nominally affected. Because it expects the impact of this proposal to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposal contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this proposal in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard considered the environmental impact of this proposal and concluded that, under paragraph 2.B.2 of Commandant Instruction M16475.1B, this proposal is categorically excluded from further environmental documentation. A Categorical Exclusion Determination and Environmental Analysis Checklist has been prepared and placed in the rulemaking docket, and will be available for inspection and copying at the address listed in **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation.

Proposed Regulation

For the reasons set out in the preamble, the Coast Guard proposes to amend Title 33, Code of Federal Regulations Part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; 49 CFR 1.46.

2. A new section 165.1115 is added to read as follows:

§ 165.1115 Copper Canyon, Lake Havasu, Colorado River—Regulated Navigation Area.

(a) *Location.* The following is a regulated navigation area: (1) In the water area of Copper Canyon, Lake Havasu, Colorado River, beginning at the approximate center of the mouth of Copper Canyon and drawing a line down the approximate center of the canyon extending shoreward to the end of the navigable waters of the canyon, and comprising a semi-rectangular area extending 30 feet on each side of the line, for a total semi-rectangular width of 60 feet. (2) This line is more precisely described as: beginning at latitude 34°25′42″N, longitude 114°18′26″W, thence southwesterly to latitude 34°25′38″N, longitude 114°18′26″W, thence southwesterly to latitude 34°25′37″N, longitude 114°18′26″W, thence southwesterly to latitude 34°25′34″N, longitude 114°18′26″W, thence southwesterly to latitude 34°25′33″N, longitude 114°18′28″W, thence southwesterly to latitude 34°25′29″N, longitude 114°18′29″W, thence to the end of the navigable waters of the canyon. All coordinates use Datum: NAD83.

(3) The semi-rectangular area shall extend 30 feet on each side of this line, for a total semi-rectangular width of 60 feet.

(b) *Definitions.* For the purpose of this section:

(1) *Vessel:* Every description of watercraft, used or capable of being used as a means of transportation on the water, regardless of mode of power.

(2) *Patrol Vessel:* Vessels designated by the Captain of the Port, San Diego, to enforce or assist in enforcing these regulations, including Coast Guard, Coast Guard Auxiliary, and San Bernardino County Sheriffs Department vessels.

(c) *Regulations.* (1) Vessels, with the exception of patrol vessels, shall not anchor, moor, loiter in, or otherwise impede the transit of any other vessel within the regulated navigation area. Furthermore, all vessels, with the exception of patrol vessels, shall expeditiously and continuously transit the regulated navigation area via the most direct route consistent with navigational safety.

(2) During periods of vessel congestion within the Copper Canyon area, as determined by the Captain of the Port or his designated on-scene representative, the regulated navigation area will be closed to all vessels, with the exception of patrol vessels. During designated closure periods, no vessel may enter, remain in, or transit through the regulated navigation area with the exception of patrol vessels. Designation of periods of vessel congestion and announcement of the closure of the regulated navigation area will be conducted by broadcast notices to mariners on VHF–FM Channel 16 no less frequently than every hour for the duration of the closure period.

(3) Each person in the regulated navigation area shall comply with the directions of the Captain of the Port or his designated on-scene representative regarding vessel operation.

Dated: March 11, 1998.

J.C. Card,

Vice Admiral, U.S. Coast Guard, Commander, Eleventh Coast Guard District.

[FR Doc. 98–8258 Filed 4–1–98; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL–5989–8]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance—Revision of Polychlorinated Biphenyls (PCBs) Criteria

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Clean Water Act (CWA) requires states to adopt numeric criteria for those priority toxic pollutants for which EPA has published criteria guidance and whose discharge or presence could reasonably be expected to interfere with designated uses of states' waters. In 1992, EPA promulgated the National Toxics Rule (NTR) establishing numeric water quality criteria for toxic pollutants in fourteen states and jurisdictions to protect human health and aquatic life. These states and jurisdictions had not adopted sufficient chemical-specific, numeric criteria for toxic pollutants necessary to comply with the Clean Water Act.

