other pollutant criteria were promulgated in the NTR, as amended, for specific water bodies, but not all inland surface waters and enclosed bays and estuaries.

3. Status of Implementation of CWA Section 303(c)(2)(B)

Shortly after the SWRCB adopted the ISWP and EBEP, several dischargers filed suit against the State alleging that it had not adopted the two plans in compliance with State law. The plaintiffs in a consolidated case included: the County of Sacramento, Sacramento County Water Agency; Sacramento Regional County Sanitation District; the City of Sacramento; the City of Sunnyvale; the City of San Jose; the City of Stockton; and Simpson Paper Company.

The dischargers alleged that the State had not adopted the ISWP and EBEP in compliance with the California Administrative Procedures Act (Gov Code, Section 11340, *et seq.*), the California Environmental Quality Act (Pub. Re Code, Section 21000, *et seq.*), and the Porter-Cologne Act (Wat. Code, Section 13200, *et seq.*). The allegation that the State did not sufficiently consider economics when adopting water quality objectives, as allegedly required by Section 13241 of the Porter Cologne Act, was an important issue in the litigation.

In October of 1993, the Superior Court of California, County of Sacramento, issued a tentative decision in favor of the dischargers. In March of 1994, the Court issued a substantively similar final decision in favor of the dischargers. Final judgments from the Court in July of 1994 ordered the SWRCB to rescind the ISWP and EBEP. On September 22, 1994, the SWRCB formally rescinded the two statewide water quality control plans. The State is currently in the process of readopting water quality control plans for inland surface waters, enclosed bays and estuaries.

CWA section 303(c)(2)(B) was fully implemented in the State of California from December of 1992, when the NTR was promulgated, until September of 1994, when the SWRCB was required to rescind the ISWP and EBEP. The provisions for California in EPA's NTR together with the approved portions of

California's ISWP and EBEP implemented the requirements of CWA section 303(c)(2)(B). However, since September of 1994, when the SWRCB rescinded the ISWP and EBEP, the requirements of section 303(c)(2)(B) have not been fully implemented in California.

The scope of today's rule is to re-establish criteria for the remaining priority toxic pollutants to meet the requirements of section 303(c)(2)(B) of the CWA. Pursuant to section 303(c)(4), the Administrator has determined that it is necessary to include in today's action criteria for priority toxic pollutants which are not covered by the NTR, as amended, or by the State through EPA-approved site-specific criteria, for waters of the United States in the State of California.

4. State-Adopted, Site-Specific Criteria for Priority Toxic Pollutants

The State has the discretion to develop site-specific criteria when appropriate (e.g., when statewide criteria appear over- or under-protective of designated uses). Periodically, the State through its RWQCBs will adopt site-specific criteria for priority toxic pollutants within respective Basin Plans. These criteria are intended to be effective throughout the Basin or throughout a designated water body. Under California law, these criteria must be publicly reviewed and approved by the RWQCB, the SWRCB, and the State's Office of Administrative Law (OAL). Once this adoption process is complete, the criteria become State law.

These criteria must be submitted to the EPA Regional Administrator for review and approval under CWA section 303. These criteria are usually submitted to EPA as part of a RWQCB Basin Plan Amendment, after the Amendment has been adopted under the State's process and has become State law.

a. State-Adopted Site-Specific Criteria *Under EPA Review*

The State of California has recently reviewed and updated all of its RWQCB Basin Plans. All of the Basin Plans have completed the State review and adoption process and have been submitted to EPA for review and approval. Some of the Basin Plans contain site-specific criteria. In these cases, the State-adopted site-specific criteria are used for water quality programs.

EPA has not yet concluded consultation under the Endangered the U.S. Department of Commerce, National Marine Fisheries Service, on EPA's tentative approval/disapproval actions on the RWQCB Basin Plans. In this situation, the more stringent of the two criteria (the State-adopted site-specific criteria in the RWQCB Basin Plans, or the Federal criteria in this final rule), would be used for water quality programs including the calculation of water quality-based effluent criteria in National Pollutant Discharge Elimination System (NPDES) permits.

b. State-Adopted Site-Specific Criteria With EPA Approval

In several cases, the EPA Regional Administrator has already reviewed and approved State-adopted site-specific criteria within the State of California. Several of these cases are discussed in this section. All of the EPA approval letters referenced in today's preamble are contained in the administrative record for today's rule.

Sacramento River. EPA has approved site-specific acute criteria for copper, cadmium and zinc in the Sacramento River, upstream of Hamilton City, in the Central Valley Region (RWQCB for the Central Valley Region) of the State of California. EPA approved these site-specific criteria by letter dated August 7, 1985. Specifically, EPA approved for the Sacramento River (and tributaries) above Hamilton City, a copper criterion of 5.6 µg/l (maximum), a zinc criterion of 16 µg/l (maximum) and a cadmium criterion of 0.22 µg/l (maximum), all in the dissolved form using a hardness of 40 mg/l as CaCO3. (These criteria were actually adopted by the State and approved by EPA as equations which vary with hardness.) These "maximum" criteria correspond to acute criteria in today's final rule. Therefore, Federal acute criteria for copper, cadmium, and zinc for the Sacramento River (and tributaries) above Hamilton City are not necessary to protect the designated uses and are not included in the final rule. However, the EPA Administrator is making a finding that it is necessary to include chronic criteria for copper, cadmium and zinc for the Sacramento River (and tributaries) above Hamilton City, as part of the statewide criteria promulgated in today's final rule.

San Joaquin River. The selenium criteria in this rule are not applicable to portions of the San Joaquin River, in the Central Valley Region, because selenium criteria have been either previously approved by EPA or previously promulgated by EPA as part of the NTR. EPA approved and disapproved State-adopted site-specific selenium criteria in portions of the San Joaquin River, in California (RWQCB for the Central Valley Region). EPA's determination on these site-specific criteria is contained in a letter dated April 13, 1990.

Specifically, EPA approved for the San Joaquin River, mouth of Merced River to Vernalis, an aquatic life selenium criterion of 12 µg/l (maximum with the understanding that the instantaneous maximum concentration may not exceed the objective more than once every three years). Today's final rule does not affect this Federally-approved, State-adopted site-specific acute criterion, and it remains in effect for the San Joaquin River, mouth of Merced River to Vernalis. Therefore, an acute criterion for selenium in the San Joaquin River, mouth of Merced River to Vernalis is not necessary to protect the designated use and thus is not included in this final rule.

By letter dated April 13, 1990, EPA also approved for the San Joaquin River, mouth of Merced River to Vernalis, a State-adopted site-specific aquatic life selenium criterion of 5 µg/l (monthly mean); however, EPA disapproved a State-adopted site-specific selenium criterion of 8 µg/l (monthly mean—critical year only) for these waters. Subsequently, EPA promulgated a chronic selenium criterion of 5 µg/l (4 day average) for waters of the San Joaquin River from the mouth of the Merced River to Vernalis in the NTR. This chronic criterion applies to all water quality programs concerning the San Joaquin River, mouth of Merced River to Vernalis. Today's final rule does not affect the Federally-promulgated chronic selenium criterion of 5 µg/l (4 day average) set forth in the NTR. This previously Federally-promulgated criterion remains in effect for the San Joaquin River, mouth of Merced River to Vernalis.

Grassland Water District, San Luis National Wildlife Refuge, and Los Banos State Wildlife Refuge. EPA approved for the Grassland Water District, San Luis National Wildlife Refuge, and Los Banos State Wildlife Refuge, a State-adopted site-specific aquatic life selenium criterion of 2 µg/l (monthly mean) by letter dated April 13, 1990. This Federally-approved, State-adopted site-specific chronic criterion remains in effect for the Grassland Water District, San Luis National Wildlife Refuge and Los Banos State Wildlife Refuge. Therefore it is not necessary to include in today's final rule, a chronic criterion for selenium for the Grassland Water District, San Luis National Wildlife Refuge and Los Banos State Wildlife Refuge, and thus, it is not included in

San Francisco Regional Board Basin Plan of 1986: EPA approved several priority toxic pollutant objectives (CWA criteria) that were contained in the 1986 San Francisco Regional Board Basin Plan, as amended by SWRCB Resolution Numbers 87–49, 87–82 and 87–92, by letters dated September 2, 1987 and December 24, 1987. This Basin Plan, the SWRCB Resolutions, and the EPA approval letters are contained in the administrative record for this rulemaking. It is not necessary to include these criteria for priority toxic pollutants that are contained in the San Francisco Regional Board's 1986 Basin Plan as amended, and approved by EPA. Priority pollutants in this situation are footnoted in the matrix at 131.38(b)(1) with footnote "b." Where gaps exist in the State adoption and EPA approval of priority toxic pollutant objectives, the criteria in today's rule apply.

EPA is assigning "human health, water and organism consumption" criteria to waters with the States' municipal or "MUN" beneficial use designation in the Basin Plan. Also, some pollutants regulated through the Basin Plan have different averaging periods, *e.g.*, one hour as compared with the rule's "short-term." However, where classes of chemicals, such as polynuclear aromatic hydrocarbons, or PAHs, and phenols, are regulated through the Basin Plan, but not specific chemicals within the category, specific chemicals within the category are regulated by today's rule.

E. Rationale and Approach for Developing the Final Rule

This section explains EPA's legal basis for today's final rule, and discusses EPA's general approach for developing the specific requirements for the State of California.

1. Legal Basis

CWA section 303(c) specifies that adoption of water quality standards is primarily the responsibility of the States. However, CWA section 303(c) also describes a role for the Federal government to oversee State actions to ensure compliance with CWA requirements. If EPA's review of the States' standards finds flaws or omissions, then the CWA authorizes EPA to correct the deficiencies (see CWA section 303(c)(4)). This water quality standards promulgation authority has been used by EPA to issue final rules on several separate occasions, including the NTR, as amended, which promulgated criteria similar to those included here for a number of States. 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.

The CWA 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 CWA. If, after EPA's disapproval, the State does not amend its rules so as to be consistent with the CWA, EPA is to promptly propose appropriate Federal water quality standards for that State. The second basis for an EPA action is in 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 using section 303(c)(4)(B) as the legal basis for today's final rule.

As discussed in the preamble to the NTR, the Administrator's determination under CWA section 303(c)(4) that criteria are necessary to meet the requirements of the Act could be supported in several ways. Consistent with EPA's approach in the NTR, EPA interprets section 303(c)(2)(B) of the CWA to allow EPA to act where the State has not succeeded in establishing numeric water quality standards for toxic pollutants. This inaction can be the basis for the Administrator's determination under section 303(c)(4) that new or revised criteria are necessary to ensure designated uses are protected.

EPA does not believe that it is necessary to support the criteria in today's rule on a pollutant-specific, water body-by-water body basis. For EPA to undertake an effort to conduct research and studies of each stream segment or water body across the State of California to demonstrate that for each toxic pollutant for which EPA has issued CWA section 304(a) criteria guidance there is a "discharge or presence" of that pollutant which could reasonably "be expected to interfere with" the designated use would impose an enormous administrative burden and would be contrary to the statutory directive for swift action manifested by the 1987 addition of section 303(c)(2)(B) to the CWA. Moreover, because these criteria are ambient criteria that define attainment of the designated uses, their application to all water bodies will result in additional controls on dischargers only where necessary to protect the designated uses.

EPA's interpretation of section 303(c)(2)(B) is supported by the language of the provision, the statutory framework and purpose of section 303, and the legislative history. In adding section 303(c)(2)(B) to the CWA, Congress understood the existing requirements in section 303(c)(1) for States to conduct triennial reviews of their water quality standards and submit the results of those reviews to EPA and in section 303(c)(4)(B) for promulgation. CWA section 303(c) includes numerous deadlines and section 303(c)(4) directs the Administrator to act "promptly" where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. 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. The legislative history of the provision demonstrates that chief Senate sponsors, including Senators Stafford, Chaffee and others wanted the provision to eliminate State and EPA delays and force quick action. Thus, to interpret CWA section 303(c)(2)(B) and (c)(4) to require such a cumbersome pollutant specific effort on each stream segment would essentially render section 303(c)(2)(B) meaningless. The provision and its legislative background indicate that the Administrator's determination to invoke section 303(c)(4)(B) authority can be met by the Administrator making a generic finding of inaction by the State without the need to develop pollutant-specific data for individual stream segments. Finally, the reference in section 303(c)(2)(B) to section 304(a) criteria suggests that section 304(a) criteria serve as default criteria, that once EPA has issued them, States were to adopt numeric criteria for those pollutants based on the 304(a) criteria, unless they had other scientifically defensible criteria. EPA also notes that this rule follows the approach EPA took nationally in promulgating the NTR for States that failed to comply with CWA section 303(c)(2)(B). 57 FR 60848, December 22, 1992. EPA incorporates the discussion in the NTR preamble as part of this rulemaking record.

This determination is supported by information in the rulemaking record showing the discharge or presence of priority toxic pollutants throughout the State. While this data is not necessarily complete, it constitutes a strong record supporting the need for numeric criteria for priority toxic pollutants with section 304(a) criteria guidance where the State does not have numeric criteria.

Today's final rule would not impose any undue or inappropriate burden on the State of California or its dischargers. It merely puts in place numeric criteria

for toxic pollutants that are already used in other States in implementing CWA programs. Under this rulemaking, the State of California retains the ability to adopt alternative water quality criteria simply by completing its criteria adoption process. Upon EPA approval of those criteria, EPA will initiate action to stay the Federally promulgated criteria and subsequently withdraw them.

2. Approach for Developing This Rule

In summary, EPA developed the criteria promulgated in today's final rule as follows. Where EPA promulgated criteria for California in the NTR, EPA has not acted to amend the criteria in the NTR. Where criteria for California were not included in the NTR, EPA used section 304(a) National criteria guidance documents as a starting point for the criteria promulgated in this rule. EPA then determined whether new information since the development of the national criteria guidance documents warranted any changes. New information came primarily from two sources. For human health criteria, new or revised risk reference doses and cancer potency factors on EPA's Integrated Risk Information System (IRIS) as of October 1996 form the basis for criteria values (see also 63 FR 68354). For aquatic life criteria, updated data sets resulting in revised criteria maximum concentrations (CMCs) and criteria continuous concentrations (CCCs) formed the basis for differences from the national criteria guidance documents. Both of these types of changes are discussed in more detail in the following sections. This revised information was used to develop the water quality criteria promulgated here for the State of California.

F. Derivation of Criteria

1. Section 304(a) Criteria Guidance Process

Under CWA section 304(a), EPA has developed methodologies and specific criteria guidance to protect aquatic life and human health. These methodologies are intended to provide protection for all surface waters on a national basis. The methodologies have been subject to public review, as have the individual criteria guidance documents. Additionally, the methodologies have been reviewed by EPA's Science Advisory Board (SAB) of external experts.

EPA has included in the record of this rule the aquatic life methodology as described in "Appendix B—Guidelines [illegible]

Uses" to the "Water Quality Criteria Documents; Availability" (45 FR 79341, November 28, 1980) as amended by the "Summary of Revisions to Guidelines 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 preamble, 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*. A copy of the 1985 Guidelines is available through the National Technical Information Service (PB85–227049), is in the administrative record for this rule, and is abstracted in Appendix A of *Quality Criteria for Water*, 1986.) EPA has also included in the administrative 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 placed into the administrative record for this rulemaking the most current individual criteria guidance for the priority toxic pollutants included in today's rule. (Note: All references to appendices are to the associated Federal Register publication.)

EPA received many comments related to the issue of what criteria should apply in the CTR if the CWA section 304(a) criteria guidance is undergoing re-evaluation, or if new data are developed that may affect a recommended criterion. As science is always evolving, EPA is faced with the challenge of promulgating criteria that reflect the best science and sound science. EPA addressed this challenge in some detail in its Federal Register current section 304(a) criteria guidance (63 FR 68335, December 10, 1998). There, EPA articulated its policy, reiterated here, that the existing criteria guidance represent the Agency's best assessment until such time as EPA's re-evaluation of a criteria guidance value for a particular chemical is complete. The reason for this is that both EPA's human health criteria guidance and aquatic life criteria guidance are developed taking into account numerous variables. For example, for human health criteria guidance, EPA evaluates many diverse toxicity studies, whose results feed into a reference dose or cancer potency estimate that, along with a number of exposure factors and determination of risk level, results in a guidance criterion. For aquatic life, EPA evaluates many diverse aquatic toxicity studies to determine chronic and acute toxicity taking into account how other factors (such as pH, temperature or hardness) affect toxicity. EPA also, to the extent possible, addresses bioaccumulation or bioconcentration. EPA then uses this toxicity information along with exposure information to determine the guidance criterion. Importantly, EPA subjects such evaluation to peer review and/or public comment.

For these reasons, EPA generally does not make a change to the 304(a) criteria guidance based on a partial picture of the evolving science. This makes sense, because to address one piece of new data without looking at all relevant data is less efficient and results in regulatory impacts that may go back and forth, when in the end the criteria guidance value does not change that much. Certain new changes, however, do warrant change in criteria guidance, such as a change in a value in EPA's Integrated Risk Information System (IRIS) because it represents the Agency consensus about human health impacts. These changes are sufficiently examined across the Agency such that EPA believes they can be incorporated into EPA's water quality criteria guidance. EPA has followed this approach in the CTR. Included in the administrative record for today's rule is a document entitled "Status of Clean Water Act Section 304(a) Criteria" which further explains EPA's policy on managing change to criteria guidance.

2. Aquatic Life Criteria

Aquatic life criteria may be expressed in numeric or narrative form. EPA's 1985 Guidelines describe an objective, internally consistent and appropriate way of deriving chemical-specific, numeric water quality criteria for the

the uses of, both fresh and salt water aquatic organisms.

An aquatic life criterion derived using EPA's CWA 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.) EPA's guidelines are designed to derive criteria that protect aquatic communities. 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 *averages*, rather than one number, in order that the criterion more accurately reflect toxicological and practical realities. The combination of a criterion maximum concentration (CMC), a short-term concentration limit, and a criterion continuous concentration (CCC), a four-day average concentration limit, are designed to provide protection of aquatic life and its uses from acute and chronic toxicity to animals and plants, without being as restrictive as a one-number criterion would have to be (1985 Guidelines, pages 4 & 5). The terms CMC and CCC are the formal names for the two (acute and chronic) values of a criterion for a pollutant; however, this document will also use the informal synonyms acute criterion and chronic criterion.

The two-number criteria are intended to identify average pollutant concentrations which will produce water quality generally suited to maintenance of aquatic life and designated 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 may be insufficient unless the time period is short because excursions higher than the average may kill or cause substantial damage in short periods.

A minimum data set of eight specified families is recommended 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. EPA's application of its guidelines to develop the criteria matrix in this rule is judged by the Agency to be appropriate for all waters of the United States (U.S.), and to all ecosystems (1985 Guidelines, page 4) including those waters of the U.S. and ecosystems in the State of California.

Fresh water and salt water (including both estuarine and marine waters) have different chemical compositions, and freshwater and saltwater species often do not inhabit the same water. To provide additional accuracy, criteria are developed for fresh water and for salt water.

For this rule, EPA updated freshwater aquatic life criteria contained in CWA section 304(a) criteria guidance first published in the early 1980's and later modified in the NTR, as amended, for the following ten pollutants: arsenic, cadmium, chromium (VI), copper, dieldrin, endrin, lindane (gamma BHC), nickel, pentachlorophenol, and zinc. The updates used as the basis for this rule are explained in a technical support document entitled, *1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water* (U.S. EPA-820-B-96-001, September 1996), available in the administrative record to this rulemaking. This document presents the derivation of each of the final CMCs and CCCs and the toxicity studies from which the updated freshwater criteria for the ten pollutants were derived.

The polychlorinated biphenyls (PCB) criteria in the criteria matrix for this rule differs from that in the NTR, as amended; for this rule, the criteria are expressed as the sum of seven aroclors, while for the NTR, as amended, the criteria are expressed for each of seven aroclors. The aquatic life criteria for PCBs in the CTR are based on the criteria contained in the 1980 criteria guidance document for PCBs which is included in the administrative record for this rule. This criteria document explains the derivation of aquatic life criteria based on total PCBs. For more information see the Response to Comments document for this rule. Today's chronic aquatic life criteria for PCBs are based on a final residue value (FRV). In EPA's guidelines for deriving aquatic life criteria, an FRV-based criterion is intended to prevent concentrations of pollutants in commercially or recreationally important aquatic species from affecting the marketability of those species or affecting the wildlife that consume aquatic life.

The proposed CTR included an updated freshwater and saltwater aquatic life criteria for mercury. In today's final rule, EPA has reserved the mercury criteria for freshwater and saltwater aquatic life, but is promulgating human health criteria for mercury for all surface waters in California. In some instances, the human health mercury criteria included in today's final rule may not protect some aquatic species or threatened or endangered species. In such instances, more stringent mercury limits may be determined and implemented through use of the State's narrative criterion. The reasons for reserving the mercury aquatic life numbers are explained in further detail in Section L, Endangered Species Act.

a. Freshwater Acute Selenium Criterion

EPA proposed a different freshwater acute aquatic life criterion for selenium for this rule than was promulgated in the NTR, as amended. EPA's proposed action was consistent with EPA's proposed selenium criterion maximum concentration for the Water Quality Guidance for the Great Lakes System (61 FR 58444, November 14, 1996). This proposal took into account data showing that selenium's two most prevalent oxidation states, selenite and selenate, present differing potentials for aquatic toxicity, as well as new data which indicated that various forms of selenium are additive. Additivity increases the toxicity of mixtures of different forms of the pollutant. The proposed approach produces a different selenium acute criterion concentration, or CMC, depending upon the relative proportions of selenite, selenate, and other forms of selenium that are present.

The preamble to the August 5, 1997, proposed rule provided a lengthy discussion of this proposed criterion for the State of California. See 62 FR 42160–42208. EPA incorporates that discussion here as part of this rulemaking record. In 1996, a similar discussion was included in the proposed rule for the Great Lakes System. Commenters questioned several aspects of the Great Lakes proposal. EPA is continuing to respond to those comments, and to follow up with additional literature review and toxicity testing. In addition, the U.S. FWS and U.S. NMFS (collectively, the Services) are concerned that EPA's proposed criterion may not be sufficiently protective of certain threatened and endangered species in California. Because the Services believe there is a lack of data to show for certain that the proposed criterion would not affect threatened and endangered species, the Services prefer that EPA further investigate the protectiveness of the

criterion before finalizing the proposed criterion. Therefore, EPA is not promulgating a final acute freshwater selenium criterion at this time.

b. Dissolved Metals Criteria

In December of 1992, in the NTR, EPA promulgated water quality criteria for several States that had failed to meet the requirements of CWA section 303(c)(2)(B). Included among the water quality criteria promulgated were numeric criteria for the protection of aquatic life for 11 metals: arsenic, cadmium, chromium (III), chromium (VI), copper, lead, mercury, nickel, selenium, silver and zinc. Criteria for two metals applied to the State of California: chromium III and selenium.