Among the criteria promulgated in the NTR were human health and aquatic life water quality criteria for polychlorinated biphenyls (PCBs). Today, EPA is proposing revisions to the human health water quality criteria for PCBs in the NTR, based on the Agency's reassessment of the cancer potency of PCBs.

DATES: Written comments must be submitted by midnight June 1, 1998.

ADDRESSES: Send written comments to W–98–06, WQS–PCBs Comment Clerk, Water Docket, MC 4101, US EPA, 401 M Street, S.W., Washington, D.C. 20460. Comments may also be submitted electronically to OW-Docket@epamail.epa.gov. The record is available for inspection from 9:00 to 4:00 p.m., Monday through Friday, excluding legal holidays at the Water Docket, East Tower Basement, USEPA, 401 M St., S.W., Washington, D.C. For

access to docket materials, please call (202) 260–3027 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: Cindy Roberts, Health and Ecological Criteria Division (4304), Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 260–2787.

SUPPLEMENTARY INFORMATION:

A. Potentially Affected Entities
B. Water Docket Information
C. Background
D. Proposed Revisions of Human Health Criteria for PCBs
E. Response to Issues Identified in Partial Settlement Agreement
F. Regulatory Assessment Requirements

A. Potentially Affected Entities

States authorized to implement the National Pollutant Discharge Elimination System (NPDES) Permit Program will need to ensure that permits they issue include any limitations on discharges necessary to comply with the standards established by the final rule. In doing so, the States will have a number of discretionary choices associated with permit writing. Entities discharging pollutants to waters of the United States in NTR states could be affected by this rulemaking. These entities may be affected since water quality criteria are part of water quality standards that in turn are used in developing NPDES permit limits. Categories and entities that may ultimately be affected include:

Category	Examples of potentially affected entities
State and Jurisdictional Governments.	NPDES Authorized states and jurisdictions.
Industry	Industries discharging to waters in NTR states and jurisdictions.
Municipalities	Publicly-owned treatment works discharging to waters of NTR states and jurisdictions.

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 this action. Other types of entities not listed in the table could also be affected. To determine whether your organization or facility may be affected by this action, you should carefully examine the applicability criteria in § 131.36 (d) of title 40 of the Code of Federal Regulations as amended by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Water Docket Information

The record for this rulemaking has been established under docket number W–98–06 and includes supporting documentation. When submitting written comments to the Water Docket, (see **ADDRESSES** section above) please reference docket number W–98–06 and submit an original and three copies of your comments and enclosures (including references). Comments must be received or postmarked by midnight June 1, 1998. Commenters who want EPA to acknowledge receipt of their comments should enclose a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted.

Electronic comments may also be submitted to the Water Docket (see **ADDRESSES** section above). Electronic comments must be submitted as an ASCII file or a WordPerfect file avoiding the use of special characters and any form of encryption. Electronic comments must be identified by the docket number, W–98–06, and be received by midnight of June 1, 1998. Comments and data will also be accepted on disks in WP5.1 format or ASCII file format. No confidential business information (CBI) should be sent via e-mail.

C. Background

In 1992, EPA promulgated numeric water quality criteria for priority toxic pollutants in twelve states (Rhode Island, Vermont, New Jersey, Florida, Michigan, Arkansas, Kansas, California, Nevada, Alaska, Idaho, Washington), Puerto Rico, and the District of Columbia (National Toxics Rule or NTR, 57 FR 60848, December 22, 1992, codified in the Code of Federal Regulations at 40 CFR 131.36). These states and jurisdictions had not adopted sufficient chemical-specific, numeric criteria for toxic pollutants necessary to comply with section 303(c)(2)(B) of the Clean Water Act. Among the criteria promulgated in the NTR were human health criteria for PCBs. The human health criteria were based on methodology issued in 1980 (''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 or ''Human Health Guidelines'').

General Electric Company and the American Forest and Paper Association, Inc. challenged a number of aspects of the NTR, including the human health water quality criteria for PCBs. *See American Forest and Paper Ass'n. Inc. et al.* v. *U.S. EPA* (Consolidated Case No. 93–0694 (RMU) D.D.C.). In particular, the plaintiffs objected to EPA's application of its cancer risk assessment methodology to its evaluation of the carcinogenicity of PCBs and the Agency's evaluation of various scientific studies relevant to the cancer risk posed by PCBs. EPA had underway a number of activities related to these objections, including reassessment of the cancer potency of PCBs (the ''cancer reassessment''), revision of the methodology to derive human health water quality criteria, and revision of the cancer guidelines, that could lead the Agency to decide to amend the human health water quality criteria for PCBs in the NTR. EPA and the plaintiffs entered into a partial settlement agreement in which EPA, among other things, agreed to a schedule for completing the final cancer reassessment. See ''Partial Settlement Agreement,'' Consolidated Case No. 93–0694 RMU, D.D.C, signed November 7, 1995.

EPA also agreed that within l8 months of the issuance of the final cancer reassessment, the Agency would propose a revision to the NTR human health criteria for PCBs, or publish a **Federal Register** notice explaining why it was not revising the NTR criteria. EPA completed the reassessment in September 1996. See ''PCBs: Cancer Dose-Response Assessment and Applications to Environmental Mixtures'' (EPA/600/P–96/001F). In today's Notice, EPA is proposing an amendment to the PCBs human health criteria in the NTR that reflects the reassessment. In the settlement agreement, EPA also agreed to consider several issues identified by the Plaintiffs; those issues are discussed in section E of this document.

D. Proposed Revisions of Human Health Criteria for PCBs

1. Reassessment of Cancer Potency of PCBs

Background

Manufactured PCBs are mixtures of forms (congeners) of the PCB molecule that differ in their chlorine content. Different mixtures can take on forms ranging from oily liquids to waxy solids. Although their chemical properties vary widely, different mixtures have many common PCB congeners. Because of their flame retardant properties, chemical stability, and insulating properties, commercial PCB mixtures

were used in many industrial applications. These chemical properties, however, also contribute to the persistence of PCBs after they are released into the environment. Because of evidence of persistence and harmful effects, domestic manufacture of commercial mixtures was stopped in 1977; existing PCBs, however, continue in use, primarily in electrical capacitors and transformers.

In the environment, PCBs also occur as mixtures of congeners, but their composition differs from the commercial mixtures. This is because after release into the environment, the composition of PCB mixtures changes over time, through partitioning, chemical transformation and preferential bioaccumulation of certain congeners. Some PCB congeners can accumulate selectively in living organisms. PCBs are widespread in the environment because of past contaminations, and humans are exposed through multiple pathways: ambient air, drinking water, and diet.

For the purpose of issuing PCBs criteria in the NTR, EPA used a single dose-response slope (7.7 per mg/kg-d average lifetime exposure); this was the value included in EPA's Integrated Risk Information System (IRIS) at that time. This value was derived from a rat feeding study by Norback and Weltman (1985), one of several studies of Aroclor 1260. With no agreed upon basis for reflecting differences among environmental mixtures, EPA used this slope factor for all PCBs. Accordingly, the 7.7 per mg/kg-d slope factor was used for all PCBs and PCB mixtures. General Electric Company challenged EPA's use of this slope factor to calculate the NTR human health criteria for PCBs on several grounds, including that the Norback and Weltman study had been reevaluated. GE argued that if the reevaluated results had been used, the cancer potency factor would have been significantly lower. EPA and General Electric entered into a settlement agreement providing that EPA would complete a reassessment of the cancer potency factor for PCBs .

Reassessment

EPA considered a number of different approaches for its reassessment, and adopted an approach that distinguishes among PCB mixtures by using information on environmental processes. Environmental processes have effects that can decrease or increase toxicity, so potency of an environmental mixture may differ from the original commercial mixture. EPA's new assessment considered all cancer studies (which used commercial mixtures only) including a new study of four Aroclors that strengthens the case that all PCBs cause cancer. EPA used this information to develop a range of dose response slopes, changing the single-dose cancer potency factor of 7.7 per mg/kg-d to a slope which ranges from 0.07 per mg/kg-d (lowest risk and persistence) to 2.0 per mg/kg-d (high risk and persistence). It is noteworthy that bioaccumulated PCBs appear to be more toxic than commercial PCBs and appear to be more persistent in the body. The reassessment uses information on environmental processes to provide guidance on choosing an appropriate slope for representative classes of environmental mixtures and different exposure pathways.