The Agency received extensive public comment during the development of the NTR regarding the most appropriate approach for expressing the aquatic life metals criteria. The principal issue was the correlation between metals that are measured and metals that are bioavailable and toxic to aquatic life. It is now the Agency's policy that the use of dissolved metal to set and measure compliance with aquatic life water quality standards is the recommended approach, because dissolved metal more closely approximates the bioavailable fraction of the metal in the water column than does total recoverable metal.

Since EPA's previous aquatic life criteria guidance had been expressed as total recoverable metal, to express the criteria as dissolved, conversion factors were developed to account for the possible presence of particulate metal in the laboratory toxicity tests used to develop the total recoverable criteria. EPA included a set of recommended freshwater conversion factors with its Metals Policy (see Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria, Martha G. Prothro, Acting Assistant Administrator for Water, October 1, 1993). Based on additional laboratory evaluations that simulated the original toxicity tests, EPA refined the procedures used to develop freshwater conversion factors for aquatic life criteria. These new conversion factors were made available for public review and comment in the amendments to the NTR on May 4, 1995, at 60 FR 22229. They are also contained in today's rule at 40 CFR 131.38(b)(2).

The preamble to the August 5, 1997, proposed rule provided a more detailed discussion of EPA's metals policy concerning the aquatic life water quality criteria for the State of California. See 62 discussion here as part of this rulemaking record. Many commenters strongly supported the Agency's policy on dissolved metals aquatic life criteria. A few commenters expressed an opinion that the metals policy may not provide criteria that are adequately protective of aquatic or other species. Responses to those comments are contained in a memo to the CTR record entitled "Discussion of the Use of Dissolved Metals in the CTR," (February 1, 2000, Jeanette Wiltse) and EPA's response to comments document which are both contained in the administrative record for the final rule.

Calculation of Aquatic Life Dissolved Metals Criteria. Metals criteria values for aquatic life in today's rule in the matrix at 131.38(b)(1) are shown as dissolved metal. These criteria have been calculated in one of two ways. For freshwater metals criteria that are hardness dependent, the metals criteria value is calculated separately for each hardness using the table at 40 CFR 131.38(b)(2). (The hardness-dependent freshwater values presented in the matrix at 40 CFR 131.38(b)(1) have been calculated using a hardness of 100 mg/l as $CaCO_3$ for illustrative purposes only.) The hardness-dependent criteria are then multiplied by the appropriate conversion factors in the table at 40 CFR 131.38(b)(2). Saltwater and freshwater metals criteria that are not hardness-dependent are calculated by taking the total recoverable criteria values (from EPA's national section 304(a) criteria guidance, as updated and described in section F.2.a.) before rounding, and multiplying them by the appropriate conversion factors. The final dissolved metals criteria values, as they appear in the matrix at 40 CFR 131.38(b)(1), are rounded to two significant figures.

Translators for Dissolved to Total Recoverable Metals Limits. EPA's National Pollutant Discharge Elimination System (NPDES) regulations require that limits for metals in permits be stated as total recoverable in most cases (see 40 CFR 122.45(c)) except when an effluent guideline specifies the limitation in another form of the metal, the approved analytical methods measure only dissolved metal, or the permit writer expresses a metal's limit in another form (e.g., dissolved, specific valence, or total) when required to carry out provisions of the CWA. This is because the chemical conditions in ambient waters frequently differ substantially from those in the effluent and these differences result in changes in the partitioning between dissolved and absorbed forms of the metal. This means that if effluent limits were additional particulate metal could dissolve in the receiving water causing the criteria to be exceeded. Expressing criteria as dissolved metal requires translation between different metal forms in the calculation of the permit limit so that a total recoverable permit limit can be established that will achieve water quality standards. Thus, it is important that permitting authorities and other authorities have the ability to translate between dissolved metal in ambient waters and total recoverable metal in effluent.

EPA has completed guidance on the use of translators to convert from dissolved metals criteria to total recoverable permit limits. The document, *The Metals Translator: Guidance for Calculating a Total Recoverable Permit Limit From a Dissolved Criterion* (EPA 823–B–96–007, June 1996), is included in the administrative record for today's rule. This technical guidance examines how to develop a metals translator which is defined as the fraction of total recoverable metal in the downstream water that is dissolved, i.e., the dissolved metal concentration divided by the total recoverable metal concentration. A translator may take one of three forms: (1) It may be assumed to be equivalent to the criteria guidance conversion factors; (2) it may be developed directly as the ratio of dissolved to total recoverable metal; and (3) it may be developed through the use of a partition coefficient that is functionally related to the number of metal binding sites on the adsorbent in the water column (e.g., concentrations of total suspended solids or TSS). This guidance document discusses these three forms of translators, as well as field study designs, data generation and analysis, and site-specific study plans to generate site-specific translators.

California Regional Water Quality Control Boards may use any of these methods in developing water quality-based permit limits to meet water quality standards based on dissolved metals criteria. EPA encourages the State to adopt a statewide policy on the use of translators so that the most appropriate method or methods are used consistently within California.

c. Application of Metals Criteria

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. In order to assure that the metals criteria are appropriate for the chemical conditions under which they

adjustment of the criteria through application of the "water-effect ratio" procedure. EPA notes that performing the testing to use a site-specific water-effect ratio is optional on the part of the State.

In the NTR, as amended, EPA identified the water-effect ratio (WER) procedure as a method for optional site-specific criteria development for certain metals. The WER approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory waters. A WER is an appropriate measure of the toxicity of a material obtained in a site water divided by the same measure of the toxicity of the same material obtained simultaneously in a laboratory dilution water.

On February 22, 1994, EPA issued *Interim Guidance on the Determination and Use of the Water Effect Ratios for Metals* (EPA 823-B-94-001) now incorporated into the updated Second Edition of the Water Quality Standards Handbook, Appendix L. A copy of the Handbook is contained in the administrative record for today's rule. In accordance with the WER guidance and where application of the WER is deemed appropriate, EPA strongly encourages the application of the WER on a watershed or water body basis as part of a water quality criteria in California as opposed to the application on a discharger by discharger basis through individual NPDES permits. This approach is technically sound and an efficient use of resources. However, discharger specific WERs for individual NPDES permit limits are possible and potentially efficient where the NPDES discharger is the only point source discharger to a specific water body.

The rule requires a default WER value of 1.0 which will be assumed, if no site-specific WER is determined. To use a WER other than the default of 1.0, the rule requires that the WER must be determined as set forth in EPA's WER guidance or by another scientifically defensible method that has been adopted by the State as part of its water quality standards program and approved by EPA.

The WER is a more comprehensive mechanism for addressing bioavailability issues than simply expressing the criteria in terms of dissolved metal. Consequently, expressing the criteria in terms of dissolved metal, as done in today's rule for California, does not completely eliminate the utility of the WER. This is particularly true for copper, a metal that forms reduced-toxicity complexes with dissolved organic matter.

The *Interim Guidance on Determination and Use of Water-Effect Ratios for Metals* explains the relationship between WERs for dissolved criteria and WERs for total recoverable criteria. Dissolved measurements are to be used in the site-specific toxicity testing underlying the WERs for dissolved criteria. Because WERs for dissolved criteria generally are little affected by elevated particulate concentrations, EPA expects those WERs to be somewhat less than WERs for total recoverable criteria in such situations. Nevertheless, after the site-specific ratio of dissolved to total metal has been taken into account, EPA expects a permit limit derived using a WER for a dissolved criterion to be similar to the permit limit that would be derived from the WER for the corresponding total recoverable criterion.

d. Saltwater Copper Criteria

The saltwater copper criteria for aquatic life in today's rule are 4.8 µg/l (CMC) and 3.1 µg/l (CCC) in the dissolved form. These criteria reflect new data including data collected from studies for the New York/New Jersey Harbor and the San Francisco Bay indicating a need to revise the former copper 304(a) criteria guidance document to reflect a change in the saltwater CMC and CCC aquatic life values. These data also reflect a comprehensive literature search resulting in added toxicity test data for seven new species to the database for the saltwater copper criteria. EPA believes these new data have national implications and the national criteria guidance now contains a CMC of 4.8 µg/l dissolved and a CCC of 3.1 µg/l dissolved. In the amendments to the NTR, EPA noticed the availability of data to support these changes to the NTR, and solicited comments. The data can be found in the draft document entitled, *Ambient Water Quality Criteria—Copper, Addendum 1995*. This document is available from the Office of Water Resource Center and is available for review in the administrative record for today's rule.

e. Chronic Averaging Period

In establishing water quality criteria, EPA generally recommends an "averaging period" which reflects the duration of exposure required to elicit effects in individual organisms (TSD, Appendix D–2). The criteria continuous concentration, or CCC, is intended to be the highest concentration that could be maintained indefinitely in a water body without causing an unacceptable effect on the aquatic community or its uses (TSD, Appendix D–1). As aquatic organisms do not generally experience steady exposure, but rather fluctuating exposures to pollutants, and because aquatic organisms can generally tolerate higher concentrations of pollutants over a shorter periods of time, EPA expects that the concentration of a pollutant can exceed the CCC without causing an unacceptable effect if (a) the magnitude and duration of exceedences are appropriately limited and (b) there are compensating periods of time during which the concentration is below the CCC. This is done by specifying a duration of an "averaging period" over which the average concentration should not exceed the CCC more often than specified by the frequency (TSD, Appendix D–1).

EPA is promulgating a 4-day averaging period for chronic criteria, which means that measured or predicted ambient pollutant concentrations should be averaged over a 4-day period to determine attainment of chronic criteria. The State may apply to EPA for approval of an alternative averaging period. To do so, the State must submit to EPA the basis for such alternative averaging period.

The most important consideration for setting an appropriate averaging period is the length of time that sensitive organisms can tolerate exposure to a pollutant at levels exceeding a criterion without showing adverse effects on survival, growth, or reproduction. EPA believes that the chronic averaging period must be shorter than the duration of the chronic tests on which the CCC is based, since, in some cases, effects are elicited before exposure of the entire duration. Most of the toxicity tests used to establish the chronic criteria are conducted using steady exposure to toxicants for a least 28 days (TSD, page 35). Some chronic tests, however, are much shorter than this (TSD, Appendix D–2). EPA selected the 4-day averaging period based on the shortest duration in which chronic test effects are sometimes observed for certain species and toxicants. In addition, EPA believes that the results of some chronic tests are due to an acute effect on a sensitive life stage that occurs some time during the test, rather than being caused by long-term stress or long-term accumulation of the test material in the organisms.

Additional discussion of the rationale for the 4-day averaging period is contained in Appendix D of the TSD. Balancing all of the above factors and data, EPA believes that the 4-day averaging period falls within the scientifically reasonable range of values for choice of the averaging period, and is an appropriate length of time of

pollutant exposure to ensure protection of sensitive organisms.

EPA established a 4-day averaging period in the NTR. In settlement of litigation on the NTR, EPA stated that it was "in the midst of conducting, sponsoring, or planning research related to the basis for and application of" water quality criteria and mentioned the issue of averaging period. See Partial Settlement Agreement in *American Forest and Paper Ass'n, Inc. et al. v. U.S. EPA* (Consolidated Case No. 93-0894 (RMU) (D.D.C.). EPA is re-evaluating issues raised about averaging periods and will, if appropriate, revise the 1985 Guidelines.

EPA received public comment relevant to the averaging period during the comment period for the 1995 Amendments to the NTR (60 FR 22228, May 4, 1995), although these public comments did not address the chronic averaging period separately from the allowable excursion frequency and the design flow. Comments recommended that EPA use the 30Q5 design flow for chronic criteria.

While EPA is undertaking analysis of the chronic design conditions as part of the revisions to the 1985 Guidelines, EPA has not yet completed this work. Until this work is complete, for the reasons set forth in the TSD, EPA continues to believe that the 4-day chronic averaging period represents a reasonable, defensible value for this parameter.

EPA added language to the final rule which will enable the State to adopt alternative averaging periods and frequencies and associated design flows where appropriate. The State may apply to EPA for approval of alternative averaging periods and frequencies and related design flows; the State must submit the bases for any changes. Before approving any change, EPA will publish for public comment, a notice proposing the changes.

f. Hardness

Freshwater aquatic life criteria for certain metals are expressed as a function of hardness because hardness and/or water quality characteristics that are usually correlated with hardness can reduce or increase the toxicities of some metals. Hardness is used as a surrogate for a number of water quality characteristics which affect the toxicity of metals in a variety of ways. Increasing hardness has the effect of decreasing the toxicity of metals. Water quality criteria to protect aquatic life may be calculated at different concentrations of hardnesses

Section 131.38(b)(2) of the final rule presents the hardness-dependent equations for freshwater metals criteria. For example, using the equation for zinc, the total recoverable CMCs at a hardness of 10, 50, 100 or 200 mg/l as $CaCO_3$ are 17, 67, 120 and 220 micrograms per liter (ug/l), respectively. Thus, the specific value in the table in the regulatory text is for illustrative purposes only. Most of the data used to develop these hardness equations for deriving aquatic life criteria for metals were in the range of 25 mg/l to 400 mg/l as $CaCO_3$, and the formulas are therefore most accurate in this range. The majority of surface waters nationwide and in California have a hardness of less than 400 mg/l as $CaCO_3$.

In the past, EPA generally recommended that 25 mg/l as $CaCO_3$ be used as a default hardness value in deriving freshwater aquatic life criteria for metals when the ambient (or actual) hardness value is below 25 mg/l as $CaCO_3$. However, use of the approach results in criteria that may not be fully protective. Therefore, for waters with a hardness of less than 25 mg/l as $CaCO_3$, criteria should be calculated using the actual ambient hardness of the surface water.

In the past, EPA generally recommended that if the hardness was over 400 mg/l, two options were available: (1) Calculate the criterion using a default WER of 1.0 and using a hardness of 400 mg/l in the hardness equation, or (2) calculate the criterion using a WER and the actual ambient hardness of the surface water in the equation. Use of the second option is expected to result in the level of protection intended in the 1985 Guidelines whereas use of the first option is thought to result in an even more protective aquatic life criterion. At high hardness there is an indication that hardness and related inorganic water quality characteristics do not have as much of an effect on toxicity of metals as they do at lower hardnesses. Related water quality characteristics do not correlate as well at higher hardnesses as they do at lower hardnesses. Therefore, if hardness is over 400 mg/l as $CaCO_3$, a hardness of 400 mg/l as $CaCO_3$ should be used with a default WER of 1.0; alternatively, the WER and actual hardness of the surface water may be used.

EPA requested comments in the NTR amendments on the use of actual ambient hardness for calculating criteria when the hardness is below 25 mg/l as $CaCO_3$, and when hardness is greater than 400 mg/l as $CaCO_3$. Most of the

using the actual hardness with the use of the water-effect ratio (1.0 unless otherwise specified by the permitting authority) when the hardness is greater than 400 mg/l as $CaCO_3$. A few commenters did not want the water-effect ratio to be mandatory in calculating hardness, and other commenters had concerns about being responsible for deriving an appropriate water-effect ratio. Overall, the commenters were in favor of using the actual hardness when calculating hardness-dependent freshwater metals criteria for hardness between 0–400 mg/l as $CaCO_3$. EPA took those comments into account in promulgating today's rule.

A hardness equation is most accurate when the relationships between hardness and the other important inorganic constituents, notably alkalinity and pH, are nearly identical in all of the dilution waters used in the toxicity tests and in the surface waters to which the equation is to be applied. If an effluent raises hardness but not alkalinity and/or pH, using the hardness of the downstream water might provide a lower level of protection than intended by the 1985 guidelines. If it appears that an effluent causes hardness to be inconsistent with alkalinity and/or pH, the intended level of protection will usually be maintained or exceeded if either (1) data are available to demonstrate that alkalinity and/or pH do not affect the toxicity of the metal, or (2) the hardness used in the hardness equation is the hardness of upstream water that does not contain the effluent. The level of protection intended by the 1985 guidelines can also be provided by using the WER procedure.

In some cases, capping hardness at 400 mg/l might result in a level of protection that is higher than that intended by the 1985 guidelines, but any such increase in the level of protection can be overcome by use of the WER procedure. For metals whose criteria are expressed as hardness equations, use of the WER procedure will generally be intended to account for effects of such water quality characteristics as total organic carbon on the toxicities of metals. The WER procedure is equally useful for accounting for any deviation from a hardness equation in a site water.

3. *Human Health Criteria*

EPA's CWA section 304(a) human health criteria guidance provides criteria recommendations to minimize adverse human effects due to substances in ambient water. EPA's CWA section 304(a) criteria guidance for human

toxicological 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.

If there are no data on how a chemical agent causes cancer, EPA's existing 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 effect (i.e., cancer). Therefore, EPA's water quality criteria *guidance for carcinogens* are presented as pollutant concentrations corresponding to increases in the risk of developing cancer. See Human Health Guidelines at 45 FR 79347.

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

Note: Recent changes in the Agency's cancer guidelines addressing these assumptions are described in the Draft Water Quality Criteria Methodology: Human Health, 63 FR 43756, August 14, 1998.

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 doses over relatively short periods of time to more realistic low doses 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. 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. 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 effect 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 effect 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 either a No Observed-Adverse Effect Level (NOAEL), Lowest Observed Adverse Effect Level (LOAEL), or other benchmark dose observed in animal studies by an "uncertainty factor" which is based on professional judgment of toxicologists and typically ranges from 10 to 10,000.

For CWA section 304(a) human health criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. Thus, the criteria are based on an assessment of risks related to the surface water exposure route only where designated uses are drinking water and fish and shellfish consumption.

The assumed exposure pathways in calculating the criteria are the consumption of 2 liters per day of water at the criteria concentration and the consumption of 6.5 grams per day of fish and shellfish contaminated at a level equal to the criteria concentration but multiplied by a "bioconcentration factor." The use of fish and shellfish 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 relate 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 and 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 the Human Health Guidelines.) This value is appropriate as it includes a margin of safety so that the general population is protected. See also EPA's discussion of the 2.0 liters/day assumption at 61 FR 65183 (Dec. 11, 1996). The 6.5 grams per day contaminated fish and shellfish consumption value was equivalent to the average per-capita consumption rate of all (contaminated and non-contaminated) freshwater and estuarine fish and shellfish for the U.S. population. See Human Health Guidelines.

EPA assumes in calculating water quality criteria that the exposed individual is an average adult with body weight of 70 kilograms. EPA assumes 6.5 grams per day of contaminated fish and shellfish consumption and 2.0 liters per day of contaminated drinking water consumption for a 70 kilogram person in calculating the criteria. Regarding issues concerning criteria development and differences in dose per kilogram of body weight, RfDs are always derived based on the most sensitive health effect endpoint. Therefore, when that basis is due to a chronic or lifetime health effect, the exposure parameters assume the exposed individual to be the average adult, as indicated above.

In the absence of this final rule, there may be particular risks to children. EPA believes that children are protected by the human health criteria contained in this final rule. Children are protected against other less sensitive adverse health endpoints due to the conservative way that the RfDs are derived. An RfD is a public health protective endpoint. It is an amount of a chemical that can be consumed on a daily basis for a lifetime without expecting an adverse effect. RfDs are based on sensitive health endpoints and

are calculated to be protective for sensitive human sub-populations including children. If the basis of the RfD was due to an acute or shorter-term developmental effect, EPA uses exposure parameters other than those indicated above. Specifically, EPA uses parameters most representative of the population of concern (*e.g.*, the health criteria for nitrates based on infant exposure parameters). For carcinogens, the risk assessments are upper bound one in a million (10^{-6}) lifetime risk numbers. The risk to children is not likely to exceed these upper bounds estimates and may be zero at low doses. The exposure assumptions for drinking water and fish protect children because they are conservative for infants and children. EPA assumes 2 liters of untreated surface water and 6.5 grams of freshwater and estuarine fish are consumed each day. EPA believes the adult fish consumption assumption is conservative for children because children generally consume marine fish not freshwater and estuarine.

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 or q1*s). Through this process, EPA develops a consensus of Agency opinion which is then used throughout EPA in risk management decision-making. 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.)

Section 304(a)(1) of the CWA requires EPA to periodically revise its criteria guidance to reflect the latest scientific knowledge. "(A) On the kind and extent of all identifiable effects on health and welfare . . . ; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on the biological community diversity, productivity, and stability, including information on the factors affecting eutrophication rates of organic and inorganic sedimentation for varying types of receiving waters." In developing up-to-date water quality criteria for the protection of human health, EPA uses the most recent IRIS [illegible] calculation. IRIS reflects EPA's most current consensus on the toxicological assessment for a chemical. In developing the criteria in today's rule, the IRIS values as of October 1995 were used together with currently accepted exposure parameters for bioconcentration, fish and shellfish and water consumption, and body weight. The IRIS cover sheet for each pollutant criteria included in today's rule is contained in the administrative record.

For the human health criteria included in today's rule, EPA used the Human Health Guidelines on which criteria recommendations from the appropriate CWA section 304(a) criteria guidance document were based. (These documents are also placed in the administrative record for today's rule.) Where EPA 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 IRIS information. Thus, there are differences between the original 1980 criteria guidance document recommendations, and those in this rule, but this rule presents EPA's most current CWA section 304(a) criteria recommendation. The basis (q1* or RfD) and BCF for each pollutant criterion in today's rule is contained in the rule's Administrative Record Matrix which is included in the administrative record for the rule. In addition, all recalculated human health numbers are denoted by an "*" in the criteria matrix in 40 CFR 131.36(b)(1) of the rule. The pollutants for which a revised human health criterion has been calculated since the December 1992 NTR include:

mercury
dichlorobromomethane
1,2-dichloropropane
1,2-trans-dichloroethylene
2,4-dimethylphenol
acenaphthene
benzo(a)anthracene
benzo(a)pyrene
benzo(b)flouranthene
benzo(k)flouranthene
2-chloronaphthalene
chrysene
dibenzo(a,h)anthracene
indeno(1,2,3-cd)pyrene
N-nitrosodi-n-propylamine
alpha-endosulfan
beta-endosulfan
endosulfan sulfate
2-chlorophenol
butylbenzyl phthalate
polychlorinated biphenyls.