The reassessment methodology determines cancer potency by using a tiered approach based on exposure pathways (such as food chain) to choose the appropriate slope values from the range. In this methodology, exposure through the food chain is associated with higher risks than other exposures. Specifically, preferential bioaccumulation through the food chain tends to concentrate certain highly chlorinated congeners which are often among the most toxic and persistent. Persistence in the body can enhance the opportunity for PCB congeners to express tumor promoting activity. Recent multimedia studies indicate that the major pathway of exposure to persistent toxic substances such as PCBs is through food (i.e., contaminated fish and shellfish consumption). Consumption of contaminated fish was considered to be the dominant source of PCB exposure. On this basis, EPA chose a cancer potency factor of 2 per mg/kg-d, the upper bound potency factor reflecting high risk and persistence, to calculate the revised human health criteria for PCBs. This upper bound slope factor of 2 per mg/kg-d is also used to assess increased risks associated with early life exposure to PCBs.

2. Calculation of Revised Human Health Criteria for PCBs

Using the cancer potency factor of 2 per mg/kg-d EPA calculated the revised human health criterion (HHC) for organism and water consumption as follows:

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

Where:

RF=Risk Factor=1×10 ($^{-6}$)
BW=Body Weight=70 kg
q1*=Cancer slope factor=2 per mg/kg-d
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:

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

Where:

RF=Risk Factor=1×10 ($^{-6}$)
BW=Body Weight=70 kg q1
*=Cancer slope factor=2 per mg/kg-d
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 the total PCBs or congener or isomer analyses. See *PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures* (EPA/600/9–96–001F). For a discussion of the body weight and water consumption factors see the Human Health Guidelines (''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). For a discussion of the BCF, see the 304(a) criteria guidance document for PCBs (''Ambient Water Quality Criteria for Polychlorinated Biphenyls'', EPA 440/5–80-068) (1980).

While EPA established ambient water quality criteria for PCBs based on bioaccumulation factors (BAFs) in the Great Lakes Water Quality Initiative, these BAFs were not used to derive national ambient water quality criteria because they did not address conditions outside the Great Lakes System (e.g., consumption weighted lipid content, freely dissolved fraction). The Great Lakes Water Quality Initiative also used a fish consumption value specific to the Great Lakes region; the 15 grams per day value represents the mean consumption rate of regional fish caught and consumed by the Great Lakes sport fishing population.

3. Criteria Expressed as Total of All Aroclors

In addition to the proposed revision of the numeric human health criteria for PCBs, EPA is proposing that the human health criterion be expressed as a total of all Aroclors. This proposal differs from the current NTR where criteria are expressed for each Arocolor. It is the Agency's view that expressing the criterion in terms of total rather than

single Aroclors better reflects current scientific thought (see also the proposed PCBs criteria in the California Toxics Rule, 62 FR 42160, August 5, 1997).

EPA's change of approach from one where each Aroclor has its own criterion to one where a single criterion applies to the sum of all Aroclors does not result in more stringent criteria. The proposed human health criterion specifies concentration limits of 0.00017 µg/L for total PCBs, in contrast to the old criteria of 0.000044 µg/L and 0.000045 µg/L for each of seven different Aroclors. Although the old criteria would, in theory, have allowed 0.000308 µg/L and 0.000315 µg/L total PCBs, respectively, if each of the seven Aroclors were at its limit, the new criterion is not more stringent than the old.