In November of 1991, the proposed NTR presented criteria for several pollutants in parentheses. These were pollutants for which, in 1980, insufficient information existed to [illegible] criteria, but for which, in 1991, sufficient information existed. Since these criteria did not undergo the public review and comment in a manner similar to the other water quality criteria presented in the NTR (for which sufficient information was available in 1980 to develop a criterion, as presented in the 1980 criteria guidance documents), they were not proposed for adoption into the water quality criteria, but were presented to serve as notice for inclusion in future State triennial reviews. Today's rule promulgates criteria for these nine pollutants:

copper
1,2-dichloropropane
1,2-trans-dichloroethylene
2,4-dimethylphenol
acenaphthene
2-chloronaphthalene
N-nitrosodi-n-propylamine
2-chlorophenol
butylbenzene phthalate.

All the criteria are based on IRIS values—either an RfD or q1*—which were listed on IRIS as of November 1991, the date of the proposed NTR. These values have not changed since the final NTR was published in December of 1992. The rule's Administrative Record Matrix in the administrative record of today's rule contains the specific RfDs, q1*s, and BCFs used in calculating these criteria.

Proposed Changes to the Human Health Criteria Methodology. EPA recently proposed revisions to the 1980 ambient water quality criteria derivation guidelines (the Human Health Guidelines). See *Draft Water Quality Criteria Methodology: Human Health*, 63 FR 43756, August 14, 1998; see also *Draft Water Quality Criteria Methodology: Human Health*, U.S. EPA Office of Water, EPA 822–Z–98–001. The EPA revisions consist of five documents: *Draft Water Quality Criteria Methodology: Human Health*, EPA 822–Z–98–001; *Ambient Water Quality Criteria Derivation Methodology Human Health, Technical Support Document, Final Draft*, EPA–822–B–98–005; and three Ambient Water Quality Criteria for the Protection of Human Health, Drafts—one each for Acrylonitrile, 1,3-Dichloropropene (1,3-DCP), and Hexachlorobutadiene (HCBD), respectively, EPA–822–R–98–006, –005, and –004. All five documents are contained in the administrative record for today's rule.

The proposed methodology revisions reflect significant scientific advances that have occurred during the past nineteen years in such key areas as cancer and noncancer risk assessments, exposure assessments and

these proposed changes and others, please refer to the Federal Register notice or the EPA document.

It should be noted that some of the proposed changes may result in significant numeric changes in the ambient water quality criteria. However, EPA will continue to rely on existing criteria as the basis for regulatory and non-regulatory decisions, until EPA revises and reissues a 304(a) criteria guidance using the revised final human health criteria methodology. The existing criteria are still viewed as scientifically acceptable by EPA. The intention of the proposed methodology revisions is to present the latest scientific advancements in the areas of risk and exposure assessment in order to incrementally improve the already sound toxicological and exposure bases for these criteria. As EPA's current human health criteria are the product of many years worth of development and peer review, it is reasonable to assume that revisiting all existing criteria, and incorporating peer review into such review, could require comparable amounts of time and resources. Given these circumstances, EPA proposed a process for revisiting these criteria as part of the overall revisions to the methodology for deriving human health criteria. This process is discussed in the Implementation Section of the Notice of *Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (see 63 FR 43771–43776, August 14, 1998).

The State of California in its Ocean Plan, adopted in 1990 and approved by EPA in 1991, established numeric water quality criteria using an average fish and shellfish consumption rate of 23 grams per day. This value is based on an earlier California Department of Health Services estimate. The State is currently in the process of readopting its water quality control plans for inland surface waters, enclosed bays, and estuaries. The State intends to consider information on fish and shellfish consumption rates evaluated and summarized in a report prepared by the State's Pesticide and Environmental Toxicology Section of the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency. The report, entitled, *Chemicals in Fish Report No. 1: Consumption of Fish and Shellfish in California and the United States*, was published in final draft form in July of 1997, and released to the public on September 16, 1997. The report is currently undergoing final evaluation, and is expected to published in final form in the near future. This final draft report is contained in the administrative record for today's rule. Although EPA has not used this fish consumption value here because this information has not yet been finalized, the State may use any appropriate higher state-specific fish and shellfish consumption rates in its readoption of criteria in its statewide plans.

a. 2,3,7,8-TCDD (Dioxin) Criteria

In today's action, EPA is promulgating human health water quality criteria for 2,3,7,8-tetrachlorodibenzo-p-dioxin ("dioxin") at the same levels as promulgated in the NTR, as amended. These criteria are derived from EPA's 1984 CWA section 304(a) criteria guidance document for dioxin.

For National Pollutant Discharge Elimination System (NPDES) purposes, EPA supports the regulation of other dioxin and dioxin-like compounds through the use of toxicity equivalencies or TEQs in NPDES permits (see discussion below). For California waters, if the discharge of dioxin or dioxin-like compounds has reasonable potential to cause or contribute to a violation of a narrative criterion, numeric water quality-based effluent limits for dioxin or dioxin-like compounds should be included in NPDES permits and should be expressed using a TEQ scheme.

EPA has been evaluating the health threat posed by dioxin nearly continuously for over two decades. Following issuance of the 1984 criteria guidance document, evaluating the health effects of dioxin and recommending human health criteria for dioxin, EPA prepared draft reassessments reviewing new scientific information relating to dioxin in 1985 and 1988. EPA's Science Advisory Board (SAB), reviewing the 1988 draft reassessment, concluded that while the risk assessment approach used in 1984 criteria guidance document had inadequacies, a better alternative was unavailable (see SAB's *Dioxin Panel Review of Documents from the Office or Research and Development relating to the Risk and Exposure Assessment of 2,3,7,8-TCDD* (EPA–SAB–EC–90–008, November 28, 1989) included in the administrative record for today's rule). Between 1988 and 1990, EPA issued numerous reports and guidances relating to the control of dioxin discharges from pulp and paper mills. See e.g., EPA Memorandum, "Strategy for the Regulation of Discharges of PHDDs & PHDFs from Pulp and Paper Mills to the Waters of the United States," from Assistant Administrator for Water to Regional Water Management Division Directors and NPDES State Directors, dated May 21, 1990 (AR NL–16); EPA Memorandum, "State Policies, Water Quality Standards, and Permit Limitations Related to 2,3,7,8-TCDD in Surface Water," from the Assistant Administrator for Water to Regional Water Management Division Directors, dated January 5, 1990 (AR VA–66). These documents are available in the administrative record for today's rule.

In 1991, EPA's Administrator announced another scientific reassessment of the risks of exposure to dioxin (see Memorandum from Administrator William K. Reilly to Erich W. Bretthauer, Assistant Administrator for Research and Development and E. Donald Elliott, General Counsel, entitled *Dioxin: Follow-Up to Briefing on Scientific Developments*, April 8, 1991, included in the administrative record for today's rule). At that time, the Administrator made clear that while the reassessment was underway, EPA would continue to regulate dioxin in accordance with existing Agency policy. Thereafter, the Agency proceeded to regulate dioxin in a number of environmental programs, including standards under the Safe Drinking Water Act and the CWA.

The Administrator's promulgation of the dioxin human health criteria in the 1992 NTR affirmed the Agency's decision that the ongoing reassessment should not defer or delay regulating this potent contaminant, and further, that the risk assessment in the 1984 criteria guidance document for dioxin continued to be scientifically defensible. Until the reassessment process was completed, the Agency could not "say with any certainty what the degree or directions of any changes in the risk estimates might be" (57 FR 60863–64).

The basis for the dioxin criteria as well as the decision to include the dioxin criteria in the 1992 NTR pending the results of the reassessment were challenged. See *American Forest and Paper Ass'n, Inc. et al. v. U.S. EPA* (Consolidated Case No. 93–0894 (RMU) D.D.C.). By order dated September 4, 1996, the Court upheld EPA's decision. EPA's brief and the Court's decision are included in the administrative record for today's rule.

EPA has undertaken significant effort toward completion of the dioxin reassessment. On September 13, 1994, EPA released for public review and comment a draft reassessment of toxicity and exposure to dioxin. See *Health Assessment Document for 2,3,7,8-Tetrachlorobenzo-p-Dioxin (TCDD) and Related Compounds*, U.S. EPA, 1994. EPA is currently addressing comments made by the public and the SAB and anticipates that the final

revised reassessment will go to the SAB in the near future. With today's rule, the Agency reaffirms that, notwithstanding the on-going risk reassessment, EPA intends to continue to regulate dioxin to avoid further harm to public health, and the basis for the dioxin criteria, both in terms of the cancer potency and the exposure estimates, remains scientifically defensible. The fact that EPA is reassessing the risk of dioxin, virtually a continuous process to evaluate new scientific information, does not mean that the current risk assessment is "wrong." It continues to be EPA's position that until the risk assessment for dioxin is revised, EPA supports and will continue to use the existing risk assessment for the regulation of dioxin in the environment. Accordingly, EPA today promulgates dioxin criteria based on the 1984 criteria guidance document for dioxin and promulgated in the NTR in 1992.

Toxicity Equivalency. The State of California, in its 1991 water quality control plans, adopted human health criteria for dioxin and dioxin-like compounds based on the concept of toxicity equivalency (TEQ) using toxicity equivalency factors (TEFs). EPA Region 9 reviewed and approved the State's use of the TEQ concept and TEFs in setting the State's human health water quality criteria for dioxin and dioxin-like compounds.

In 1987, EPA formally embraced the TEQ concept as an interim procedure to estimate the risks associated with exposures to 210 chlorinated dibenzo-p-dioxin and chlorinated dibenzofuran (CDD/CDF) congeners, including 2,3,7,8-TCDD. This procedure uses a set of derived TEFs to convert the concentration of any CDD/CDF congener into an equivalent concentration of 2,3,7,8-TCDD. In 1989, EPA updated its TEFs based on an examination of relevant scientific evidence and a recognition of the value of international consistency. This updated information can be found in EPA's 1989 *Update to the Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and -dibenzofurans (CDDs and CDFs)* (EPA/625/3-89/016, March 1989). EPA had been active in an international effort aimed at adopting a common set of TEFs (International TEFs/89 or I-TEFs/89), to facilitate information exchange on environmental contamination of CDD/CDF. This document reflects EPA's support of an internationally consistent set of TEFs, the I-TEFs/89. EPA uses I-TEFs/89 in many of its regulatory programs.

In 1994, the World Health Organization (WHO) convened an expert panel to develop a consensus scheme for dioxins and furans to include toxicity from dioxin-like compounds (Ahlborg et al., 1994). However, no changes were made to the TEFs for dioxins and furans. In 1998, the WHO re-evaluated and revised the previously established TEFs for dioxins (Ds), furans (Fs) and dioxin-like compounds (Vanden Bers, 1998). The nomenclature for this TEF scheme is TEQDFP-WHO98, where TEQ represents the 2,3,7,8-TCDD Toxic Equivalence of the mixture, and the subscript DFP indicates that dioxins (Ds) furans (Fs) and dioxin-like compounds (P) are included in the TEF scheme. The subscript 98 following WHO displays the year changes were made to the TEF scheme.

EPA intends to use the 1998 WHO TEF scheme in the near future. At this point however, EPA will support the use of either the 1989 interim procedures or the 1998 WHO TEF scheme but encourages the use of the 1998 WHO TEF scheme in State programs. EPA expects California to use a TEF scheme in implementing the 2,3,7,8-TCDD water quality criteria contained in today's rule. The TEQ and TEF approach provide a methodology for setting NPDES water quality-based permit limits that are protective of human health for dioxin and dioxin-like compounds.

Several commenters requested EPA to promulgate criteria for other forms of dioxin, in addition to 2,3,7,8-TCDD. EPA's draft reassessment for dioxin examines toxicity based on the TEQ concept and I-TEFs/89. When EPA completes the dioxin reassessment, the Agency intends to adopt revised 304(a) water quality criteria guidance based on the reassessment for dioxin. If necessary, EPA will then act to amend the NTR and CTR to reflect the revised 304(a) water quality criteria guidance.

b. Arsenic Criteria

EPA is not promulgating human health criteria for arsenic in today's rule. EPA recognizes that it promulgated human health water quality criteria for arsenic for a number of States in 1992, in the NTR, based on EPA's 1980 section 304(a) criteria guidance for arsenic established, in part, from IRIS values current at that time. However, a number of issues and uncertainties existed at the time of the CTR proposal concerning the health effects of arsenic. These issues and uncertainties were summarized in "Issues Related to Health Risk of Arsenic" which is contained in the administrative record for today's rule. During the period of this rulemaking action, EPA affects by the National Research Council (NRC) arm of the National Academy of Sciences. EPA received the NRC report in March of 1999. EPA scientists reviewed the report, which recommended that EPA lower the Safe Drinking Water Act arsenic maximum contaminant level (MCL) as soon as possible. The arsenic MCL is currently 50 µg/L. The bladder cancer analysis in the NRC report will provide part of the basis for the risk assessment of a proposed revised arsenic MCL in the near future. After promulgating a revised MCL for drinking water, the Agency plans to revise the CWA 304(a) human health criteria for arsenic in order to harmonize the two standards. Today's rule defers promulgating arsenic criteria based on the Agency's previous risk assessment of skin cancer. In the meantime, permitting authorities in California should rely on existing narrative water quality criteria to establish effluent limitations as necessary for arsenic. California has previously expressed its science and policy position by establishing a criterion level of 5 µg/L for arsenic. Permitting authorities may, among other considerations, consider that value when evaluating and interpreting narrative water quality criteria.

c. Mercury Criteria

The human health criteria promulgated here use the latest RfD in EPA's Integrated Risk Information System (IRIS) and the weighted average practical bioconcentration factor (PBCF) from the 1980 section 304(a) criteria guidance document for mercury. EPA considered the approach used in the Great Lakes Water Quality Guidance ("Guidance") incorporating Bioaccumulation Factors (BAFs), but rejected this approach for reasons outlined below. The equation used here to derive an ambient water quality criterion for mercury from exposure to organisms and water is:

$$HHC = \frac{RfD \times BW}{WC + (FC \times PBCF)}$$

Where:
RfD = Reference Dose
BW = Body Weight
WC = Water Consumption
FC = Total Fish and Shellfish Consumption per Day
PBCF = Practical Bioconcentration Factor (weighted average)

For mercury, the most current RfD from IRIS is 1×10^{-4} mg/kg/day. The RfD used a benchmark dose as an estimate of a No Observed Adverse Effect Level (NOAEL). The benchmark dose was

for extra risk to all neurological effects observed in 81 Iraqi children exposed in utero as reported in Marsh, et. al. (1987). Maternal hair mercury was the measure of exposure. Extra risk refers to an adjustment for background incidence of a given health effect. Specifically, the extra risk is the added incidence of observing an effect above the background rate relative to the proportion of the population of interest that is not expected to exhibit such as effect. The resulting estimate was the lower 95% statistical bound on the 10% extra risk; this was 11 ppm mercury in maternal hair. This dose in hair was converted to an equivalent ingested amount by applying a model based on data from human studies; the resulting benchmark dose was 1×10^{-3} mg/kg body weight/day. The RfD was calculated by dividing the benchmark dose by a composite uncertainty factor of 10. The uncertainty factor was used to account for variability in the human population, in particular the wide variation in biological half-life of methylmercury and the variation that is observed in the ration of hair mercury to mercury in the blood. In addition the uncertainty factor accounts for lack of a two-generation reproductive study and the lack of data on long-term effects of childhood mercury exposures. The RfD thus calculated is 1×10^{-4} mg/kg body weight/day or 0.1 µg/kg/day. The body weight used in the equation for the mercury criteria, as discussed in the Human Health Guidelines, is a mean adult human body weight of 70 kg. The drinking water consumption rate, as discussed in the Human Health Guidelines, is 2.0 liters per day.

The bioconcentration factor or BCF is defined as the ratio of chemical concentration in the organism to that in surrounding water. Bioconcentration occurs through uptake and retention of a substance from water only, through gill membranes or other external body surfaces. In the context of setting exposure criteria it is generally understood that the terms "BCF" and "steady-state BCF" are synonymous. A steady-state condition occurs when the organism is exposed for a sufficient length of time that the ratio does not change substantially.

The BCFs that were used herein are the "Practical Bioconcentration Factors (PBCFs)" that were derived in 1980. 5500 for fresh water, 3765 for estuarine coastal waters, and 9000 for open oceans. See pages C-100-1 of Ambient Water Quality Criteria for Mercury (EPA 440/5-80-058) for a complete discussion on the PBCF. Because of the way they were derived, these PBCFs take into account uptake from food as well as uptake from water. A weighted average PBCF was calculated to take into account the average consumption from the three waters using the following equation:

$$\text{Weighted Average Practical BCF} = \frac{\sum(FC \times PBCF)}{\sum(FC)} = \frac{(0.00172)(5500) + (0.00478)(3765) + (0.0122)(9000)}{0.00172 + 0.00478 + 0.0122} = \frac{137.3}{0.0187} = 7342.6$$

Given the large value for the weighted average PBCF, the contribution of drinking water to total daily intake is negligible so that assumptions concerning the chemical form of mercury in drinking water become less important. The human health mercury criteria promulgated for this rule are based on the latest RfD as listed in IRIS and a weighted PBCF from the 1980 § 304(a) criteria guidance document for mercury.

On March 23, 1995 (60 FR 15366), EPA promulgated the Great Lakes Water Quality Guidance ("Guidance"). The Guidance incorporated bioaccumulation factors (BAFs) in the derivation of criteria to protect human health because it is believed that BAFs are a better predictor than BCFs of the concentration of a chemical within fish tissue since BAFs include consideration of the uptake of contaminants from all routes of exposure. A bioaccumulation factor is defined as the ratio (in L/kg) of a substance's concentration in tissue to the concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time. The final Great Lakes Guidance establishes a hierarchy of four methods for deriving BAFs for non-polar organic chemicals: (1) Field-measured BAFs; (2) predicted BAFs derived using a field-measured biota-sediment accumulation factor; (3) predicted BAFs derived by multiplying a laboratory-measured BCF by a food chain multiplier, and (4) predicted BAFs derived by multiplying a BCF calculated from the log Kow by a food chain multiplier. The final Great Lakes Guidance developed BAFs for trophic levels three and four fish of the Great Lakes Basin. Respectively, the BAFs for mercury for trophic level 3 and 4 fish were: 27,900 and 140,000.

The BAF promulgated in the GLI was developed specifically for the Great Lakes System. It is uncertain whether the BAFs of 27,900 and 140,000 are appropriate for use in California at this time; therefore, today's final rule does not use the GLI BAF in establishing human health criteria for mercury in California. The magnitude of the BAF for mercury in a given system depends on how much of the total mercury is present in the methylated form. Methylation rates vary widely from one water body to another for reasons that are not fully understood. Lacking the data, it is difficult to determine if the BAF used in the GLI represents the true potential for mercury to bioaccumulate in California surface waters. The true, average BAF for California could be higher or lower. For more information see EPA's Response to Comments document in the administrative record for this rule (specifically comments CTR-002-007(b) and CTR-016-007).

EPA is developing a national BAF for mercury as part of revisions to its 304(a) criteria for human health; however, the BAF methodology that will be used is currently under evaluation as part of EPA's revisions to its National Human Health Methodology (see section F.3 above). EPA applied a similar methodology in its Mercury Study Report to Congress (MSRC) to derive a BAF for methylmercury. The MSRC is available through NTIS (EPA-452/R-97-003). Although a BAF was derived in the MSRC, EPA does not intend to use this BAF for National application. EPA is engaged in a separate effort to incorporate additional mercury bioaccumulation data that was not considered in the MSRC, and to assess uncertainties with using a National BAF approach for mercury. Once the proposed revised human health methodology, including the BAF component, is finalized, EPA will revise its 304(a) criteria for mercury to reflect changes in the underlying methodology, recommendations contained in the MSRC, and recommendations in a National Academy of Science report on human health assessment of methylmercury. When EPA changes its 304(a) criteria recommendation for mercury, States and Tribes will be expected to review their water quality standards for mercury and make any revisions necessary to ensure their standards are scientifically defensible.

New information may become available regarding the bioaccumulation

of mercury in certain water bodies in California. EPA supports the use of this information to develop site-specific criteria for mercury. Further, if a California water body is impaired due to mercury fish tissue or sediment contamination, loadings of mercury could contribute to or exacerbate the impairment. Therefore, one option regulatory authorities should consider is to include water quality-based effluent limits (WQBELs) in permits based on mass for discharges to the impaired water body. Such WQBELs must be derived from and comply with applicable State water quality standards (including both numeric and narrative criteria) and assure that the discharge does not cause or contribute to a violation of water quality standards.

d. Polychlorinated Biphenyls (PCBs) Criteria

The NTR, as amended, calculated human health criteria for PCBs using a cancer potency factor of 7.7 per mg/kg-day from the Agency's IRIS. This cancer potency factor was derived from the Norback and Weltman (1985) study which looked at rats that were fed Aroclor 1260. The study used the linearized multistage model with a default cross-species scaling factor (body weight ratio to the ¾ power). Although it is known that PCB mixtures vary greatly as to their potency in producing biological effects, for purposes of its carcinogenicity assessment, EPA considered Aroclor 1260 to be representative of all PCB mixtures. The Agency did not pool data from all available congener studies or generate a geometric mean from these studies, since the Norback and Weltman study was judged by EPA as acceptable, and not of marginal quality, in design or conduct as compared with other studies. Thereafter, the Institute for Evaluating Health Risks (IEHR, 1991) reviewed the pathological slides from the Norback and Weltman study, and concluded that some of the malignant liver tumors should have been interpreted as nonmalignant lesions, and that the cancer potency factor should be 5.1 per mg/kg-day as compared with EPA's 7.7 per mg/kg-day.

The Agency's peer-reviewed reassessment of the cancer potency of PCBs, published in a final report, *PCBs: Cancer Dose-Response Assessment and Applications to Environmental Mixtures* (EPA/600/P–96/001F), adopts a different approach that distinguishes among PCB mixtures by using information on environmental processes. (The report is included in the administrative record of mixtures only) to develop a range of cancer potency factors, then uses information on environmental processes to provide guidance on choosing an appropriate potency factor for representative classes of environmental mixtures and different pathways. The reassessment provides that, depending on the specific application, either central estimates or upper bounds can be appropriate. Central estimates describe a typical individual's risk, while upper bounds provide assurance (*i.e.*, 95% confidence) that this risk is not likely to be underestimated if the underlying model is correct. Central estimates are used for comparing or ranking environmental hazards, while upper bounds provide information about the precision of the comparison or ranking. In the reassessment, the use of the upper bound values were found to increase cancer potency estimates by two or three-fold over those using central tendency. Upper bounds are useful for estimating risks or setting exposure-related standards to protect public health, and are used by EPA in quantitative cancer risk assessment. Thus, the cancer potency of PCB mixtures is determined using a tiered approach (based on environmental exposure routes with upper bound potency factors (using a body weight ratio to the ¾ power) ranging from 0.07 (lowest risk and persistence) to 2 (high risk and persistence) per mg/kg-day for average lifetime exposures to PCBs. It is noteworthy that bioaccumulated PCBs appear to be more toxic than commercial PCBs and appear to be more persistent in the body. For exposure through the food chain, risks can be higher than other exposures.