First, several of these Aroclors are not prevalent in commerce or in the environment. Aroclor 1242 alone accounted for 52 percent of U.S. PCB production, and Aroclors 1016, 1242, 1254, and 1260 together account for over 90 percent. It is, therefore, highly unlikely that the seven Aroclors would be present in similar concentrations. Second, from what we know about how PCBs degrade and partition into different environmental media and bioaccumulate in living organisms, it is unlikely that an environmental sample characterized in terms of Aroclors would resemble original Aroclor in any definable way. For example, PCBs in fish or sediment would likely contain PCB congeners of high chlorine content and, consequently, be characterized as ''like'' Aroclor 1254 or 1260, while PCBs present in water would likely contain PCB congeners of lower chlorine content and, thus, be characterized as ''like'' one or two Aroclors of lower chlorine content. Third, when environmental samples have been characterized in terms of Aroclor mixtures, experience shows that no more than two or three Aroclors are used. For these reasons, it is unlikely that an environmental sample could be characterized in terms of similar concentrations of the seven different Aroclors.

More importantly, it is not consistent with current scientific knowledge to characterize environmental PCBs as if they were Aroclors. Environmental processes can profoundly alter the composition of PCB mixtures through partitioning, chemical transformation, and preferential bioaccumulation.

E. Response to Issues Identified in Partial Settlement Agreement

As noted above, in the Partial Settlement Agreement EPA agreed to consider specific issues identified by the plaintiffs in developing the proposed rule.

1. The effect that the reduction in PCB concentrations in fish due to cooking and cleaning has on the human intake of PCBs through fish consumption.

In determining the PCB criteria proposed here, EPA used the 1980 methodology consumption rate of 6.5 grams/person/day representing the estimated mean per capita freshwater/estuarine finfish and shellfish consumption rate for the U.S. population.

In methodology to be proposed for public comment in 1998, EPA expects to recommend the use of ''as consumed'' intake rates, that should reflect the potential exposure from fish consumption better than using uncooked weights. States would have the flexibility to consider raw fish consumption if they believe that the population that they are targeting are consumers of raw fish if data are limited to uncooked weights (provided an adjustment for cooking loss is made). EPA is considering several issues regarding whether to use cooked or uncooked weights when estimating the fish consumption rates. One issue concerns the fact that weight loss in cooking is typically about 20 percent. If the mass of a toxicant in the fish tissue remains constant, then the concentration in the fish tissue will increase (the weight of the fish tissue decreased). However, if the mass of toxicant in the fish tissue decreases, the concentration in the fish tissue may decrease (Zabik, et al., 1993). This issue is complicated as different chemicals accumulate in different parts of the fish. Therefore, the method of preparation and cooking can greatly affect the potential intake of the contaminant. In addition, there is the relatively unexplored area of how the cooking process may change the ''parent'' compound to a by-product, or form a different compound altogether. EPA will solicit public comment on these issues when it solicits comment on the revised methodology. Until these issues relating to fish consumption are further considered, EPA does not believe it should change the current fish consumption value for this rule.

2. Statistical analysis, including Monte Carlo analysis, of studies to determine average daily human fish consumption.

In determining the PCB criteria proposed here, EPA used the 1980 methodology consumption rate of 6.5 grams/person/day representing the estimated mean per capita freshwater/estuarine finfish and shellfish consumption rate for the U.S. population. The source of the 6.5 grams/person/day was a fish consumption survey conducted in 1973 and 1974 by the National Purchase Diaries (NPD), a market research and consulting firm specializing in the analysis of consumer purchasing behavior.

Among the anticipated proposed changes to the 1980 methodology, default fish and shellfish consumption values will be presented for the general population, for sport fishers, and for subsistence fishers, replacing the single value of 6.5 grams/day used in the 1980 Human Health guidance. For contaminants that may cause effects resulting from acute exposures, default rates will be provided for children and for women of childbearing age. The proposed revision to the 1980 methodology is expected to encourage States to use fish and shellfish intake levels derived from local data on fish and shellfish consumption in place of the default values provided. However, EPA's proposal is expected to recommend that the fish and shellfish intake level chosen be protective of highly exposed populations. EPA will solicit public comment on the proposed change when it solicits comment on the revised methodology.

3. The impact of biodegradation of PCBs in the environment in determining an appropriate water quality criterion for PCBs.

As previously mentioned, EPA has completed its reassessment of the cancer potency of PCBs. The PCB criteria proposed today were developed after finalizing the cancer reassessment document.

After release into the environment, PCB mixtures change through partitioning, biodegradation, transformation, and bioaccumulation, differing considerably from commercial mixtures. USEPA has devoted an entire section in the PCBs' Reassessment (1996) (4.1. APPLICATION TO PCB MIXTURES IN THE ENVIRONMENT, pp. 39–43) to the question of how toxicity values for commercial mixtures can be applied to mixtures in the environment.

4. The scientific basis of proposed models for establishing bioaccumulation factors (BAFs), including: (a) the extent to which such models account for the sources of PCBs to fish tissue, including the water column and various strate of sediment, and dissolved, undissolved, and adsorbed PCBs; and (b) the variability of field-calculated BAFs for PCBs among various water bodies and the reasons for such variations.

In determining the PCB criteria proposed here, EPA used the same

bioconcentration factor, 31,200 L/kg, as used in the 1980 criteria guidance document.

In the revised human health methodology, EPA expects to recommend the use of bioaccumulation factors (BAF) in place of BCFs. The revised methodology would incorporate specific characteristics and behavior of bioaccumulative chemicals. For certain chemicals where uptake from exposure to multiple media is important, the revised methodology would emphasize the assessment of bioaccumulation (i.e., uptake from water, food, sediments) over bioconcentration (i.e., uptake from water).

As an alternative to expressing ambient water quality criteria as a water concentration, under the revised human health methodology, criteria may also be expressed in terms of fish tissue concentration. For some substances, particularly those that are expected to exhibit substantial bioaccumulation, the ambient water quality criteria derived may have extremely low values, possibly below the practical limits for detecting and quantifying the substance in the water column. It may be more practical and meaningful in these cases to focus on the concentration of those substances in fish tissue, since fish ingestion would be the predominant source of exposure for these substances that bioaccumulate.

It should be noted that the changes outlined above may result in significant numeric changes in the ambient water quality criteria. EPA will continue to rely on existing criteria as the basis for regulatory and non-regulatory decisions, until EPA revises and reissues those criteria using the revised final human health criteria methodology. The existing criteria are still viewed as scientifically acceptable by EPA. The intention of the 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. Revisiting all existing criteria would require considerable time and resources. Given these circumstances, EPA intends to propose a process for revising these criteria as part of the overall revisions to the methodology for deriving human health criteria that is expected to be published in the Federal Register in 1998.

F. Regulatory Assessment Requirements

1. Executive Order (E.O.) 12866, Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51,735 (October 4, 1993)) the Agency must determine whether the regulatory action is ''significant'' and therefore 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 (E.O.) 12866 and is therefore not subject to OMB review.

2. The 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 an EPA Rule 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 EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal 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 EPA regulatory proposals with significant federal intergovernmental mandates, and 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 UMRA) for State, local, or Tribal governments or the private sector. The proposed rule imposes no enforceable duty on any State, local or Tribal governments or the private sector. This rule proposes revised ambient water quality criteria which, when combined with State-adopted designated uses constitute water quality standards for those water bodies with adopted uses. Therefore, the proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. As stated above, the rule imposes no enforceable requirements on any party, including small governments. Moreover, any water quality standards, including those proposed here apply broadly to waters in the States and may potentially affect any discharger to such waters and, therefore, will not uniquely affect small governments. Additionally, the proposed rule results in ambient water quality criteria for human health that are less stringent than those currently in the NTR and therefore any effects on small governments should be reduced by adoption, and future implementation by the States. Thus, this proposed rule is not subject to the requirements of section 203 of UMRA.

3. Executive Order 12875, Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or Tribal government unless the Federal Government provides the necessary funds to pay the direct costs incurred by the State, local or Tribal government or EPA provides the Office of Management and Budget a description of the extent of the Agency's's prior consultation and written communications with representatives of affected State, local and Tribal governments, the nature of

their concerns, and an Agency statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and Tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

For the same reasons as stated above in section E.2, EPA has determined this proposed rule does not impose federal mandates on State, local or Tribal governments. Thus, today's proposed rule is not subject to E.O. 12875.