EPA issued the final reassessment report on September 27, 1996, and updated IRIS to include the reassessment on October 1, 1996. EPA updated the human health criteria for PCBs in the *National Toxics Rule* on September 27, 1999. For today's rule, EPA derived the human health criteria for PCBs using a cancer potency factor of 2 per mg/kg-day, an upper bound potency factor reflecting high risk and persistence. This decision is based on recent multimedia studies indicating that the major pathway of exposure to persistent toxic substances such as PCBs is via dietary exposure (*i.e.*, contaminated fish and shellfish consumption).

Following is the calculation of the human health criterion (HHC) for organism and water consumption:

$$HHC = \frac{RF \times BW \times (1{,}000\ \mu g/mg)}{q1^* \times (WC + FC \times BCF)}$$

Where:

RF = Risk Factor = 1×10^{-6}
BW = Body Weight = 70 kg
q1* = Cancer slope factor = 2 per mg/kg-day
WC = Water Consumption = 2 l/day
FC = Fish and Shellfish Consumption = 0.0065 kg/day
BCF = Bioconcentration Factor = 31,200
the HHC (µg/l) = 0.00017 µg/l (rounded to two significant digits).

Following is the calculation of the human health criterion for organism only consumption:

$$HHC = \frac{RF \times BW \times (1{,}000\ \mu g/mg)}{q1^* \times FC \times BCF}$$

Where:

RF = Risk Factor = 1×10^{-6}
BW = Body Weight = 70 kg
q1* = Cancer slope factor = 2 per mg/kg-day
FC = Total Fish and Shellfish Consumption per Day = 0.0065 kg/day
BCF = Bioconcentration Factor = 31,200
the HHC (µg/l) = 0.00017 µg/l (rounded to two significant digits).

The criteria are both equal to 0.00017 µg/l and apply to total PCBs. *See PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures* (EPA/600/6–96–001F). For a discussion of the body weight, water consumption, and fish and shellfish consumption factors, see the Human Health Guidelines. For a discussion of the BCF, see the 304(a) criteria guidance document for PCBs (included in the administrative record for today's rule).

e. Excluded Section 304(a) Human Health Criteria

As is the case in the NTR, as amended, today's rule does not promulgate criteria for certain priority pollutants for which CWA section 304(a) criteria guidance exists because those criteria were not based on toxicity to humans or aquatic organisms. The basis for those particular criteria is 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 CWA section 303(c)(2)(B), EPA is promulgating criteria only for those priority toxic pollutants whose criteria recommendations are based on toxicity. The CWA section 304(a) human health criteria based on organoleptic effects for zinc and 3-methyl-4-chlorophenol are excluded for this reason. See the 1992

f. Cancer Risk Level

EPA's CWA 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 case 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.

As part of the proposed rule, EPA requested and received comment on the adoption of a 10^{-5} risk level for carcinogenic pollutants. The effect of a 10^{-5} risk level would have been to increase (i.e., make less stringent) carcinogenic pollutant criteria values (noted in the matrix by footnote c) that are not already promulgated in the NTR, by one order of magnitude. For example, the organism-only criterion for gamma BHC (pollutant number 105 in the matrix) is 0.013 µg/l; the criterion based on a 10^{-5} risk level would have been 0.19 µg/l. EPA received several comments that indicated a preference for a higher (10^{-4} and 10^{-5}) risk level for effluent dependent waters or other types of special circumstances.

In today's rule, EPA is promulgating criteria that protect the general population at an incremental cancer risk level of one in a million (10^{-6}) for all priority toxic pollutants regulated as carcinogens, consistent with the criteria promulgated in the NTR for the State of California. Standards adopted by the State contained in the Enclosed Bays and Estuaries Plan (EBEP), and the Inland Surface Waters Plan (ISWP), partially approved by EPA on November 6, 1991, and the Ocean Plan approved by EPA on June 28, 1990, contained a risk level of 10^{-6} for most carcinogens. The State has historically protected at a 10^{-6} risk level for carcinogenic pollutants.

EPA, in its recent human health methodology revisions, proposed acceptable lifetime cancer risk for the general population in the range of 10^{-5} to 10^{-6}. EPA also proposed that States and Tribes ensure the most highly exposed populations do not exceed a 10^{-4} risk level. However, EPA's draft methodology revisions also stated that it will derive 304(a) criteria at a 10^{-6} risk level, which the Agency believes reflects the appropriate risk for the general population and which applies a risk management policy which ensures protection for all exposed population groups. (Draft Water Quality Criteria Methodology: Human Health, EPA 822–Z–98–001, August 1998, Appendix II, page 72).

Subpopulations within a State may exist, such as recreational and subsistence anglers, who as a result of greater exposure to a contaminant are at greater risk than the standard 70 kilogram person eating 6.5 grams per day of fish and shellfish and drinking 2.0 liters per day of drinking water with pollutant levels meeting the water quality criteria. EPA acknowledges that at any given risk level for the general population, those segments of the population that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level permitted by criteria derived on the basis of a risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish consumption rate would still be protected at a 10^{-5} risk level. Similarly, individuals consuming 100 times the general population rate would be protected at a 10^{-4} risk level. EPA therefore believes that derivation of criteria at the 10^{-6} risk level is a reasonable risk management decision protective of designated uses under the CWA. While outside the scope of this rule, EPA notes that States and Tribes, however, have the discretion to adopt water quality criteria that result in a higher risk level (e.g., 10^{-5}). EPA expects to approve such criteria if the State or Tribe has identified the most highly exposed subpopulation within the State or Tribe, demonstrates the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation.

This demonstration has not happened in California. Further, the information that is available on highly exposed subpopulations in California supports the need to protect the general population at the 10^{-6} level. California has cited the Santa Monica Bay Seafood Consumption Study as providing the best available data set for estimating consumption of sport fish and shellfish in California for both marine or freshwater sources (Chemicals in Fish Report No. 1: Consumption of Fish and Shellfish in California and the United States, Final Draft Report, July 1997). Consumption rates of sport fish and shellfish of 21 g/day, 50 g/day, 107 g/day, and 161 g/day for the median, mean, 90th, and 95th percentile rates, respectively, were determined from this study. Additional consumption of commercial species in the range of approximately 8 to 42 g/day would further increase these values. Clearly the consumption rates for the most highly exposed subpopulation within the State exceeds 10 times the 6.5 g/day rates used in the CTR. Therefore, use of a risk level of 10^{-5} for the general population would not be sufficient to protect the most highly exposed population in California at a 10^{-4} risk level. On the other hand, even the most highly exposed subpopulations cited in the California study do not have consumption rates approaching 100 times the 6.5 g/day rates used in the CTR. The use of the 10^{-6} risk level to protect average level consumers does not subject these subpopulations to risk levels as high as 10^{-4}.

EPA believes its decision to establish a 10^{-6} risk level for the CTR is also consistent with EPA's policy in the NTR to select the risk level that reflect the policies or preferences of CWA programs in the affected States. California adopted standards for priority toxic pollutants for its ocean waters in 1990 using a 10^{-6} risk level to protect human health (California Ocean Plan, 1990). In April 1991 and again in November 1992, California adopted standards for its inland surface waters and enclosed bays and estuaries in its Inland Surface Waters Plan (ISWP) and its Enclosed Bays and Estuaries Plan (EBEP) using a 10^{-6} risk level. To be consistent with the State's water quality standards, EPA used a 10^{-6} risk level for California in the NTR at 57 FR 60867. The State has continued using a 10^{-6} risk level to protect human health for its standards that were not withdrawn with the ISWP and EBEP. The most recent expression of risk level preference is contained in the Draft Functional Equivalent Document, Amendment of the Water Quality Control Plan for Ocean Waters of California, October 1998, where the State recommended maintaining a consistent risk level of 10^{-6} for the human health standards that it was proposing to revise.

EPA received several comments requesting a 10^{-5} risk level based on the risk level chosen for the Great Lakes Water Quality Guidance (the Guidance). There are several differences between the guidelines for the derivation of human health criteria contained in the Guidance and the California Toxics Rule (CTR) that make a 10^{-5} risk factor appropriate for the Guidance, but not for the CTR. These differences result in criteria developed using the 10^{-5} risk factor in the Guidance being at least as stringent as criteria derived under the CTR using a 10^{-6} risk factor. The relevant aspects of the Guidance include:

- Use of fish consumption rates that are considerably higher than fish consumption rates for the CTR.
- Use of bioaccumulation factors rather than bioconcentration factors in

estimating exposure, considerably increasing the dose of carcinogens to sensitive subgroups.

• Consideration of additivity of effects of mixtures for both carcinogenic and noncarcinogenic pollutants.

This combination of factors increase the calculated carcinogenic risk substantially under the Guidance (the combination would generally be more than one order of magnitude), making a lower overall risk factor acceptable. The Guidance risk factor provides, in fact, criteria with at least the same level of protection against carcinogens as criteria derived with a higher risk factor using the CTR. A lower risk factor for the CTR would not be appropriate absent concomitant changes in the derivation procedures that provide equivalent risk protection.

G. Description of Final Rule

1. Scope

Paragraph (a) in 40 CFR 131.38, entitled "Scope," states that this rule is a promulgation of criteria for priority toxic pollutants in the State of California for inland surface waters, enclosed bays, and estuaries. Paragraph (a) in 40 CFR 131.38 also states that this rule contains an authorizing compliance schedule provision.

2. EPA Criteria for Priority Toxic Pollutants

EPA's criteria for California are presented in tabular form at 40 CFR 131.38. For ease of presentation, the table that appears combines water quality criteria promulgated in the NTR, as amended, that are outside the scope of this rulemaking with the criteria that are within the scope of today's rule. This is intended to help readers determine applicable water quality criteria for the State of California. The table contains footnotes for clarification.

Paragraph (b) in 40 CFR 131.38 presents a matrix of the applicable EPA aquatic life and/or human health criteria for priority toxic pollutants in California. Section 303(c)(2)(B) of the CWA addresses only pollutants listed as "toxic" pursuant to section 307(a) of the CWA for which EPA has developed section 304(a) criteria guidance. 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. Of these, the Agency identified a list of 126 "priority toxic pollutants" to implement the CWA (see 40 CFR 131.36(b)). Reference in this rule to priority toxic pollutants, toxic

EPA has not developed both aquatic life and human health CWA section 304(a) criterion guidance for all of the priority toxic pollutants. The matrix in 40 CFR 131.38(b) contains human health criteria in Column D for 92 priority toxic pollutants which are divided into Column 1: criteria for water consumption (i.e., 2.0 liters per day) and aquatic organism consumption (i.e., 6.5 grams per day of aquatic organisms); and Column 2: criteria for aquatic organism consumption only. The term aquatic organism includes fish and shellfish such as shrimp, clams, oysters and mussels. One reason the total number of priority toxic pollutants with criteria today differs from the total number of priority toxic pollutants contained in earlier published CWA section 304(a) criteria guidance is 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 protection. See pollutant 5 in today's rule at 40 CFR 131.38(b). Another reason is that EPA is promulgating human health criteria for nine priority pollutants for which health-based national criteria have been calculated based on information obtained from EPA's IRIS database. (EPA provided notice of these nine criteria in the NTR for inclusion in future State triennial reviews. See 57 FR 60848, 60890).

The matrix contains aquatic life criteria for 23 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 TSD. For example, water body 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 short-term concentrations and that the criteria continuous concentrations (the chronic criteria) are four-day averages. It should also be noted that for certain metals, the actual criteria are equations which are included as footnotes to the matrix. The toxicity of these metals is water hardness dependent and may be adjusted. The values shown in the table are illustrative only, based on a hardness expressed as calcium 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. 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 of the table.

The final rule at 40 CFR 131.38(c) establishes the applicability of the criteria to the State of California. 40 CFR 131.38(d) is described later in Section F. of this preamble. EPA has included in this rule provisions necessary to implement numeric criteria in a way that maintains the level of protection intended. These provisions are included in 40 CFR 131.38(c) of today's rule. 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 for various purposes. These low flow values become design flows for sizing treatment plants and developing water quality-based effluent limits and/or TMDLs. Historically, these 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 *TSD*, EPA introduced hydrologically and biologically based analyses for the protection of aquatic life and human health. (These concepts have been expanded subsequently in EPA's *Technical Guidance Manual for Performing Waste load Allocations, Book 6, Design Conditions*, U.S. EPA, 1986. These analyses 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 design flows for instream flows and thereby maintain the adequacy of the criteria for priority toxic pollutants.) EPA recommended either of two methods for calculating acceptable low flows, the traditional hydrologic method developed by the U.S. Geological Survey or a biological based method developed by EPA. Other methods for evaluating the instream flow record may be available; use of these methods may result in TMDLs and/or water quality-based effluent limitations which adequately protect human health and/or aquatic life. The results of either of these two methods, or an equally protective alternative method, may be used.

The State of California may adopt specific design flows for streams and

important to specify design flows in today's rule so that, in the absence of state 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.

The low flows specified in the rule explicitly contain duration and frequency of occurrence which represent certain probabilities of occurrence. Likewise, the criteria for 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 pollution variation. Dynamic modeling techniques, as described in the TSD, 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. Either dynamic modeling or steady state modeling can be used to implement the criteria promulgated today. For simplicity, only steady state conditions are discussed here. Clearly, if the criteria were implemented using design flows that are too high, the resulting toxic controls would not be adequate because the resulting ambient concentrations would exceed EPA's criteria.

In the case of aquatic life, assuming exceedences occur more frequently than once in three years on the average, exceedences would result in diminished vitality of stream ecosystems characterized by the loss of desired species. Numeric water quality criteria should apply at all flows that are equal to or greater than flows specified below. The low flow values are:

Type of criteria	Design flow
Acute Aquatic Life (CMC)	1 Q 10 or 1 B 3
Chronic Aquatic Life (CCC)	7 Q 10 or 4 B 3
Human Health	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 exceedences for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);

EPA is requiring that the harmonic mean flow be applied with human health criteria. The harmonic mean is a standard calculated statistical value. 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. (For a description of harmonic means see "Design Stream Flows Based on Harmonic Means," Lewis A. Rossman, Jr. of Hydraulics Engineering, Vol. 116, No. 7, July, 1990.)

All waters (including lakes, estuaries, and marine waters), whether or not suitable for such hydrologic calculations, are subject to the criteria promulgated today. Such criteria will need to be attained at the end of the discharge pipe, unless the State authorizes a mixing zone. Where the State plans to authorize a mixing zone, the criteria would apply at the locations allowed by the mixing zone. For example, the chronic criteria (CCC) would apply at the defined boundary of the chronic 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 water quality criteria 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 based on the actual criteria necessary to protect aquatic life and human health become measurable. The Agency does not believe it is appropriate to promulgate criteria that are not sufficiently protective. EPA discusses this issue further in its Response to Comment Document for today's final rule.

EPA does believe, however, that the use of analytical detection limits are appropriate for assessing *compliance* with National Pollutant Discharge Elimination System (NPDES) permit limits. This view of the role of detection limits was first articulated in guidance for translating dioxin criteria into NPDES permit limits. See "Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the U.S." Memorandum from the Assistant Administrator for Water to the Regional Water Management Division Directors, May 21, 1990. This guidance presented a model for addressing toxic pollutants which have criteria less than current detection limits. EPA, in more recent guidance, recommends the use of the "minimum level", or ML for reporting sample results to assess compliance with WQBELs (TSD page 111). The ML, also called the "quantification level," is the level at which the entire analytical system gives recognizable mass spectra and acceptable calibration points, i.e., the point at which the method can reliably quantify the amount of pollutant in the sample. States can use their own procedures to average and otherwise account for monitoring data, *e.g.*, quantifying results below the ML. These results can then be used to assess compliance with WQBELs. (See 40 CFR part 132, Appendix F, Procedure 6.B.) This approach is applicable to priority toxic pollutants with criteria less than current detection limits. EPA's guidance explains that standard analytical methods may be used for purposes of assessing compliance with permit limits, but not for purposes of establishing water quality criteria or *permit limits*. Under the CWA, analytical methods are appropriately used in connection with NPDES permit limit compliance assessments. 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 promulgated 40 CFR 131.36(c)(3) to determine when freshwater or saltwater aquatic life criteria apply. This provision incorporates a time parameter to better define the critical condition. The structure of the paragraph is to establish

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 freshwater and saltwater aquatic communities, EPA is *establishing* the following: (1) The freshwater criteria apply at salinities of 1 part per thousand and below at locations where this occurs 95% or more of the time; (2) saltwater 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 an appropriate 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 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 salt 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.

Paragraph (d) in 40 CFR 131.38 lists the designated water and use classifications for which the criteria apply. The criteria are applied to the beneficial use designations adopted by the State of California. EPA has not promulgated any new use classifications in this rule.

Exceedences Frequency. In a water quality criterion for aquatic life, EPA recommends an allowable frequency for excursions of the criteria. See 1985 Guidelines, pages 11–13. This allowable frequency provides an appropriate period of time during which the aquatic community can recover from the effect of an excursion and then function [illegible] for a period of time before the as an occurrence of when the average concentration over the duration of the averaging period is above the CCC or the CMC. As ecological communities are naturally subjected to a series of stresses, the allowable frequency of pollutant stress may be set at a value that does not significantly increase the frequency or severity of all stresses combined. See also TSD, Appendix D. In addition, providing an allowable frequency for exceeding the criterion recognizes that it is not generally possible to assure that criteria are never exceeded. (TSD, page 36.)

Based on the available data, today's rule requires that the acute criterion for a pollutant be exceeded no more than once in three years on the average. EPA is also requiring that the chronic criterion for a pollutant be exceeded no more than once in three years on the average. EPA acknowledges that States may develop allowable frequencies that differ from these allowable frequencies, so long as they are scientifically supportable, but believes that these allowable frequencies are protective of the designated uses where EPA is promulgating criteria.

The use of aquatic life criteria for developing water quality-based effluent limits in permits requires the permitting official to use an appropriate wasteload allocation model. (TSD, Appendix D–6.) As discussed above, there are generally two methods for determining design flows, the hydrologically-based method and the biologically-based method.

The biologically-based method directly uses the averaging periods and frequencies specified in the aquatic life criteria for determining design flows. (TSD, Appendix D–8.) Because the biologically-based method calculates the design flow directly from the duration and allowable frequency, it most accurately provides the allowed number of excursions. The hydrologically-based method applies the CMC at a design flow equal to or equivalent to the 1Q10 design flow (i.e., the lowest one-day flow with an average recurrence frequency of once in ten years), and applies the CCC at the 7Q10 design flow (i.e., the lowest average seven consecutive day flow with a recurrence frequency of once in ten years).

EPA established a three year allowable frequency in the NTR. In settlement of the litigation on the NTR, EPA stated that it was in the midst of conducting, sponsoring, or planning research aimed at addressing scientific issues related to the basis for and application of water quality criteria and mentioned the issue of allowable frequency. See Partial Settlement *Paper Ass'n, Inc. et al. v. U.S. EPA* (Consolidated Case No. 93–0694 (RMU) D.D.C. To that end, EPA is reevaluating issues raised about allowable frequency as part of its work in revising the 1985 Guidelines.

EPA recognizes that additional data concerning (a) the probable frequency of lethal events for an assemblage of taxa covering a range of sensitivities to pollutants, (b) the probable frequency of sublethal effects for such taxa, (c) the differing effects of lethal and sublethal events in reducing populations of such taxa, and (d) the time needed to replace organisms lost as a result of toxicity, may lead to further refinement of the allowable frequency value. EPA has not yet completed this work. Until this work is complete, EPA believes that where EPA promulgates criteria, the three year allowable frequency represents a value in the reasonable range for this parameter.

3. Implementation.

Once the applicable designated uses and water quality criteria for a water body are determined under the National Pollutant Discharge Elimination System (NPDES) program, discharges to the water body must be characterized and the permitting authority must determine the need for permit limits. If a discharge causes, has the reasonable potential to cause, or contributes to an excursion of a numeric or narrative water quality criteria, the permitting authority must develop permit limits as necessary to meet water quality standards. These permit limits are water quality-based effluent limitations or WQBELs. The terms "cause," "reasonable potential to cause," and "contribute to" are the terms in the NPDES regulations for conditions under which water quality-based permit limits are required. See 40 CFR 122.44(d)(1).

Since the publication of the proposed CTR, the State of California adopted procedures which detail how water quality criteria will be implemented through NPDES permits, waste discharge requirements, and other regulatory approaches. These procedures entitled, *Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California* were adopted on March 2, 2000. Once these procedures are submitted for review under CWA section 303(c), EPA will review them as they relate to water quality standards, and approve or disapprove them.

Several commenters understood the language in the preamble to the

to mean that site-specific criteria, variances, and other actions would be prohibited or severely limited by the CTR. Site-specific criteria, variances and other actions modifying criteria are neither prohibited nor limited by the CTR. The State, if it so chooses, still can make these changes to its water quality standards, subject to EPA approval. However, with this Federal rule in effect, the State cannot implement any modifications that are less stringent than the CTR without an amendment to the CTR to reflect these modifications. EPA will make every effort to expeditiously accommodate Federal rulemaking of appropriate modifications to California's water quality standards. In the preamble to the proposed CTR, and here today, EPA is emphasizing that these efforts to amend the CTR on a case-by-case basis will generally increase the time before a modification can be implemented.

4. Wet Weather Flows

EPA has for a longtime maintained that CWA section 301(b)(1)(C) applies to NPDES permits for discharges from municipal separate storm sewer systems. Recently, the U.S. Court of Appeals for the Ninth Circuit upheld NPDES permits issued by EPA for five Arizona municipal separate storm sewer systems and addressed this issue specifically, *Defenders of Wildlife, et al. v. Browner*, No. 98–71080 (9th Cir., October 1999). The Court held that the CWA does not require "strict compliance" with State water quality standards for municipal storm sewer permits under section 301(b)(1)(C), but that at the same time, the CWA does give EPA discretion to incorporate appropriate water quality-based effluent limitations under another provision, CWA section 402(p)(3)(B)(iii).