4. The Regulatory Flexibility Act (RFA) as Amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996

Under the RFA, (5 U.S.C. 601 *et seq.*), as amended by SBREFA, EPA generally is required to conduct an initial regulatory flexibility analysis (IRFA) describing the impact of the regulatory action on small entities as part of proposed rulemaking. However, under section 605(b) of the RFA, if the Administrator for the Agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare an IRFA. Pursuant to section 605(b) of the RFA, 5 U.S.C. 605(b), the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, the Agency did not prepare an initial regulatory flexibility analysis.

The RFA requires analysis of the impacts of a rule on the small entities *subject to the rule's requirements. See United Dates Distribution Companies* v. *FERC*, 88 F.3d 1105, 1170 (D.C. Cir. 1996). Today's rule establishes no requirements applicable to small entities, and so is not susceptible to regulatory flexibility analysis as prescribed by the RFA . (''[N]o [regulatory flexibility] analysis is necessary when an agency determines that the rule will not have a significant economic impact on a substantial number of small entities *that are subject to the requirements of the rule*, ''*United Distribution* at 1170, *quoting Mid-Tex Elec. Co-op* v. *FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985) (emphasis added by *United Distribution* court)). The Agency is thus certifying that today's rule will not have a significant economic impact on a substantial number of small entities, within the meaning of the RFA.

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. 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 program. The CWA requires that all NPDES permits must include any limits on discharges that are necessary to meet state water quality standards. The States have discretion in deciding how to meet the water quality standards and in developing discharge limits as needed to meet the standards. While State implementation of federally-promulgated water quality criteria or standards may result in new or revised discharge limits being placed on small entities, the criteria or standards themselves do not apply to any discharger, including small entities.

Today's proposed rule as explained above, does not itself establish any requirements that are applicable to small entities. As a result of this action, the States will need to ensure that permits they issue include any limitations on dischargers necessary to comply with the water quality standards established by the criteria in today's proposed rule. In so doing, States will have a number of discretionary choices associated with permit writing. While 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.

Furthermore, today's proposed rule results in ambient water quality criteria for human health that are less stringent than those currently in the NTR. Consequently, the economic effect of today's proposed rule should be positive in States subject to the NTR. Any adverse economic impact on small entities associated with measures taken to implement the current PCB criteria of the NTR should be reduced by adoption of the proposed revision.

5. The Paperwork Reduction Act

This proposed rule requires no new or additional information collection activities subject to the Paperwork Reduction Act, (44 U.S.C. 3501 *et seq.*) Therefore, no Information Collection Request will be submitted to the Office of Management and Budget for review.

6. National Technology Transfer and Advancement Act (NTTAA)

Under Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), the Agency is required 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, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through the Office of Management and Budget, an explanation of the reasons for not using such standards.

The Agency does not believe that this proposed rule addresses any technical standards subject to the NTTAA. A commenter who disagrees with this conclusion should indicate how today's notice is subject to the NTTAA and identify any potentially applicable voluntary consensus standards.

7. EO 13045—Protection of Children From Environmental Health Risks and Safety Risks

On April 21, 1997, the President issued Executive Order 13045 entitled Protection of Children From Environmental Health Risks and Safety Risks (62 FR 19883). Under section 5 of the Order, a federal agency submitting a ''covered regulatory action'' to OMB for review under Executive Order 12866 must provide information regarding the environmental health or safety affects of the planned regulation on children. A ''covered regulatory action'' is defined in section 2–202 as a substantive action in a rulemaking, initiated after the date of this order or for which a Notice of Proposal rulemaking is published 1 year after the date of this order, that is likely to result in a rule that may: be ''economically significant'' under Executive Order 12866 and concern an environmental health risk or safety risk that any agency has reason to believe may disproportionally affect children. As discussed below, this final rule is not a ''covered regulatory action'' as defined in the Order and accordingly is not subject to section 5 of the Order.