The Court based its decision on the structure of section 402(p)(3), which contains distinct language for discharges of industrial storm water and municipal storm water. In section 402(p)(3)(A), Congress requires that "dischargers associated with industrial activity shall meet all applicable provisions of [section 402] and section [301]." 33 U.S.C. section 1342(p)(3)(A). The Court noted, therefore, that by incorporation, industrial storm water discharges need to achieve "any more stringent limitation, including those necessary to meet water quality standards * * *" The Court explained that industrial storm water discharges "must comply strictly with State water quality standards" but that Congress chose not to include a similar provision for municipal storm sewer discharges, including instead a requirement for controls to reduce pollutants to the maximum extent practicable or MEP standard in section 402(p)(3)(B). Reading the two related sections together, the Court concluded that section 402(p)(3)(B)(iii) does not require "strict compliance" by municipal storm sewer discharges according to section 301(b)(1)(C). At the same time, however, the Court found that the language in CWA section 402(p)(3)(B)(ii) which states that permits for discharges from municipal storm sewers shall require "such other provisions as the Administrator of the state determines appropriate for the control of such pollutants" provides EPA with discretion to incorporate provisions lending to ultimate compliance with water quality standards.

EPA believes that compliance with water quality standards through the use of Best Management Practices (BMPs) is appropriate. EPA articulated its position on the use of BMPs in storm water permits in the policy memorandum entitled, "Interim Permitting Approach for Water Quality Based Effluent Limitations in Storm Water Permits" which was signed by the Assistant Administrator for Water, Robert Perciasepe on August 1, 1996 (61 FR 43761, August 9, 1996). A copy of this memorandum is contained in the administrative record for today's rule. The policy affirms the use of BMPs as a means to attain water quality standards in municipal storm water permits, and embraces BMPs as an interim permitting approach.

The interim permitting approach uses BMPs in first-round storm water permits and expanded or better-tailored BMPs in subsequent permits, where necessary, to provide for the attainment of water quality standards. In cases where adequate information exists to develop more specific conditions or limitations to meet water quality standards, these conditions or limitations are to be incorporated into storm water permits, as necessary and appropriate.

This interim permitting approach, however, only applies to EPA. EPA encourages the State to adopt a similar policy for municipal storm water permits. This interim permitting approach provides time, where necessary, to more fully assess the range of issues and possible options for the control of storm water discharges for the protection of water quality. More information on this issue is included in the response to comment document in response to specific storm water issues raised by commenters.

5. Schedules of Compliance

A compliance schedule refers to an enforceable sequence of interim requirements in a permit leading to ultimate compliance with water quality-based effluent limitations or WQBELs in accordance with the CWA. The authorizing compliance schedule provision authorizes, but does not require, the permit issuing authority in the State of California to include such compliance schedules in permits under appropriate circumstances. The State of California is authorized to administer the National Pollutant Discharge Elimination System (NPDES) program and may exercise its discretion when deciding if a compliance schedule is justified because of the technical or financial (or other) infeasibility of immediate compliance. An authorizing compliance schedule provision is included in today's rule because of the potential for existing dischargers to have new or more stringent effluent limitations for which immediate compliance would not be possible or practicable.

New and Existing Dischargers: The provision allows compliance schedules only for an "existing discharger" which is defined as any discharger which is not a "new California discharger." A "new California discharger" includes "any building, structure, facility, or installation from which there is, or may be, a 'discharge of pollutants', the construction of which commences after the effective date of this regulation." These definitions are modeled after the existing 40 CFR 122.2 definitions for parallel terms, but with a cut-off date modified to reflect this rule. Only "new California dischargers" are required to comply immediately upon commencement of discharge with effluent limitations derived from the criteria in this rule. For "existing dischargers" whose permits are reissued or modified to contain new or more stringent limitstions based upon certain water quality requirements, the permit could allow up to five years, or up to the length of a permit, to comply with such limitations. The provision applies to new or more stringent effluent limitations based on the criteria in this EPA rule.

EPA has included "increasing dischargers" within the category of "existing dischargers" since "increasing dischargers" are existing facilities with a change—an increase—in their discharge. Such facilities may include those with seasonal variations. "Increasing dischargers" will already have treatment systems in place for their current discharge, thus, they have less

opportunity than a new discharger does to design and build a new treatment system which will meet new water quality-based requirements for their changed discharge. Allowing existing facilities with an increasing discharge a compliance schedule will avoid placing the discharger at a competitive disadvantage vis-a-vis other existing dischargers who are eligible for compliance schedules.

Today's rule does not prohibit the use of a short-term "shake-down period" for new California dischargers as is provided for new sources or new dischargers in 40 CFR 122.29(d)(4). These regulations require that the owner or operator of (1) a new source, (2) a new discharger (as defined in 40 CFR 122.2) which commenced discharge after August 13, 1979, or (3) a recommencing discharger, shall install and implement all pollution control equipment to meet the conditions of the permit before discharging. The facility must also meet all permit conditions in the shortest feasible time (not to exceed 90 days). This shake-down period is not a compliance schedule. This approach may be used to address violations which may occur during a new facility's start-up, especially where permit limits are water quality-based and biological treatment is involved.

The burden of proof to show the necessity of a compliance schedule is on the discharger, and the discharger must request approval from the permit issuing authority for a schedule of compliance. The discharger should submit a description of the minimum required actions or evaluations that must be undertaken in order to comply with the new or more restrictive discharge limits. Dates of completion for the required actions or evaluations should be included, and the proposed schedule should reflect the shortest practicable time to complete all minimum required actions.

Duration of Compliance Schedules: Today's rule provides that compliance schedules may provide for up to five years to meet new or more stringent effluent limitations in those limited circumstances where the permittee can demonstrate to the permit authority that an extended schedule is warranted. EPA's regulations at 122.47 require compliance with standards as soon as possible. This means that permit authorities should not allow compliance schedules where the permittee fails to demonstrate their necessity. This provision should not be considered a default compliance schedule duration for existing facilities.

[illegible] results, and adopt and implement new or revised water quality-based effluent limitations, EPA believes that five years is sufficient time within which to complete this process. See the preamble to the proposed rule.

Under this rule, where a schedule of compliance exceeds one year, interim requirements are to be specified and interim progress reports are to be submitted at least annually to the permit issuing authority, or at least one year time intervals.

The rule allows all compliance schedules to extend up to a maximum duration of five years, which is the maximum term of any NPDES permit. See 40 CFR 122.46. The discharger's opportunity to obtain a compliance schedule occurs when the existing permit for that discharge is issued, reissued or modified to contain more stringent limits based on the water quality criteria in today's rule. Such compliance schedules, however, cannot be extended to any indefinite point of time in the future because the compliance schedule provision in this rule will sunset on May 18, 2005. The sunset applies to the authorizing provision in today's rule (40 CFR 131.38(e)), not to individual schedules of compliance included in specific NPDES permits. Delays in reissuing expired permits (including those which continue in effect under applicable NPDES regulations) cannot indefinitely extend the period of time during which a compliance schedule is in effect. This would occur where the permit authority includes the single maximum five-year compliance schedule in a permit that is reissued just before the compliance schedule provision sunsets (having been previously issued without WQBELS, using the rule's criteria on the eve of the effective date of this rule). Instead, the effect of the sunset provisions is to limit the longest time period for compliance to ten years after the effective date of this rule.

EPA recognizes that where a permit is modified during the permit term, and the permittee needs the full five years to comply, the five-year schedule may extend beyond the term of the modified permit. In such cases, the rule allows for the modified permit to contain a compliance schedule with an interim limit by the end of the permit term. When the permit is reissued, the permit authority may extend the compliance schedule in the next permit, provided that, taking into account the amount of time allowed under the previous permit, the entire compliance schedule contained in the permit shall not exceed five years. Final permit limits and the record for the permit. Final compliance dates must occur within five years from the date of permit issuance, reissuance, or modification, unless additional or less time is provided for by law.

EPA would prefer that the State adopt an authorizing compliance schedule provision but recognizes that the State may not be able to complete this action for some time after promulgation of the CTR. Thus, EPA has chosen to promulgate the rule with a sunset provision which states that the authorizing compliance schedule provision will cease or sunset on May 18, 2005. However, if the State Board adopts, and EPA approves, a statewide authorizing compliance schedule provision significantly prior to May 18, 2005, EPA will act to stay the authorizing compliance schedule provision in today's rule. Additionally, if a Regional Board adopts, and the State Board adopts and EPA approves, a Regional Board authorizing compliance schedule provision, EPA will act to stay today's provision for the appropriate or corresponding geographic region in California. At that time, the State Board's or Regional Board's authorizing compliance schedule provision will govern the ability of the State regulatory entity to allow a discharger to include a compliance schedule in a discharger's NPDES permit.

Antibacksliding: EPA wishes to address the potential concern over antibacksliding where revised permit limits based on new information are the result of the completion of additional studies. The Agency's interpretation of the CWA is that the antibacksliding requirements of section 402(o) of the CWA do not apply to revisions to effluent limitations made before the scheduled date of compliance for those limitations.

State Compliance Schedule Provisions: EPA supports the State in adopting a statewide provision independent of or as part of the effort to readopt statewide water quality control plans, or in adopting individual basin-wide compliance schedule provisions through its nine Regional Water Quality Control Boards (RWQCBs). The State and RWQCBs have broad discretion to adopt a provision, including discretion on reasonable lengths of time for final compliance with WQBELs. EPA recognizes that practical time frames within which to set interim goals may be necessary to achieve meaningful, long-term improvements in water quality in California.

At this time, two RWQCBs have adopted an authorizing compliance

their respective Basin Plans during the Boards' last triennial review process. The Basin Plans have been adopted by the State and have come to EPA for approval. Thus, the Basin Plans' provisions are effective for the respective Basins. If and when EPA approves of either Regional Basin Plan, EPA will expeditiously act to amend the CTR, staying its compliance schedule provision, for the appropriate geographic region.

6. Changes From Proposed Rule

A few changes were made in the final rule from the proposal both as a result of the Agency's consideration of issues raised in public comments and Endangered Species Act consultation with the U.S. Fish and Wildlife Service (FWS) and U.S. National Marine Fisheries Service (NMFS). The important changes include: reserving the mercury aquatic life criteria; reserving the selenium freshwater acute aquatic life criterion; reserving the chloroform human health criteria; and adding a sunset provision to the authorizing compliance schedule provision. EPA also clarified that the CTR will not replace priority toxic pollutant criteria which were adopted by the San Francisco Regional Water Quality Control Board in its 1986 Basin Plan, adopted by the State Board, and approved by EPA; specifying the harmonic mean for human health criteria for non-carcinogens and adding a provision which explicitly allows the State to adopt and implement an alternative averaging period, frequency, and design flow for a criterion after opportunity for public comment.

The first two changes, the reservation of mercury criteria and selenium criterion, are discussed in more detail below in Section L, The Endangered Species Act (ESA). The selenium criterion is also discussed in more detail above in Section E., Derivation of Criteria, in subsection 2.b., Freshwater Acute Selenium Criterion. EPA has also decided to reserve a decision on numeric criteria for chloroform and therefore not promulgate chloroform criteria in the final rule. As part of a large-scale regulation promulgated in December 1998 under the Safe Drinking Water Act, EPA published a health-based goal for chloroform (the maximum contaminant level goal or MCLG) of zero, see 63 FR 69390, Dec. 16, 1998. EPA provided new data and analyses concerning chloroform for public review and comment, including a different, mode of action approach for estimating the cancer risk, 63 FR 15674, March 31, 1998, but did not reach a conclusion on how to use that new information in establishing the final MCLG, pending further review by the Science Advisory Board. EPA has now concluded that any further actions on water quality criteria should take into account the new data and analysis as reviewed by the SAB. This decision is consistent with a recent federal court decision vacating the MCLG for chloroform (*Chlorine Chemistry Council v. EPA*, No. 98–1627 (DC Cir., Mar. 31, 2000)). EPA intends to reassess the human health 304(a) criteria recommendation for chloroform. For these reasons, EPA has decided to reserve a decision on numeric criteria for chloroform in the CTR and not promulgate water quality criteria as proposed. Permitting authorities in California should continue to rely on existing narrative criteria to establish effluent limitations as necessary for chloroform.

The sunset provision for the authorizing compliance schedule provision has been added to ease the transition from a Federal provision to the State's provision that was adopted in March 2000 as part of its new statewide implementation plan. The sunset provision is discussed in more detail in Section G.5 of today's preamble. The CTR matrix at 40 CFR 131.38(b)(1) makes it explicit that the rule does not supplant priority toxic pollutant criteria which were adopted by the San Francisco Regional Water Quality Control Board in its 1986 Basin Plan, adopted by the State Board, and approved by EPA. This change is discussed more fully in Section D.4. of today's preamble. EPA modified the design flow for implementing human health criteria for non-carcinogens from a 30Q5 to a harmonic mean. Human health criteria for non-carcinogens are based on an RfD, which is an acceptable daily exposure over a lifetime. EPA matched the criteria for protection over a human lifetime with the longest stream flow averaging period, i.e., the harmonic mean. Lastly, the CTR now contains language which is intended to make it easier for the State to adopt and implement an alternative averaging period, frequency and related design flow, for situations where the default parameters are inappropriate. This language is found at 40 CFR 131.38(c)(2)(iv).

H. Economic Analysis

This final rule establishes ambient water quality criteria which, by themselves, do not directly impose economic impacts (see section K). These criteria combined with the State-adopted designated uses for inland surface waters, enclosed bays and estuaries, and implementation policies, will establish water quality standards. Until the State implements these water quality standards, there will be no effect of this rule on any entity. The State will implement these criteria by ensuring that NPDES permits result in discharges that will meet these criteria. In so doing, the State will have considerable discretion.

EPA has analyzed the indirect potential costs and benefits of this rule. In order to estimate the indirect costs and benefits of the rule, an appropriate baseline must be established. The baseline is the starting point for measuring incremental costs and benefits of a regulation. The baseline is established by assessing what would occur in the absence of the regulation. At present, State Basin Plans contain a narrative water quality criterion stating that all waters shall be maintained free of toxic substances in concentrations that produce detrimental physiological responses in human, plant, animal, or aquatic life. EPA's regulation at 40 CFR 122.44(d)(1)(vi) requires that where a discharge causes or has the reasonable potential to cause an excursion above a narrative criterion within a State water quality standard, the permitting authority must establish effluent limits but may determine limits using a number of options. These options include establishing "effluent limits on a case-by-case basis, using EPA's water quality criteria published under section 304(a) of the CWA, supplemented where necessary by other relevant information" (40 CFR 122.44(d)(1)(vi)(B)). Thus, to the extent that the State is implementing its narrative criteria by applying the CWA section 304(a) criteria, this rule does not impose any incremental costs because the criteria in this rule are identical to the CWA section 304(a) criteria. Alternatively, to the extent that the State is implementing its narrative criteria on a "case-by-case basis" using "other relevant information" in its permits this rule may impose incremental indirect costs because the criteria in these permits may not be based on CWA 304(a) criteria. Both of these approaches to establishing effluent limits are in full compliance with the CWA.

Because a specific basis for effluent limits in all existing permits in California is not known, it is not possible to determine a precise estimate of the indirect costs of this rule. The incremental costs of the rule may be as low as zero, or as high as $61 million. The high estimate of costs is based on the possibility that most of the effluent limits now in effect are not based on 304(a) criteria. EPA evaluated these

indirect costs using two different approaches. The first approach uses existing discharge data and makes assumptions about future State NPDES permit limits. Actual discharge levels are usually lower than the level set by current NPDES permit limits. This approach, representing the low-end scenario, also assumes that some of the discretionary mechanisms that would enhance flexibility (e.g., site specific criteria, mixing zones) would be granted by the State. The second approach uses a sample of existing permit limits and assumes that dischargers are actually discharging at the levels contained in their permits and makes assumptions about limits statewide that would be required under the rule. This approach, representing the high-end scenario, also assumes that none of the discretionary mechanisms that would enhance flexibility (e.g., site specific criteria, mixing zones) would be granted by the State. These two approaches recognize that the State has significant flexibility and discretion in how it chooses to implement standards within the NPDES permit program. The EA by necessity includes many assumptions about how the State will implement the water quality standards. These assumptions are based on a combination of EPA guidance and current permit conditions for the facilities examined in this analysis. To account for the uncertainty of EPA's implementation assumptions, this analysis estimates a wide range of costs and benefits. By completing the EA, EPA intends to inform the public about how entities might be potentially affected by State implementation of water quality standards in the NPDES permit program. The costs and benefits sections that follow summarize the methodology and results of the analysis.

1. Costs

EPA assessed the potential compliance costs that facilities may incur to meet permit limits based on the criteria in today's rule. The analysis focused on direct compliance costs such as capital costs and operation and maintenance costs (O&M) for end-of-pipe pollution control, indirect source controls, pollution prevention, monitoring, and costs of pursuing alternative methods of compliance.

The population of facilities with NPDES permits that discharge into California's enclosed bays, estuaries and inland surface waters includes 184 major dischargers and 1,057 minor dischargers. Of the 184 major facilities, 128 are publicly owned treatment works (POTWs) and 56 are industrial facilities. industrial users discharge wastewater to those POTWs. In the EA for the proposed CTR, EPA used a three-phased process to select a sample of facilities to represent California dischargers potentially affected by the State's implementation of permit limits based on the criteria contained in this rule.

The first phase consisted of choosing three case study areas for which data was thought to exist. The three case studies with a total of 5 facilities included: the South San Francisco Bay (the San Jose/Santa Clara Water Pollution Control Plant and Sunnyvale Water Pollution Control Plant), the Sacramento River (the Sacramento Regional Wastewater Treatment Plant), and the Santa Ana River (the City of Riverside Water Quality Control Plant and the City of Colton Municipal Wastewater Treatment Facility). The second phase consisted of selecting five additional major industrial dischargers to complement the case-study POTWs.

The third phase involved selecting 10 additional facilities to improve the basis for extrapolating the costs of the selected sample facilities to the entire population of potentially affected dischargers. The additional 10 facilities were selected such that the group examined: (1) Was divided between major POTWs and major industrial discharger categories in proportion to the numbers of facilities in the State; (2) gave greater proportionate representation to major facilities than minor facilities based on a presumption that the majority of compliance costs would be incurred by major facilities; (3) gave a proportionate representation to each of four principal conventional treatment processes typically used by facilities in specified industries in California; and (4) was representative of the proportionate facilities located within the different California Regional Water Quality Control Boards. Within these constraints, facilities were selected at random to complete the sample.

In the EA for today's final rule, EPA primarily used the same sample as the EA for the proposed rule with some modifications. EPA increased the number of minor POTWs and minor industrial facilities in the sample. EPA randomly selected four new minor POTW facilities and five new minor industrial facilities to add to the sample. The number of sample facilities selected in each area under the jurisdiction of a Regional Water Quality Control Board was roughly proportional to the universe of facilities in each area.

For those facilities that were projected costs of compliance. Using a decision matrix or flow chart, costs were developed for two different scenarios—a "low-end" cost scenario and a "high-end" cost scenario—to account for a range of regulatory flexibility available to the State when implementing permit limits based on the water quality criteria. The assumptions for baseline loadings also vary over the two scenarios. The low-end scenario generally assumed that facilities were discharging at the maximum effluent concentrations taken from actual monitoring data, while the high-end scenario generally assumed that facilities were discharging at their current effluent limits. The decision matrix specified assumptions used for selection of control options, such as optimization of existing treatment processes and operations, in-plant pollutant minimization and prevention, and end-of-pipe treatment.

The annualized potential costs that direct and indirect dischargers may incur as a result of State implementation of permit limits based on water quality standards using today's criteria are estimated to be between $33.5 million and $61 million. EPA believes that the costs incurred as a result of State implementation of these permit limits will approach the low-end of the cost range. Costs are unlikely to reach the high-end of the range because State authorities are likely to choose implementation options that provide some degree of flexibility or relief to point source dischargers. Furthermore, cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because the analysis tended to use conservative assumptions in calculating these permit limits and in establishing baseline loadings. The baseline loadings for the high-end were based on current effluent limits rather than actual pollutant discharge data. Most facilities discharge pollutants in concentrations well below current effluent limits. In addition, both the high-end and low-end cost estimates in the EA may be slightly overstated since potential costs incurred to reduce chloroform discharges were included in these estimates. EPA made a decision to reserve the chloroform human health criteria after the EA was completed.

Under the low-end cost scenario, major industrial facilities and POTWs would incur about 27 percent of the potential costs, indirect dischargers would incur about 70 percent of the potential costs, while minor dischargers would incur about 3 percent. Of the major direct dischargers, POTWs would

among 128 major POTWs in the State, the average cost per plant would be $61,000 per year. Chemical and petroleum industries would incur the highest cost of the industrial categories (5.6 percent of the annual costs, with an annual average of $25,200 per plant). About 57 percent of the low-end costs would be associated with pollution prevention activities, while nearly 38 percent would be associated with pursuing alternative methods of compliance under the regulations.

Under the high-end cost scenario, major industrial facilities and POTWs would incur about 94 percent of the potential costs, indirect dischargers would incur about 17 percent of the potential costs, while minor dischargers would incur about 5 percent. Among the major, direct dischargers, two categories would incur the majority of potential costs—major POTWs (82 percent), Chemical/Petroleum Products (9 percent). The average annual per plant cost for different industry categories would ranges from zero to $324,000. The two highest average cost categories would be major POTWs ($324,000 per year) and Chemical/Petroleum Products ($221,264 per year). The shift in proportion of potential costs between direct and indirect dischargers is due to the assumption that more direct dischargers would use end-of-pipe treatment under the high-end scenario. Thus, a smaller proportion of indirect dischargers would be impacted under the high-end scenario since some municipalities are projected to add end-of-pipe treatment which would reduce the need for controls from indirect dischargers. Over 91 percent of the annual costs are for waste minimization and treatment optimization costs. Waste minimization would represent nearly 84% of the total annual costs. Capital and operation and maintenance costs would make up less than 9 percent of annual costs.

Cost-Effectiveness: Cost-effectiveness is estimated in terms of the cost of reducing the loadings of toxic pollutants from point sources. The cost-effectiveness is derived by dividing the projected annual costs of implementing permit limits based on water quality standards using today's criteria by the toxicity-weighted pounds (pound-equivalents) of pollutants removed. Pound-equivalents are calculated by multiplying pounds of each pollutant removed by the toxic weight (based on the toxicity of copper) for that pollutant.

Based on this analysis, State implementation of permit limits based on today's criteria would be responsible for the reduction of about 1.1 million to 2.7 million toxic pound-equivalents per year, or 15 to 50 percent of the toxic-weighted baseline loadings for the high- and low-end scenarios, respectively. The cost-effectiveness of the scenarios would range from $22 (high-end scenario) to $31 (low-end scenario) per pound-equivalent.

2. Benefits

The benefits analysis is intended to provide insight into both the types and potential magnitude of the economic benefits expected as a result of implementation of water quality standards based on today's criteria. To the extent feasible, empirical estimates of the potential magnitude of the benefits were developed and then compared to the estimated costs of implementing water quality standards based on today's criteria.

To perform a benefits analysis, the types or categories of benefits that apply need to be defined. EPA relied on a set of benefits categories that typically apply to changes in the water resource environment. Benefits were categorized as either use benefits or passive (nonuse) benefits depending on whether or not they involve direct use of, or contact with, the resource. The most prominent use benefit categories are those related to recreational fishing, boating, and swimming. Another use benefit category of significance is human health risk reduction. Human health risk reductions can be realized through actions that reduce human exposure to contaminants such as exposure through the consumption of fish containing elevated levels of pollutants. Passive use benefits are those improvements in environmental quality that are valued by individuals apart from any use of the resource in question.

Benefits estimates were derived in this study using an approach in which benefits of discrete large-scale changes in water quality beyond present day conditions were estimated wherever feasible. A share of those benefits was then apportioned to implementation of water quality standards based on today's criteria. The apportionment estimate was based on a three-stage process. First, EPA assessed current total loadings from all sources that are contributing to the toxics-related water quality problems observed in the State. This defines the overall magnitude of loadings. Second, the share of total loadings that are attributable to sources that would be controlled through implementation of water quality standards based on today's criteria was estimated. Since this analysis was designed to focus only on those controls imposed on point sources, this stage of the process entailed estimating the portion of total loadings originating from point sources. Third, the percentage reduction in loadings expected due to implementation of today's criteria was estimated and then multiplied by the share of point source loadings to calculate the portion of benefits that could be attributed to implementation of water quality standards based on today's criteria.

Total monetized annual benefits were estimated in the range of $6.9 to $74.7 million. By category, annual benefits would be $1.3 to $4.6 million for avoided cancer risk, $2.2 to $15.2 million for recreational angling, and $3.4 to $54.9 million for passive use benefits.

There are numerous categories of potential or likely benefits that have been omitted from the quantified and monetized benefit estimates. In terms of potential magnitudes of benefit, the following are likely to be significant contributors to the underestimation of the monetized values presented above:

• Improvements in water-related (in-stream and near-stream) recreation apart from fishing. The omission of potential motorized and nonmotorized boating, swimming, picnicking, and related in-stream and stream-side recreational activities from the benefits estimates could contribute to an appreciable underestimation of total benefits. Such recreational activities have been shown in empirical research to be highly valued, and even modest changes in participation and or user values could lead to sizable benefits statewide. Some of these activities can be closely associated with water quality attributes (notably, swimming). Other recreational activities may be less directly related to the water quality improvements, but might nonetheless increase due to their association with fishing, swimming, or other activities in which the participants might engage.

• Improvements in consumptive and nonconsumptive land-based recreation, such as hunting and wildlife observation. Improvements in aquatic habitats may lead (via food chain and related ecologic benefit mechanisms) to healthier, larger, and more diverse populations of avian and terrestrial species, such as waterfowl, eagles, and otters. Improvements in the populations for these species could manifest as improved hunting and wildlife viewing opportunities, which might in turn increase participation and user day values for such activities. Although the scope of the benefits analysis has not allowed a quantitative assessment of these values at either pre- or post-rule

conditions, it is conceivable that these benefits could be appreciable.

• Improvements in human health resulting from reduction of non-cancer risk. EPA estimated that implementation of water quality standards based on the criteria would result in a reduction of mercury concentrations in fish tissue and, thus, a reduction in the hazard from consumption of mercury contaminated fish. However, EPA was unable to monetize benefits due to reduced non-cancer health effects.

• Human health benefits for saltwater anglers outside of San Francisco Bay were not estimated. The number of saltwater anglers outside of San Francisco Bay is estimated to be 673,000 (based on Huppert, 1989, and U.S. FWS, 1998). The omission of other saltwater anglers may cause human health benefits to be underestimated. In addition, benefit estimates in the EA may be slightly overstated since potential benefits from reductions in chloroform discharges were included in these estimates. EPA made a decision to reserve the chloroform human health criteria after the EA was completed.

EPA received a number of comments which requested the Agency use the cost-benefit analysis in the EA as a factor in setting water quality criteria. EPA does not use the EA as a basis in determining protective water quality criteria. EPA's current regulations at 40 CFR 131.11 state that the criteria must be based on sound scientific rationale and must protect the designated use. From the outset of the water quality standards program, EPA has explained that while economic factors may be considered in designating uses, they may not be used to justify criteria that are not protective of those uses. 44 FR 25223–226, April 30, 1979. See e.g. *Mississippi Commission on Natural Resources* v. *Costle*, 625 F. 2d 1269, 1277 (5th Cir. 1980). EPA reiterated this interpretation of the CWA and its implementing regulations in discussing section 304(a) recommended criteria guidance stating that "they are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects and do not reflect consideration of economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water." 63 FR 36742 and 36762, July 7, 1998.

I. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

J. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating any regulation for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows an Agency to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, it must have developed under section 203 of the UMRA a small government Agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of the affected small governments to have meaningful and timely input in the development of regulatory proposals with significant Federal intergovernmental mandates, and EPA informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act (UMRA)) for State, local, or tribal governments or the private sector. Today's rule imposes no enforceable duty on any State, local or Tribal governments or the private sector; rather, the CTR promulgates ambient water quality criteria which, when combined with State-adopted uses, will create water quality standards for those water bodies with adopted uses. The State will then use these resulting water quality standards in implementing its existing water quality control programs. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. This rule establishes ambient water quality criteria which, by themselves do not directly impact any entity. The State will implement these criteria by ensuring that NPDES permits result in discharges that will meet these criteria. In so doing, the State will have considerable discretion. Until the State implements these water quality standards, there will be no effect of this rule on any entity. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

K. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires Federal agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact of a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business according to RFA default definitions for

standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities.

Under the CWA water quality standards program, States must adopt water quality standards for their waters that must be submitted to EPA for approval. If the Agency disapproves a State standard and the State does not adopt appropriate revisions to address EPA's disapproval, EPA must promulgate standards consistent with the statutory requirements. EPA has authority to promulgate criteria or standards in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. These State standards (or EPA-promulgated standards) are implemented through various water quality control programs including the National Pollutant Discharge Elimination System (NPDES) program that limits discharges to navigable waters except in compliance with an EPA permit or permit issued under an approved State NPDES program. The CWA requires that all NPDES permits must include any limits on discharges that are necessary to meet State water quality standards.

Thus, under the CWA, EPA's promulgation of water quality criteria or standards establishes standards that the State, in turn, implements through the NPDES permit process. The State has considerable discretion in deciding how to meet the water quality standards and in developing discharge limits as needed to meet the standards. In circumstances where there is more than one discharger to a water body that is subject to water quality standards or criteria, a State also has discretion in deciding on the appropriate limits for the different dischargers. While the State's implementation of federally-promulgated water quality criteria or standards may result indirectly in new or revised discharge limits for small entities, the criteria or standards themselves do not apply to any discharger, including small entities.

Today's rule, as explained above, does not itself establish any requirements that are applicable to small entities. As a result of EPA's action here, the State of California will need to ensure that permits it issues include limits as necessary to meet the water quality standards established by the criteria in today's rule. In so doing, the State will have a number of discretionary choices associated with permit writing. While California's implementation of today's rule may ultimately result in some new or revised permit conditions for some dischargers, including small entities, EPA's action today does not impose any of these as yet unknown requirements on small entities.

The RFA requires analysis of the economic impact of a rule only on the small entities subject to the rule's requirements. Courts have consistently held that the RFA imposes no obligation on an Agency to prepare a small entity analysis of the effect of a rule on entities not regulated by the rule. *Motor & Equip. Mfrs. Ass'n v. Nichols*, 142 F.3d 449, 467 & n.15 (D.C. Cir. 1998)(quoting *United States Distribution Companies v. FERC*, 88 F.3d 1105, 1170 (D.C. Cir. 1996); see also *American Trucking Association, Inc. v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999). This final rule will have a direct effect only on the State of California which is not a small entity under the RFA. Thus, individual dischargers, including small entities, are not directly subject to the requirements of the rule. Moreover, because of California's discretion in implementing these standards, EPA cannot assess the extent to which the promulgation of this rule may subsequently affect any dischargers, including small entities. Consequently, certification under section 605(b) is appropriate. *State of Michigan, et al. v. U.S. Environmental Protection Agency*, No. 98–1497 (D.C. Cir. Mar. 3, 2000), slip op. at 41–42.

L. Paperwork Reduction Act

This action requires no new or additional information collection, reporting, or record keeping subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

M. Endangered Species Act

Pursuant to section 7(a) of the Endangered Species Act (ESA), EPA has consulted with the U.S. Fish and Wildlife Service and the U.S. National Marine Fisheries Service (collectively, the Services) concerning EPA's rulemaking action for the State of California. EPA initiated informal consultation in early 1994, and completed formal consultation in April 2000. As a result of the consultation, EPA modified some of the provisions in the final rule.

As part of the consultation process, EPA submitted to the Services a Biological Evaluation for their review in October of 1997. This evaluation found that the proposed CTR was not likely to jeopardize the continued existence of any Federally listed species or result in the destruction or adverse modification of designated critical habitat. In April of 1998, the Services sent EPA a draft Biological Opinion which tentatively found that EPA's proposed rule would jeopardize the continued existence of several Federally listed species and result in the destruction or have adverse effect on designated critical habitat. After lengthy discussions with the Services, EPA agreed to several changes in the final rule and the Services in turn issued a final Biological Opinion finding that EPA's actions would not likely jeopardize the continued existence of any Federally listed species or result in the destruction or adverse modification of designated critical habitat. EPA's Biological Evaluation and the Services' final Biological Opinion are contained in the administrative record for today's rule.

In order to ensure the continued protection of Federally listed threatened and endangered species and to protect their critical habitat, EPA agreed to reserve the aquatic life criteria for mercury and the acute freshwater aquatic life criterion for selenium. The Services believe that EPA's proposed criteria are not sufficiently protective of Federally listed species and should not be promulgated. EPA agreed that it would reevaluate these criteria in light of the Services concerns before promulgating them for the State of California. Other commitments made by EPA are described in a letter to the Services dated December 16, 1999; this letter is contained in the administrative record for today's rule.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. This rule is not a major rule as defined

by 5 U.S.C. 804(2). This rule will be effective May 18, 2000.

O. Executive Order 13084, Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments nor does it impose substantial direct compliance cots on them. Today's rule will only address priority toxic pollutant water quality criteria for the State of California and does not apply to waters in Indian country. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

P. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, not to use available and applicable voluntary consensus standards.

This final rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

Q. Executive Order 13132 on Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not affect the nature of the relationship between EPA and States generally, for the rule only applies to water bodies in California. Further, the rule will not substantially affect the relationship of EPA and the State of California, or the distribution of power or responsibilities between EPA and the State. The rule does not alter the State's authority to issue NPDES permits or the State's considerable discretion in implementing these criteria. The rule simply implements Clean Water Act section 303(c)(2)(B) requiring numeric ambient water quality criteria for which EPA has issued section 304(a) recommended with previous regulatory guidance that the Agency has issued to implement CWA section 303(c)(2)(B). Further, this rule does not preclude the State from adopting water quality standards that meet the requirements of the CWA. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

Although section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with State and local government representatives in developing this rule. EPA and the State reached an agreement that to best utilize its respective resources, EPA would promulgate water quality criteria and the State would concurrently work on a plan to implement the criteria. Since the proposal of this rule, EPA has kept State officials fully informed of changes to the proposal. EPA has continued to invite comment from the State on these changes. EPA believes that the final CTR incorporates comments from State officials and staff.

R. Executive Order 13045 on Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. As a matter of EPA policy, we therefore have assessed the environmental health or safety effects of ambient water quality criteria on children. The results of this assessment are contained in section F.3., Human Health Criteria.

List of Subjects in 40 CFR Part 131

Environmental protection, Indians—*lands*, *Intergovernmental relations*, Reporting and recordkeeping

Dated: April 27, 2000.

Carol Browner,

Administrator.

For the reasons set out in the preamble, part 131 of chapter I of title 40 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.*

Subpart D—[Amended]

2. Section 131.38 is added to subpart D to read as follows:

§ 131.38 Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California.

(a) *Scope.* This section promulgates criteria for priority toxic pollutants in the State of California for inland surface waters and enclosed bays and estuaries. This section also contains a compliance schedule provision.

(b)(1) Criteria for Priority Toxic Pollutants in the State of California as described in the following table:

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A		B Freshwater		C Saltwater		D Human Health (10^{-6} risk for carcinogens) For consumption of:	
# Compound	CAS Number	Criterion Maximum Conc. [d] B1	Criterion Continuous Conc. [d] B2	Criterion Maximum Conc. [d] C1	Criterion Continuous Conc. [d] C2	Water & Organisms (µg/L) D1	Organisms Only (µg/L) D2
1. Antimony	7440360					14 a,s	4300 a,t
2. Arsenic [b]	7440382	340 i,m,w	150 i,m,w	69 i,m	36 i,m		
3. Beryllium	7440417					n	n
4. Cadmium [b]	7440439	4.3 e,i,m,w,x	2.2 e,i,m,w	42 i,m	9.3 i,m	n	n
5a. Chromium (III)	16065831	550 e,i,m,o	180 e,i,m,o			n	n
5b. Chromium (VI) [b]	18540299	16 i,m,w	11 i,m,w	1100 i,m	50 i,m	n	n
6. Copper [b]	7440508	13 e,i,m,w,x	9.0 e,i,m,w	4.8 i,m	3.1 i,m	1300	
7. Lead [b]	7439921	65 e,i,m	2.5 e,i,m	210 i,m	8.1 i,m	n	n
8. Mercury [b]	7439976	[Reserved]	[Reserved]	[Reserved]	[Reserved]	0.050 a	0.051 a
9. Nickel [b]	7440020	470 e,i,m,w	52 e,i,m,w	74 i,m	8.2 i,m	610 a	4600 a
10. Selenium [b]	7782492	[Reserved] p	5.0 q	290 i,m	71 i,m	n	n
11. Silver [b]	7440224	3.4 e,i,m		1.9 i,m			
12. Thallium	7440280					1.7 a,s	6.3 a,t
13. Zinc [b]	7440666	120 e,i,m,w,x	120 e,i,m,w	90 i,m	81 i,m		
14. Cyanide [b]	57125	22 o	5.2 o	1 r	1 r	700 a	220,000 a,j
15. Asbestos	1332214					7,000,000 fibers/L k,s	
16. 2,3,7,8-TCDD (Dioxin)	1746016					0.000000013 c	0.000000014 c
17. Acrolein	107028					320 s	780 t
18. Acrylonitrile	107131					0.059 a,c,s	0.66 a,c,t
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,s	4.4 a,c,t
22. Chlorobenzene	108907					680 a,s	21,000 a,j,t
23. Chlorodibromomethane	124481					0.401 a,c	34 a,c
24. Chloroethane	75003						
25. 2-Chloroethylvinyl Ether	110758						

26. Chloroform	67663					[Reserved]	[Reserved]
27. Dichlorobromomethane	75274					0.56 a,c	46 a,c
28. 1,1-Dichloroethane	75343						
29. 1,2-Dichloroethane	107062					0.38 a,c,s	99 a,c,i
30. 1,1-Dichloroethylene	75354					0.057 a,c,s	3.2 a,c,i
31. 1,2-Dichloropropane	78875					0.52 a	39 a
32. 1,3-Dichloropropylene	542756					10 a,s	1,700 a,i
33. Ethylbenzene	100414					3,100 a,s	29,000 a,i
34. Methyl Bromide	74839					48 a	4,000 a
35. Methyl Chloride	74873					n	n
36. Methylene Chloride	75092					4.7 a,c	1,600 a,c
37. 1,1,2,2-Tetrachloroethane	79345					0.17 a,c,s	11 a,c,i
38. Tetrachloroethylene	127184					0.8 c,s	8.85 c,i
39. Toluene	108883					6,800 a	200,000 a
40. 1,2-Trans-Dichloroethylene	156605					700 a	140,000 a
41. 1,1,1-Trichloroethane	71556					n	n
42. 1,1,2-Trichloroethane	79005					0.60 a,c,s	42 a,c,i
43. Trichloroethylene	79016					2.7 c,s	81 c,i
44. Vinyl Chloride	75014					2 c,s	525 c,i
45. 2-Chlorophenol	95578					120 a	400 a
46. 2,4-Dichlorophenol	120832					93 a,s	790 a,i
47. 2,4-Dimethylphenol	105679					540 a	2,300 a
48. 2-Methyl-4,6-Dinitrophenol	534521					13.4 s	765 i
49. 2,4-Dinitrophenol	51285					70 a,s	14,000 a,i
50. 2-Nitrophenol	88755						
51. 4-Nitrophenol	100027						
52. 3-Methyl-4-Chlorophenol	59507						
53. Pentachlorophenol	87865	19 f,w	15 f,w	13	7.9	0.28 a,c	8.2 a,c,i
54. Phenol	108952		–			21,000 a	4,600,000 a,i
55. 2,4,6-Trichlorophenol	88062					2.1 a,c	6.5 a,c
56. Acenaphthene	83329					1,200 a	2,700 a
57. Acenaphthylene	208968						
58. Anthracene	120127					9,600 a	110,000 a

59. Benzidine	92875					0.00012 a,c,s	0.00054 a,c,t
60. Benzo(a)Anthracene	56553					0.0044 a,c	0.049 a,c
61. Benzo(a)Pyrene	50328					0.0044 a,c	0.049 a,c
62. Benzo(b)Fluoranthene	205992					0.0044 a,c	0.049 a,c
63. Benzo(ghi)Perylene	191242						
64. Benzo(k)Fluoranthene	207089					0.0044 a,c	0.049 a,c
65. Bis(2-Chloroethoxy)Methane	111911						
66. Bis(2-Chloroethyl)Ether	111444					0.031 a,c,s	1.4 a,c,t
67. Bis(2-Chloroisopropyl)Ether	39638329					1,400 a	170,000 a,t
68. Bis(2-Ethylhexyl)Phthalate	117817					1.8 a,c,s	5.9 a,c,t
69. 4-Bromophenyl Phenyl Ether	101553						
70. Butylbenzyl Phthalate	85687					3,000 a	5,200 a
71. 2-Chloronaphthalene	91587					1,700 a	4,300 a
72. 4-Chlorophenyl Phenyl Ether	7005723						
73. Chrysene	218019					0.0044 a,c	0.049 a,c
74. Dibenzo(a,h)Anthracene	53703					0.0044 a,c	0.049 a,c
75. 1,2-Dichlorobenzene	95501					2,700 a	17,000 a
76. 1,3-Dichlorobenzene	541731					400 a	2,600
77. 1,4-Dichlorobenzene	106467					400 a	2,600
78. 3,3-Dichlorobenzidine	91941					0.04 a,c,s	0.077 a,c,t
79. Diethyl Phthalate	84662					23,000 a,s	120,000 a,t
80. Dimethyl Phthalate	131113					313,000 a,s	2,900,000 a,t
81. Di-n-Butyl Phthalate	84742					2,700 a,s	12,000 a,t
82. 2,4-Dinitrotoluene	121142					0.11 c,s	9.1 c,t
83. 2,6-Dinitrotoluene	606202						
84. Di-n-Octyl Phthalate	117840						
85. 1,2-Diphenylhydrazine	122667					0.040 a,c,s	0.54 a,c,t
86. Fluoranthene	206440					300 a	370 a
87. Fluorene	86737					1,300 a	14,000 a
88. Hexachlorobenzene	118741					0.00075 a,c	0.00077 a,c
89. Hexachlorobutadiene	87683					0.44 a,c,s	50 a,c,t
90. Hexachlorocyclopentadiene	77474					240 a,s	17,000 a,j,t
91. Hexachloroethane	67721					1.9 a,c,s	8.9 a,c,t

92. Indeno(1,2,3-cd) Pyrene	193395					0.0044 a,c	0.049 a,c
93. Isophorone	78591					8.4 c,s	600 c,t
94. Naphthalene	91203						
95. Nitrobenzene	98953					17 a,s	1,900 a,j,t
96. N-Nitrosodimethylamine	62759					0.00069 a,c,s	8.1 a,c,t
97. N-Nitrosodi-n-Propylamine	621647					0.005 a	1.4 a
98. N-Nitrosodiphenylamine	86306					5.0 a,c,s	16 a,c,t
99. Phenanthrene	85018						
100. Pyrene	129000					960 a	11,000 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	0.95 w		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	0.24 w	0.056 w	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	110 a	240 a
113. beta-Endosulfan	33213659	0.22 g	0.056 g	0.034 g	0.0087 g	110 a	240 a
114. Endosulfan Sulfate	1031078					110 a	240 a
115. Endrin	72208	0.086 w	0.036 w	0.037 g	0.0023 g	0.76 a	0.81 a
116. Endrin Aldehyde	7421934					0.76 a	0.81 a
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
119-125. Polychlorinated biphenyls (PCBs)			0.014 u		0.03 u	0.00017 c,v	0.00017 c,v
126. Toxaphene	8001352	0.73	0.0002	0.21	0.0002	0.00073 a,c	0.00075 a,c
Total Number of Criteria		22	21	22	20	82	90

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Footnotes to Table in Paragraph (b)(1):

a. Criteria revised to reflect the Agency q1* or RfD, as contained in the Integrated Risk Information System (IRIS) as of October 1, 1998. The fish tissue bioconcentration factor (BCF) from the 1980 documents was retained in each case.

b. Criteria apply to California waters except for those waters subject to objectives in Tables III–2A and III–2B of the San Francisco Regional Water Quality Control Board's (SFRWQCB) 1986 Basin Plan that were adopted by the SFRWQCB and the State Water Resources Control Board, approved by EPA, and which continue to apply.

c. Criteria are based on carcinogenicity of 10 (-6) risk.

d. Criteria Maximum Concentration (CMC) equals the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time without deleterious effects. Criteria Continuous Concentration (CCC) equals 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 equals micrograms per liter.

e. Freshwater aquatic life criteria for metals are expressed as a function of total hardness (mg/L) in the water body. The equations are provided in matrix at paragraph (b)(2) of this section. Values displayed above in the matrix correspond to a total hardness of 100 mg/l.

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) − 4.869). CCC = exp(1.005(pH) − 5.134).

g. This criterion is based on 304(a) aquatic life criterion issued in 1980, and was issued in one of the following documents: Aldrin/Dieldrin (EPA 440/5–80–019), Chlordane (EPA 440/5–80–027), DDT (EPA 440/5–80–038), Endosulfan (EPA 440/5–80–046), Endrin (EPA 440/5–80–047), Heptachlor (440/5–80–052) Hexachlorocyclohexane (EPA 440/5–80–054), Silver (EPA 440/5–80–071). The Minimum Data Requirements and derivation procedures were different in the 1980 Guidelines than in the 1985 Guidelines. For example, a "CMC" derived using the 1980 Guidelines was derived to be used as an instantaneous maximum. If assessment is to be done using an averaging period, the values given should be divided by 2 to obtain a value that is more comparable to a CMC derived using the 1985 Guidelines.

h. These totals simply sum the criteria in each column. For aquatic life, there are 23 priority toxic pollutants with some type of freshwater or saltwater, acute or chronic criteria. For human health, there are 92 priority toxic pollutants with either "water + organism" or "organism 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 pollutants includes only a single listing for chromium.

i. Criteria for these metals are expressed as = column B1 or C1 value × WER; CCC = column B2 or C2 value × WER.

j. No criterion 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 GWA 304(a) criterion for asbestos is the MCL.

l. [Reserved]

m. These freshwater and saltwater criteria for metals are expressed in terms of the dissolved fraction of the metal in the water column. Criterion values were calculated by using EPA's Clean Water Act 304(a) guidance values (described in the total recoverable fraction) and then applying the conversion factors in § 131.36(b)(1) and (2).

n. EPA is not promulgating human health criteria for these contaminants. However, permit authorities should address these contaminants in NPDES permit actions using the State's existing narrative criteria for toxics.

o. These criteria were promulgated for specific waters in California in the National Toxics Rule ("NTR"), at § 131.36. The specific waters to which the NTR criteria apply include: Waters of the State defined as bays or estuaries and waters of the State defined as inland, i.e., all surface waters of the State not ocean waters. These waters specifically include the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta. This section does not apply instead of the NTR for this criterion.

p. A criterion of 20 ug/l was promulgated for specific waters in California in the NTR and was promulgated in the total recoverable form. The specific waters to which the NTR criterion applies include: Waters of the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta; and waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to the mouth of the Merced River. This section does not apply instead of the NTR for this criterion. The State of California adopted and EPA approved a site specific criterion for the San Joaquin River, mouth of Merced to Vernalis; therefore, this section does not apply to these waters.

q. This criterion is expressed in the total recoverable form. This criterion was promulgated for specific waters in California in the NTR and was promulgated in the total recoverable form. The specific waters to which the NTR criterion applies include: Waters of the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta; and waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to Vernalis. This criterion does not apply instead of the NTR for these waters. This criterion applies to additional waters of the United States in the State of California pursuant to 40 CFR 131.38(c). The State of California adopted and EPA approved a site-specific criterion for the Grasslands Water District, San Luis

State Wildlife Refuge; therefore, this criterion does not apply to these waters.

r. These criteria were promulgated for specific waters in California in the NTR. The specific waters to which the NTR criteria apply include: Waters of the State defined as bays or estuaries including the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta. This section does not apply instead of the NTR for these criteria.

s. These criteria were promulgated for specific waters in California in the NTR. The specific waters to which the NTR criteria apply include: 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. This section does not apply instead of the NTR for these criteria.

t. These criteria were promulgated for specific waters in California in the NTR. The specific waters to which the NTR criteria apply include: Waters of the State defined as bays and estuaries including San Francisco Bay upstream to and including Suisun Bay and 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) without a MUN use designation. This section does not apply instead of the NTR for these criteria.

u. PCBs are a class of chemicals which include aroclors 1242, 1254, 1221, 1232, 1248, 1260, and 1016, CAS numbers 53469219, 11097691, 11104282, 11141165, 12672296, 11096825, and 12674112, respectively. The aquatic life criteria apply to the sum of this set of seven aroclors.

v. This criterion applies to total PCBs, e.g., the sum of all congener or isomer or homolog or aroclor analyses.

w. This criterion has been recalculated pursuant to the 1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water, Office of Water, EPA–820–B–96–001, September 1996. See also Great Lakes Water Quality Initiative Criteria Documents for the Protection of Aquatic Life in Ambient Water, Office of Water, EPA–80–B–95–004, March 1995.

x. The State of California has adopted and EPA has approved site specific criteria for the Sacramento River (and tributaries) above Hamilton City; therefore, these criteria do not apply to these waters.

General Notes to Table in Paragraph (b)(1)

1. The table in this paragraph (b)(1) lists all of EPA's priority toxic pollutants whether or not criteria guidance are available. Blank spaces indicate the absence of national section 304(a) criteria guidance. Because of variations in chemical nomenclature systems, this listing of toxic pollutants does not duplicate the listing in Appendix A to 40 CFR Part 423–126 Priority Pollutants. 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: zinc, 3-

3. Freshwater and saltwater aquatic life criteria apply as specified in paragraph (c)(3) of this section.

(2) Factors for Calculating Metals Criteria. Final CMC and CCC values should be rounded to two significant figures.

(i) $CMC = WER \times \{Acute\ Conversion\ Factor\} \times (\exp\{m_A[\ln(hardness)]+b_A\})$

(ii) $CCC = WER \times \{Acute\ Conversion\ Factor\} \times (\exp\{m_C[\ln(hardness)]+b_C\})$

(iii) Table 1 to paragraph (b)(2) of this section:

Metal	m_A	b_A	m_C	b_C
Cadmium	1.128	−3.6867	0.7852	−2.715
Copper	0.9422	−1.700	0.8545	−1.702
Chromium (III)	0.8190	3.688	0.8190	1.561
Lead	1.273	−1.460	1.273	−4.705
Nickel	0.8460	2.255	0.8460	0.0584
Silver	1.72	−6.52		
Zinc	0.8473	0.884	0.8473	0.884

Note to Table 1: The term "exp" represents the base e exponential function.

(iv) Table 2 to paragraph (b)(2) of this section:

Metal	Conversion factor (CF) for freshwater acute criteria	CF for freshwater chronic criteria	CF for saltwater acute criteria	CF for saltwater chronic criteria
Antimony	[d]	[d]	[d]	[d]
Arsenic	1.000	1.000	1.000	1.000
Beryllium	[d]	[d]	[d]	[d]
Cadmium	[b] 0.944	[b] 0.909	0.994	0.994
Chromium (III)	0.316	0.860	[d]	[d]
Chromium (VI)	0.982	0.962	0.993	0.993
Copper	0.960	0.960	0.83	0.83
Lead	[b] 0.791	[b] 0.791	0.951	0.951
Mercury				
Nickel	0.998	0.997	0.990	0.990
Selenium		[c]	0.998	0.998
Silver	0.85	[d]	0.85	[d]
Thallium	[d]	[d]	[d]	[d]
Zinc	0.978	0.986	0.946	0.946

Footnotes to Table 2 of Paragraph (b)(2):

[a] Conversion Factors for chronic marine criteria are not currently available. Conversion Factors for acute marine criteria have been used for both acute and chronic marine criteria.

[b] Conversion Factors for these pollutants in freshwater are hardness dependent. CFs are based on a hardness of 100 mg/l as calcium carbonate ($CaCO_3$). Other hardness can be used; CFs should be recalculated using the equations in table 3 to paragraph (b)(2) of this section.

[c] Bioaccumulative compound and inappropriate to adjust to percent dissolved.

[d] EPA has not published an aquatic life criterion value.

Note to Table 2 of Paragraph (b)(2): The term "Conversion Factor" represents the recommended conversion factor for converting a metal criterion expressed as the total recoverable fraction in the water column to a criterion expressed as the dissolved fraction in the water column. See "Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" October 1, 1993, by Martha G. Prothro, Acting Assistant Administrator for Water available from Water Resource Center, USEPA, Mailcode RC4100, M Street SW, Washington, DC 20460 and the note to § 131.36(b)(1).

(v) Table 3 to paragraph (b)(2) of this section:

	Acute	Chronic
Cadmium	$CF = 1.136672 - [(\ln\{hardness\})(0.041838)]$	$CF = 1.101672 - [(\ln\{hardness\})(0.041838)]$
Lead	$CF = 1.46203 - [(\ln\{hardness\})(0.145712)]$	$CF = 1.46203 - [(\ln\{hardness\})(0.145712)]$

(c) *Applicability.* (1) The criteria in paragraph (b) of this section apply to the State's designated uses cited in paragraph (d) of this section and apply concurrently with any criteria adopted by the State, except when State regulations contain criteria which are more stringent for a particular parameter and use, or except as provided in footnotes p, q, and x to the table in paragraph (b)(1) of this section.

(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 other Federally-adopted and State-adopted 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 water body including at the point of discharge into the water body.

(ii) The State shall not use a low flow value below which numeric standards can be exceeded that is less stringent than the flows in Table 4 to paragraph (c)(2) of this section for streams and rivers.

(iii) Table 4 to paragraph (c)(2) of this section:

Criteria	Design flow
Aquatic Life Acute Criteria (CMC)	1 Q 10 or 1 B 3
Aquatic Life Chronic Criteria (CCC)	7 Q 10 or 4 B 3
Human Health Criteria	Harmonic Mean Flow

Note to Table 4 of Paragraph (c)(2): 1. CMC (Criteria Maximum Concentration) is 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 short-term average not to be exceeded more than once every three years on the average.

2. CCC (Continuous Criteria Concentration) is the water quality criteria to protect against chronic effects in aquatic life and is the highest in stream 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.

3. 1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically.

4. 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).

5. 7 Q 10 is the lowest average 7 consecutive day low flow with an average recurrence frequency of once in 10 years determined hydrologically.

6. 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).

(iv) If the State does not have such a low flow value below which numeric standards do not apply, then the criteria included in paragraph (d) of this section apply at all flows.

(v) If the CMC short-term averaging period, the CCC four-day averaging period, or once in three-year frequency is inappropriate for a criterion or the site to which a criterion applies, the State may apply to EPA for approval of an alternative averaging period, frequency, and related design flow. The State must submit to EPA the bases for any alternative averaging period, frequency, and related design flow. Before approving any change, EPA will publish for public comment, a document proposing the change.

(3) The freshwater and saltwater aquatic life criteria in the matrix in paragraph (b)(1) 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 except for selenium in the San Francisco Bay estuary where the applicable criteria are the freshwater criteria in Column B (refer to footnotes p and q to the table in paragraph (b)(1) of this section); 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 water body is dominated by freshwater aquatic life and that freshwater criteria are more appropriate; or conversely, the biology of the water body is dominated by saltwater aquatic life and that saltwater criteria are more appropriate. Before approving any change, EPA will publish for public comment a document proposing the change.

(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, for waters with a hardness of 400 mg/l or less as calcium carbonate, the actual ambient hardness of the surface water shall be used in those equations. For waters with a hardness of over 400 mg/l as calcium carbonate, a hardness of 400 mg/l as calcium carbonate shall be used with a default Water Effect Ratio (WER) of 1, or the actual hardness of the ambient surface water shall be used with a WER. 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 design flows and mixing zones.

(iii) The criteria for metals (compounds #1—#13 in the table in paragraph (b)(1) of this section) are expressed as dissolved except where otherwise noted. For purposes of calculating aquatic life criteria for metals from the equations in footnote i to the table in paragraph (b)(1) of this section and the equations in paragraph (b)(2) of this section, the water effect ratio is generally computed as a specific pollutant's acute or chronic toxicity value measured in water from the site covered by the standard, divided by the respective acute or chronic toxicity value in laboratory dilution water. To use a water effect ratio other than the default of 1, the WER must be determined as set forth in Interim Guidance on Determination and Use of Water Effect Ratios, U.S. EPA Office of Water, EPA–823–B–94–001, February 1994, or alternatively, other scientifically defensible methods adopted by the State as part of its water quality standards program and approved by EPA. 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 must be determined as required in paragraph (d)(4)(ii) of this section. Water hardness must be calculated from the measured calcium and magnesium ions present, and the ratio of calcium to magnesium should be approximately the same in standard laboratory toxicity testing water as in the site water.

(d)(1) Except as specified in paragraph (d)(3) of this section, 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"), 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)(2) of this section, without exception. These criteria apply to waters identified in the Basin Plans. More particularly, these criteria apply to waters identified in the Basin Plan chapters designating beneficial uses for waters within the region. 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)(2) 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.)

(2) The criteria from the table in paragraph (b)(1) of this section apply to the water and use classifications defined in paragraph (d)(1) of this section as follows:

Water and use classification	Applicable criteria
(i) All inland waters of the United States or enclosed bays and estuaries that are waters of the United States that include a MUN use designation.	(A) Columns B1 and B2—all pollutants (B) Columns C1 and C2—all pollutants (C) Column D1—all pollutants
(ii) All inland waters of the United States or enclosed bays and estuaries that are waters of the United States that do not include a MUN use designation.	(A) Columns B1 and B2—all pollutants (B) Columns C1 and C2—all pollutants (C) Column D2—all pollutants

(3) Nothing in this section is intended to apply instead of specific criteria, including specific criteria for the San Francisco Bay estuary, promulgated for California in the National Toxics Rule at § 131.36.

(4) The human health criteria shall be applied at the State-adopted $10^{(-6)}$ risk level.

(5) Nothing in this section applies to waters located in Indian Country.

(e) *Schedules of compliance.* (1) It is presumed that new and existing point source dischargers will promptly comply with any new or more restrictive water quality-based effluent limitations ("WQBELs") based on the water quality criteria set forth in this section.

(2) When a permit issued on or after May 18, 2000 to a new discharger contains a WQBEL based on water quality criteria set forth in paragraph (b) of this section, the permittee shall comply with such WQBEL upon the commencement of the discharge. A new discharger is defined as any building, structure, facility, or installation from which there is or may be a "discharge of pollutants" (as defined in 40 CFR 122.2) to the State of California's inland surface waters or enclosed bays and estuaries, the construction of which commences after May 18, 2000.

(3) Where an existing discharger reasonably believes that it will be infeasible to promptly comply with a new or more restrictive WQBEL based on the water quality criteria set forth in this section, the discharger may request approval from the permit issuing authority for a schedule of compliance.

(4) A compliance schedule shall require compliance with WQBELs based on water quality criteria set forth in paragraph (b) of this section as soon as possible, taking into account the dischargers' technical ability to achieve compliance with such WQBEL.

(5) If the schedule of compliance exceeds one year from the date of permit issuance, reissuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The dates of completion between each requirement may not exceed one year. If the time necessary for completion of any requirement is more than one year and is not readily divisible into stages for completion, the permit shall require, at a minimum, specified dates for annual submission of progress reports on the status of interim requirements.

(6) In no event shall the permit issuing authority approve a schedule of compliance for a point source discharge which exceeds five years from the date of permit issuance, reissuance, or modification, whichever is sooner. Where shorter schedules of compliance are prescribed or schedules of compliance are prohibited by law, those provisions shall govern.

(7) If a schedule of compliance exceeds the term of a permit, interim permit limits effective during the permit shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect final permit limits and final compliance dates. Final compliance dates for final permit limits, which do not occur during the term of the permit, must occur within five years from the date of issuance, reissuance or modification of the permit which initiates the compliance schedule. Where shorter schedules of compliance are prescribed or schedules of compliance are prohibited by law, those provisions shall govern.

(8) The provisions in this paragraph (e), Schedules of compliance, shall expire on May 18, 2005.

[FR Doc. 00-11106 Filed 5-17-00; 8:45 am]
BILLING CODE 6560-50-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 3

Transactions Other Than Contracts, Grants, or Cooperative Agreements for Prototype Projects

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule; public meeting.

SUMMARY: The Director of Defense Procurement is sponsoring a public meeting to discuss the proposed rule on conditions for appropriate use and audit policy for transactions for prototype projects published in the **Federal Register** at 66 FR 58422 on November 21, 2001.

DATES: The meeting will be held on March 27, 2002 from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the National Contract Management Association (NCMA), which is located at 1912 Woodford Road, Vienna, Virginia 22182. Directions to NCMA are available at *http://www.acq.osd.mil/dp/dsps/ot/pr.htm.*

FOR FURTHER INFORMATION CONTACT: David Capitano, Office of Cost, Pricing, and Finance, by telephone at 703–602–4245, by FAX at 703–602–0350, or by e-mail at *david.capitano@osd.mil.*

SUPPLEMENTARY INFORMATION: The Director of Defense Procurement would like to hear the views of interested parties on what they believe to be the key issues pertaining to the proposed rule on Transactions Other Than Contracts, Grants, or Cooperative Agreements for Prototype Projects published in the **Federal Register** at 66 FR 58422 on November 21, 2001. A listing of some of the possible issues for discussion, as well as copies of the written public comments submitted in response to the November 21, 2001 proposed rule, are available at *http://www.acq.osd.mil/dp/dsps/ot/pr.htm.*

Dated: February 27, 2002.

L.M. Bynum,

Alternative OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 02–5157 Filed 2–28–02; 11:52 am]

BILLING CODE 5001–08–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 151

[USCG–2001–10486]

RIN 2115–AG21

Standards for Living Organisms in Ship's Ballast Water Discharged in U.S. Waters

AGENCY: Coast Guard, DOT.

ACTION: Advance notice of proposed rulemaking; request for comments.

SUMMARY: The Coast Guard seeks comments on the development of a ballast water treatment goal, and an interim ballast water treatment standard. The Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 and the National Invasive Species Act of 1996 require the Coast Guard to regulate ballast water management practices to prevent the discharge of shipborne ballast water from releasing harmful nonindigenous species into U.S. waters of the Great Lakes, and to issue voluntary guidelines to prevent the introduction of such species through ballast water operations in other waters of the U.S. These Acts further provide that the Coast Guard must assess compliance with the voluntary guidelines and if compliance is inadequate must issue regulations that make the guidelines mandatory. These guidelines and regulations must be based on open ocean ballast water exchange and/or environmentally sound alternatives that the Coast Guard determines to be at least as "effective" as ballast water exchange in preventing and controlling infestations of aquatic nuisance species (ANS). The Coast Guard will use the public's comments to help define a ballast water treatment goal and standard, both of which are essential parts of determining whether alternative ballast water management methods are environmentally sound and at least as effective as open ocean ballast water exchange (BWE) in preventing and controlling infestations of ANS.

DATES: Comments and related material must reach the Coast Guard on or before June 3, 2002.

ADDRESSES: To make sure that your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility (USCG–2001–10486), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at http://dms.dot.gov.

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice, call Dr. Richard Everett, Project Manager, Office of Operating and Environmental Standards (G–MSO), Coast Guard, telephone 202–267–0214. If you have questions on viewing or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202–366–5149.

SUPPLEMENTARY INFORMATION:

Other NISA Rulemaking to Date

This rulemaking follows the publication of the Final Rule (USCG–1998–3423) on November 21, 2001 (66 FR 58381), for the Implementation of the National Invasive Species Act of 1996, that finalizes regulations for the Great Lakes ecosystems and voluntary ballast water management guidelines for all other waters of the United States, including reporting for nearly all vessels entering waters of the United States. Both rules follow the publication of the notice and request for comments for Potential Approaches To Setting Ballast Water Treatment Standards (USCG–2001–8737) on May 1, 2001, notice and request for comments on Approval for Experimental Shipboard Installations of Ballast Water Treatment Systems (USCG–2001–9267) on May 22, 2001, and the publication of notice of meetings; request for comments on The Ballast Water Management Program (USCG–2001–10062) on July 11, 2001.

Request for Comments

The Coast Guard encourages

rulemaking by submitting written data, views or arguments. Persons submitting comments should include their name and address, identify the docket number for this rulemaking (USCG–2001–10486), and the specific section of this proposal to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. Persons wanting acknowledgement of receipt of comments should enclose a stamped, self-addressed postcard or envelope. Don't submit the same comment or attachment more than once. Don't submit anything you consider to be confidential business information, as all comments are placed in the docket and are thus open to public inspection and duplication. The Coast Guard will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We have no plans for any public meetings, unless you request one. Some of the information that helped us prepare this notice came from the following meetings that have already been held: meetings of the Ballast Water and Shipping Committee (BWSC) of the Federal Aquatic Nuisance Species Task Force; the workshop on ballast water treatment standards sponsored by the Global Ballast Water Program (Globallast) of the International Maritime Organization (IMO) in March 2001; and two technical workshops we held in April and May 2001. If you want a meeting, you may request one by writing to the Docket Management Facility at the address under **ADDRESSES.** Explain why you think a meeting would be useful. If we determine that oral presentations would aid this rulemaking, we will hold a public hearing at a time, date, and place announced by later notice in the **Federal Register.**

Background and Purpose

Congress, in the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (NANPCA), as amended by the National Invasive Species Act of 1996 (NISA), directs the Coast Guard to issue regulations and guidelines for ballast water management (BWM). The goal of BWM is to prevent discharged ballast water from introducing harmful nonindigenous species (NIS) to U.S. waters.

Responding to NANPCA's directive, we published a final rule (58 FR 18330, [illegible]) that established ballast water treatment (BWT) for the Great Lakes. These requirements appear in 33 CFR part 151, subpart C, and were later extended to include the Hudson River north of the George Washington Bridge (59 FR 67632, December 30, 1994), as required by the statute. In 1999, responding to NISA's directive, we published an interim rule (64 FR 26672, May 17, 1999) that sets voluntary BWM guidelines for all other U.S. waters, and BWM reporting requirements for most ships entering U.S. waters.

NANPCA and NISA require BWT to be executed by mid-ocean ballast water exchange (BWE), or by a Coast Guard-approved alternative BWT method. The alternative BWT must be at least as effective as BWE in preventing and controlling infestations of aquatic nuisance species (ANS). Therefore, in order to evaluate the effectiveness of alternative BWT methods, the Coast Guard must first define for programmatic purposes what "as effective as [BWE]" means. The purpose of this notice, in part, is to present for public comment various approaches to clarifying this term.

On May 1, 2001, we published a notice and request for public comments (66 FR 21807) that invited comment on four conceptual approaches to BWT standards for assessing relative effectiveness to BWE, and posed questions, all of which were developed in meetings of the BWSC. The comments we received revealed a wide range of opinion (see "*Comments on the May 1, 2001, Notice*" below), indicating the need for more discussion.

The present notice reflects comments received in response to the May 1, 2001 notice. It also draws on information taken from the Globallast workshop (March 2001). Finally, it draws on discussions of the four conceptual BWT approaches by participants invited to the April and May 2001 Coast Guard workshops. (The report of the Globallast workshop is available at *http://globallast.imo.org.* Reports from the Coast Guard workshops, when completed, will be available at *http://dms.dot.gov.*)

Comments on the May 1, 2001, Notice

We received 22 written responses to our May 1, 2001 request for comments, which set out 4 optional approaches for BWT standards, posed 5 questions related to setting the standard, and posed 3 questions relating to implementation issues. We will summarize responses to the implementation questions when we propose a specific implementation approach and testing protocol at a later [illegible] about setting standards, along with a summary of the comments we received, and our response.

1. *Should a standard be based on BWE, best available technology [BAT], or the biological capacity of the receiving ecosystem? What are the arguments for, or against, each option?* Thirteen respondents specifically addressed this question. Five commenters, all associated with the shipping industry, recommended that a quantification of the effectiveness of BWE be used to set the standard. All five also stated that the language of NISA dictates this approach. Four commenters favored a BAT approach. Four commenters favored a biological capacity approach.

Participants in both the Globallast and Coast Guard workshops recommended against basing a ballast water treatment standard on the effectiveness, either theoretical or measured, of BWE. The Globallast report on the findings of the workshop stated: "It is not appropriate to use equivalency to ballast water exchange as an effectiveness standard for evaluating and approving/accepting new ballast water treatment technologies, as the relationship between volumetric exchange and real biological effectiveness achieved by ballast water exchange is extremely poorly defined. This relationship cannot be established without extremely expensive empirical testing." Participants in the two Coast Guard workshops recommended that standards be based on the level of protection needed to prevent biological invasions. The recommendations are neither endorsed nor discredited by the Coast Guard.

2. *If BWE is the basis for a standard, what criterion should be used to quantify effectiveness: the theoretical effectiveness of exchange, the water volume exchanged (as estimated with physical/chemical markers), the effectiveness in removing or killing all or specific groups of organisms, or something else; and why?* Twelve commenters specifically addressed this question. None of the 12 thought that theoretical efficacy should be used. Three recommended using volumetric effectiveness, and five considered measured effectiveness in killing/removing organisms to be the most appropriate measure. One commenter thought that all three metrics should be used, and four commenters re-expressed their opinion that exchange should not be the basis for the standard.

3. *How specifically should the effectiveness of either BWE or best available technology be determined (i.e.,* [illegible]

vessels) before setting a standard based on the capabilities of these processes? Ten respondents specifically addressed this question. One commenter recommended determining the effectiveness of exchange on a ship-by-ship basis, two thought effectiveness should be calculated for different "risk classes" of vessels or sectors of the shipping industry, one recommended that exchange be evaluated with hydrodynamic models before being evaluated on test vessels, and six advocated the use of a broad average effectiveness calculated across many types of vessels and trading patterns.

4. *What are the advantages and disadvantages of considering the probability of conducting a safe and effective BWE on every voyage when estimating the overall effectiveness of BWE?* Eleven respondents specifically addressed this question. Six comments came from vendors of ballast water treatment systems or from public and private resource protection entities. Five of these said the probability of conducting an exchange must be considered at some level, in order to better represent BWE's "real world" capability. The sixth said we should take only completed exchanges into account, because class societies could not attest to the effectiveness of systems when safety exemptions were considered. All five shipping industry commenters also advocated looking only at completed exchanges, because too many variables affect whether or not a full exchange can be conducted. The Coast Guard considers the feasibility of conducting a mid-ocean exchange to be one of the significant issues in evaluating BWE.

5. *What are the advantages and disadvantages of expressing a BWT standard in terms of absolute concentrations of organisms versus the percent of inactivation or removal of organisms?* Twelve respondents specifically addressed this question. Several expressed concern that if ballast water were taken on in a location with a very low concentration, the vessel might not have to use any treatment to meet a concentration standard. Conversely, several commenters argued that a high percentage reduction in organisms, when the initial concentration was very high, could still result in the discharge of a high concentration of organisms. These concerns should be kept in mind when commenting on the alternative standards presented below. It is important to note that, for purposes of testing the theoretical effectiveness of a technology, if testing is conducted using the highest expected natural concentrations of organisms as the concentrations in the test medium (as recommended by participants in the Globallast and the USCG workshops), the percent reduction approach effectively becomes a concentration approach. This is because the standard percent reduction (for example, 95%) of an absolute concentration produces an absolute concentration of remaining organisms. On the other hand, for purposes of assessing compliance with the standard at the level of an individual vessel, the two approaches could have very different results.

Further Comments Needed

We seek more comments because the discussion of BWT standards has focused, until now, on the suitability of basing standards on existing technology, rather than on developing new technology that better meets the congressional intent of eliminating ballast water discharge as a source of harmful NIS.

As we noted above, the governing statutes (NANCPA and NISA) specify the use of BWE and provide that any alternative form of BWT be at least as effective as BWE in preventing and controlling the spread of ANS. At present, no alternatives have been approved, in part, perhaps, because the effectiveness of the BWE benchmark itself is not well defined. Furthermore, concerns have been voiced that mid-ocean BWE is difficult to quantify in practice, cannot be safely performed on all transoceanic voyages, and by current definition cannot be conducted on voyages that take place within 200 miles of shore and in waters shallower than 2000 meters deep.

There are only limited scientific data on the effectiveness of BWE. A few empirical studies (see references: 5, 13, 14, 15, 18) listed in this notice, indicate that BWE results in the actual exchange of 88% to 99% of the water carried in a ballast tank. The average result is quite close to the theoretical 95% efficiency of Flow-Through Exchange.

However, knowing that we exchanged 88–99% of the water does not necessarily tell us we eliminated 88–99% of the danger of ANS remaining in the ballast tank. Some of the empirical studies (see references: 5, 13, 14, 15, 18) also looked at that aspect of BWE. They found that BWE resulted in reducing the number of organisms by varying degrees, from 39% to 99.9%, depending on the taxonomic groups and ships studied.

The variability in this data reflects the fact that the studies involved different ships under experimentally uncontrolled conditions, used different methods of calculating the percentage of water exchanged, and used different taxonomic groups to evaluate BWE's effectiveness in reducing the presence of ANS.

Technical experts at the Coast Guard and IMO workshops, and comments by the National Oceanic and Atmospheric Administration, agree that scientifically determining even the quantitative effectiveness of BWE (leaving aside its qualitative effectiveness) will be challenging.

We think Congress viewed BWE as a practical but imperfect tool for treating ballast water, and wanted to ensure that approved alternatives would not be less effective than BWE is known to be. As currently practiced, BWE produces varying results and sometimes may remove as few as 39% of the possible harmful organisms from the ballast tank. BWE is affected by a number of variables, cannot be used on coastal voyages (as currently defined), and often cannot be used by a ship on any of it's voyages due to safety concerns.

The Coast Guard is currently considering an approach in which an alternative BWT method would be judged to be at least as effective as BWE if it:

- Produces predictable results,
- Removes or inactivates a high proportion of organisms,
- Functions effectively under most operating conditions, and
- Moves toward a goal that expresses the congressional intent to eliminate ballast water discharge as a source of harmful NIS.

In this notice, we are seeking comments that will help us define the standards and goals that would meet these criteria.

Issues for further comment

Your comments are welcome on any aspect of this notice, including the submission of alternative goals or standards that were not presented in today's notice. The possible goals and standards presented here are intended to stimulate discussion that will ultimately lead to a standard for assessing BWT effectiveness that will have broad scientific and public support. We particularly seek your input on the "Questions" we raise below. The Questions (Q1–Q6) refer to the following possible Goals (G1–G3) and Standards (S1–S4).

Possible Goals

G1. No discharge of zooplankton and photosynthetic organisms (including holoplanktonic, meroplanktonic, and demersal zooplankton, phytoplankton and propagules of macroalgae and

aquatic angiosperms), inclusive of all life-stages. For bacteria, Enterococci and Escherichia coli will not exceed 35 per 100 ml and 126 per 100 ml of treated water, respectively.

G2. Treat for living organisms at least to the same extent as drinking water.

G3. Ballast water treatment technologies would demonstrate, through direct comparison with ballast water exchange, that they are at least as effective as ballast water exchange in preventing and controlling infestations of aquatic nuisance species for the vessel's design and route.

Possible Standards

S1. Achieve at least 95% removal, kill or inactivation of a representative species from each of six representative taxonomic groups: vertebrates, invertebrates (hard-shelled, soft shelled, soft-bodied), phytoplankton, macroalgae. This level would be measured against ballast water intake for a defined set of standard biological, physical and chemical intake conditions. For each representative species, those conditions are:

- The highest expected natural concentration of organisms in the world as derived from available literature and
- A range of values for salinity, turbidity, temperature, pH, dissolved oxygen, particulate organic matter, and dissolved organic matter. (GLOBALLAST PROPOSAL "A".)

S2. Remove, kill or inactivate all organisms larger than 100 microns in size. (GLOBALLAST PROPOSAL "B".)

S3. Remove 99% of all coastal holoplanktonic, meroplanktonic, and demersal zooplankton, inclusive of all life-stages (eggs, larvae, juveniles, and adults). Remove 95% of all photosynthetic organisms, including phytoplankton and propagules of macroalgae and aquatic angiosperms, inclusive of all life stages. Enterococci and Escherichia coli will not exceed 35 per 100 ml and 126 per 100 ml of treated water, respectively. (COAST GUARD WORKSHOP PROPOSAL "A".)

S4. Discharge no organisms greater than 50 microns in size, and treat to meet federal criteria for contact recreation (currently 35 Enterococci/ 100 ml for marine waters and 126 E. coli /100 ml for freshwaters). (COAST GUARD WORKSHOP PROPOSAL "B".)

Note: The capability of current technology to remove or kill 95%–99% of the zooplankton or phytoplankton, or to remove 100% of organisms larger than 50 or 100 microns, under the operational flow and volume conditions characteristic of most commercial ocean-going vessels, is not well established. Workshop participants felt these removal efficiencies are practical and realistic initial targets. BWT to these levels would provide increased protection compared to no BWT at all, or to BWE carried out only when vessel design and operating conditions permit.

Questions

In answering the questions, please refer to Questions, Goals, and Standards by their designations (for example: Q1, G2, S3).

The following questions refer to the goals (G1–G3) and standards (S1–S4) set out in "Issues for Further Comment," above.

Q1. Should the Coast Guard adopt G1, G2, G3, or some other goal (please specify) for BWT?

Q2. Should the Coast Guard adopt any of the standards, S1–S4 as an interim BWT standard? (You also may propose alternative quantitative or qualitative standards.)

Q3. Please provide information on the effectiveness of current technologies to meet any of the possible standards. Please comment, with supporting technical information if possible, on the workshop participants' assessment that these standards are "practical and realistic initial targets".

Q4. General comments on how to structure any cost-benefit or cost-effectiveness analysis that evaluates the above four possible standards. We are requesting comments on how the Coast Guard should measure the benefits to society of the above possible standards in either qualitative or quantitative terms. How would the benefits be measured considering each possible standard would continue to allow the introduction of invasive species, but at different rates? What would the costs be to industry in each of the four proposals? How would the cost to industry differ by possible standard?

Q5. What impact would the above four standards have on small businesses that own and operate vessels?

Q6. What potential environmental impacts would the goals or standards carry?

Issues for Future Consideration

The possible goals and standards in today's notice set out basic biological parameters for the discharge of aquatic organisms ranging from bacteria to higher taxonomic groups and are intended to provide a starting point for discussion. If the framework for addressing BWT effectiveness that is discussed in this notice were adopted, the final standards would be derived from a process that incorporates the expertise of the scientific community.

We know that many practical problems will need to be addressed in setting up a program for testing and approving BWT alternatives. We think it is premature to ask for comments on these issues until an approach (or at least an interim approach) for assessing BWT effectiveness is chosen, because many procedural aspects of the testing process will be dependent on the specific nature of the selected approach. However, we may ultimately need to address issues such as using standard indicators as evaluation tools, as participants in both Globallast and the Coast Guard workshops recommended. This would depend on:

- Identifying and validating species or physical/chemical metrics that can be used as practical and efficient standard indicators. This in turn would depend on:
- Improving sampling and analytic techniques by:
- Setting detection limits and degrees of statistical uncertainty for methods and protocols used to enumerate the abundance of organisms in treated ballast water, and on
- Setting standard testing conditions for the concentrations of indicators and a suite of physical and chemical parameters. For example, testing might be based on what the available literature shows to be the highest expected natural concentration in the world for each indicator species or variable under a range of conditions for other parameters. (This approach was recommended by participants in both the Globallast and USCG workshops.) The suite of parameters would include turbidity, dissolved and particulate organic material, salinity, pH, and temperature.

Preliminary Regulatory Evaluation

At this early stage in the process, the Coast Guard cannot anticipate whether any proposed or final rules will be considered significant, economically or otherwise, under Executive Order 12866 or under the Department of Transportation regulatory policies and procedures [44 FR 11034, February 26, 1979]. At this time, the economic impact of any regulations that may result from this notice cannot be accurately determined. The Coast Guard plans to use comments received on this advance notice of proposed rulemaking to assess these economic impacts. We will then prepare either a regulatory assessment or a detailed regulatory evaluation as appropriate, which will be placed in the docket.

To facilitate the comment process on this notice, Table 1 below presents cost information compiled from recent technical literature on ballast water technologies. Several points should be

First, these cost estimates are not all expressed in a constant unit. Comparisons of estimates across studies, therefore, should be conducted with caution. Second, cost estimates from the Cawthron (1998) and Agriculture, Fisheries, and Forestry—Australia (2001) reports are converted from Australian dollars based on exchange rates published October 16, 2001 ($0.5136 AUD = $1.00 US Dollar). Third, these cost estimates are not expressed in constant dollars; they have not been adjusted for inflation. Finally, these costs are derived primarily through experimental and pilot projects, not actual application in the field.

At this time, the Coast Guard does not endorse any of these studies in any way; we have not yet conducted detailed cost-benefit analysis on this subject. We are making this information available to facilitate public discussion of the questions that we are posing above. We also welcome any comments and supporting documentation, pertaining to the cost estimates summarized below.

TABLE 1.—COST ESTIMATES FOR BALLAST WATER ALTERNATIVE TECHNOLOGIES FROM THE RECENT LITERATURE

Ref.	Technology	Cost	Remark
1	Ballast water exchange	$4.79–$7.28 per cubic meter	Costs are reduced approximately 50 percent if gravity ballasting can be accomplished.
4	Ballast water exchange	$4,500 fuel cost per exchange	56,000 tons of ballast water flow through 3 volumes; time for exchange about 3 days.
4	Ballast water exchange	$3,100–$8,800 for fuel and pump maintenance per exchange.	Estimates for conditions on container ships, bulk carriers, and two types of tankers; 3 dilutions; time for exchange ranged from 33 to 55 hours.
4	Ballast water exchange	$16,000–$80,000 total cost of exchange.	Estimates for conditions on VLCC and Suezmax bulker.
9	Ballast water exchange	Qualitative discussion of cost implications.	Time lost during transit.
16	Ballast water exchange	$0.02–$0.10 per metric ton of ballast water.	Estimates based on study of California ports.
1	Onshore treatment facility	$0.66–$27.00 per cubic meter	Cost estimates driven by additional infrastructure required in ports.
6	Onshore treatment facility	$1.4 billion for entire treatment facility	Facility in Valdez, Alaska; only ballast water treatment facility currently in use in U.S.; covers 1,000 acres of land, processes about 16m gallons of ballast water daily.
6	Onshore treatment facility	$9m–19m for infrastructure; $0.09–$0.41 per metric ton of ballast water treated.	Estimate based on port-based facility located on land or a floating platform.
9	Onshore treatment facility	Qualitative discussion of cost implications.	Costs minimized in onshore facility located where vessels are already required to stop for customs and quarantine inspection; time delay for docking and deballasting.
16	Onshore treatment facility	$7.6m–$49.7m for infrastructure; $142,000–$223,000 for annual maintenance; $1.40–$8.30 per metric ton of ballast water treated.	Estimates based on study of California ports.
1	Thermal treatment	$10.83–$17.52 per cubic meter	Heating/flushing process.
6	Thermal treatment	Qualitative discussion of cost implications.	Very expensive labor and materials cost to retrofit heating coils in ballast tanks; if additional heat generation required then fuel consumption increases.
11	Thermal treatment	$75,000–$275,000 per system	Most cost effective in warmer waters.
1	UV treatment	$31.66–$186.53 per cubic meter	Low cost estimate represents UV used alone; high cost estimate reflects combination with hydrocyclone.
2	UV treatment	$10,200–$545,000 per system for infrastructure; $2,200–$11,000 per system for annual maintenance.	Cost estimates for 1,200 GPM and 8,000 GPM systems.
7	UV treatment	$250,000–$1m life-cycle per treatment system.	Study part of technology demonstration project.
9	UV treatment	Qualitative discussion of cost implications.	Capital investment very high; cost for installation and pipe modifications.
1	Chemical treatment	$0.47–$77.88 per cubic meter	Estimate based only on operating cost.
7	Chemical treatment	$2m–$4m life-cycle per treatment system.	Study part of technology demonstration project.
9	Chemical treatment	Qualitative discussion of cost implications.	installation and engineering of chemical dosing system is expensive; low cost effectiveness; large capital investment.
9	Filtration	Qualitative discussion of cost implications.	Large capital investment; cost of disposal of concentrated filtrate.
8	Rapid response	$1.5m per strike	Australia, method involved quarantine of the port and destruction of organisms when detected on a vessel in port.

As with the cost information provided above, the Coast Guard does not currently endorse any of these studies in any way; we have not yet conducted our own detailed assessment of their methodologies and results. Rather, we are making this information available to facilitate public discussion of the questions that we are posing above. We

also welcome any comments, and supporting documentation pertaining to the damage estimates summarized below.

Aquatic Nuisance Species

Adverse environmental and economic effects of some ANS have been documented in a number of studies. As with the cost information provided above, the Coast Guard does not currently endorse any of these studies in any way; we have not yet conducted our own detailed assessment of their methodologies and results. Rather, we are making this information available to facilitate public discussion of the questions that we are posing above. We also welcome any comments, and supporting documentation pertaining to the damage estimates summarized below.

The most studied species, the zebra mussel, has affected the ecology and economy of the Great Lakes since introduction in the late 1980s. Some scientists believe the mussel is responsible for "profound changes in the lower food web of the Great Lakes" and massive algal blooms (see reference: 3). Zebra mussels may clog intake pipes for industrial and municipal plants, and may cause extended shut downs in order to chemically treat the pipes. In the Great Lakes basin, the annual cost of zebra mussel control has been estimated at from $100 to $400 million. Dramatically altering the Great Lakes ecosystems, zebra mussels have now spread throughout the Mississippi River drainage basin, thousands of inland lakes, and are threatening the West Coast (see reference: 3). There is evidence that The San Francisco and Chesapeake Bays, Gulf of Mexico, and Hawaiian coral reef may be threatened by other non-indigenous fish, mollusks, crustaceans, and aquatic plants (see reference: 3). A 1999 report (see reference: 12) estimates that the environmental damage caused by non-indigenous species in the United States (both land and water) is $138 billion per year. The report further states that there are approximately 50,000 foreign species and the number is increasing. It is estimated that about 42% of the species on the Threatened or Endangered species lists are at risk primarily because of non-indigenous species.

The above damage estimate pertains to all non-indigenous species, both land and water. Table 2 below, adapted from the report (see reference: 12), presents estimates of the annual damages and costs of aquatic species in the United States.

TABLE 2.—ONE ESTIMATE OF THE TOTAL ANNUAL COST OF AQUATIC INVASIVE SPECIES IN BILLIONS OF DOLLARS

[See reference: 12]

Species	Total [1]
Aquatic weeds	$0.110
Fish	1.000
Green crab	0.044
Zebra mussel	5.000
Asian clam	1.000
Shipworm	0.205
Total	7.359

[1] Total annual cost of species.

Small Entities

We are unable, at this time, to determine whether, under the Regulatory Flexibility Act (5 U.S.C. 601–612), any regulations resulting from this ANPRM would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

If you think your business, organization, or governmental jurisdiction qualifies as a small entity and that a rule establishing standards for evaluating the effectiveness of BWT would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this ANPRM so that they can better evaluate its potential effects on them and participate in the rulemaking. If you believe that this ANPRM could lead to a final regulation that would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions, please contact Dr. Richard Everett where listed under **FOR FURTHER INFORMATION CONTACT**, above.

Collection of Information

Any final rule resulting from this ANPRM could call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.). At this time we are unable, however, to estimate the number of responders or the burden of responding on each responder. We will include our estimates of this information in a later notice of proposed rulemaking and allow for comments on those estimates before issuing a final rule. As always, you are not required to respond to an information collection unless it displays a valid OMB approval number.

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have not yet analyzed whether any rule resulting from this ANPRM would have implications for federalism, but we are aware of efforts by various states to stem invasive species in their waters. We will continue to consult with the states through the Ballast Water Working Group.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. As stated above, we do not yet know the costs that would be associated with any rule resulting from this ANPRM. The Coast Guard will publish information regarding costs using the comments received on this ANPRM in a future publication.

Taking of Private Property

We anticipate that any proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

We anticipate that any proposed rule would meet the applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We anticipate that any proposed rule will be analyzed under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, and any such rule would not

risk to safety that might disproportionately affect children.

Indian Tribal Governments

We anticipate that any proposed rule would not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would likely not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. However, we recognize that ANS may pose significant concerns for some tribal governments and are committed to working with tribes as we proceed with this rulemaking.

To help the Coast Guard establish regular and meaningful consultation and collaboration with Indian and Alaskan Native tribes, we published a notice in the **Federal Register** (66 FR 36361, July 11, 2001) requesting comments on how to best carry out the Order. We invite your comments on how any rule resulting from this ANPRM might impact tribal governments, even if that impact may not constitute a "tribal implication" under the Order, and how best to address the ANS concerns of the tribal governments.

Energy Effects

We have not analyzed this ANPRM under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have not determined whether it is a "significant energy action" under that order because we do not know whether any resulting rule would be a "significant regulatory action" under Executive Order 12866. Once we determine the economic significance of any rule stemming from this ANPRM, we will determine whether a Statement of Energy Effects is required.

Environment

The Coast Guard will consider the environmental impact of any proposed rule that results from this advance notice of proposed rulemaking. We will include either Environmental Assessment or Environmental Impact Statement in the docket for any such rulemaking as appropriate.

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Dated: August 27, 2001.

Paul J. Pluta,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety and Environmental Protection.

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BILLING CODE 4910–15–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AH42

Evidence for Accrued Benefits

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans

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