This proposed rule does not meet the threshold requirement for a ''covered regulatory action.'' This Notice of Proposed Rulemaking will be published prior to April 21, 1998, and, as discussed in paragraph E.1 above, is not a significant rule under Executive Order

12866. While this proposal is not subject to E.O.13045, we note that this proposed water quality criteria is selected to be protective of sensitive subpopulations, including children.

List of Subjects in 40 CFR Part 131

Environmental protection, Water pollution control, Water quality standards, Toxic pollutants.

Dated: March 27, 1998.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble title 40, chapter I part 131 of the Code of Federal Regulations is proposed to be 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.*

2. Section 131.36 is amended:

a. The table in paragraph (b)(1) is amended by revising the entries for 119, 120, 121, 122, 123, 124, 125, by adding an entry and revising the total number of criteria at the end of the table, and adding footnote q. (Footnotes d, and g are republished for the convenience of the reader.)

b. Paragraph (d)(3)(ii) is amended by revising entries ''B2'' and ''C2'' under the heading ''Applicable Criteria''.

c. Paragraph (d)(9)(ii) is amended by revising entry ''B2'' under the heading ''Applicable Criteria'' to read as follows:

§ 131.36 Toxics criteria for those states not complying with Clean Water Act Section 303(c)(2)(B).

* * * * *

(b)(1) * *

A		B Freshwater		C Saltwater		D Human health (10^6 risk for carcinogens for consumption of:	
(No.) Compound	CAS No.	Criterion maximum conc. d (µg/L) B1	Criterion continuous conc. d (µg/L) B2	Criterion maximum conc. d (µg/L) C1	Criterion continuous conc. d (µzg/L) C2	Water & organism (µg/L) D1	Organisms only (µg/L) D2
*	*	*	*	*		*	*
119 PCB–1242	53469219		0.014 g		0.03 g		
120 PCB–1254	11097691		0.014 g		0.03 g		
121 PCB–1221	11104282		0.014 g		0.03 g		
122 PCB–1232	11141165		0.014 g		0.03 g		
123 PCB–1248	12672296		0.014 g		0.03 g		
124 PCB–1260	11096825		0.014 g		0.03 g		
125a PCB–1016	12674112		0.014 g		0.03 g		
125b Polychlorinated biphenyls (PCBs)			0.014 g		0.03 g	0.00017 q	0.00017 q
Total No. of Criteria (h)=		24	29	23	27	85	84

Footnotes:

* * * * * * *

d. Criteria Maximum Concentration (CMC) = the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time (1-hour average) without deleterious effects. Criteria Continuous Concentration (CCC) = the highest concentration of a pollutant to which aquatic life can be exposed for an extended period of time (4 days) without deleterious effects. µg/L = micrograms per liter.

* * * * * * *

g. Aquatic life criteria for these compounds were issued in 1980 utilizing the 1980 Guidelines for criteria development. The acute values shown are final acute values (FAV) which by the 1980 Guidelines are instantaneous values as contrasted with a CMC which is a one-hour average.

* * * * * * *

q. This criterion applies to total PCBs (i.e., the sum of all congener or all isomer analyses).

* * * * * * *

(d) * * *

(3) * * *

(ii) * * *

Use classification	Applicable criteria
* * *	* *
	Column B2—all except #105, 107, 108, 111, 112, 113, 115, 117, 118, 119, 120, 121, 122, 123, 124, and 125a.
* * *	* *
	Column C2—all except #105, 107, 108, 111, 112, 113, 115, 117, 118, 119, 120, 121, 122, 123, 124, and 125a.
* * *	* *

(9) * * *

(ii) * * *

Use classification	Applicable criteria
* * *	* *
	Column B2—all except #9, 13, 105, 107, 108, 111–113, 115, 117, 119–125a and 126; and
* * *	* *

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[MD Docket No. 98–36; FCC 98–40]

Assessment and Collection of Regulatory Fees For Fiscal Year 1998

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing to revise its Schedule of Regulatory Fees in order to recover the amount of regulatory fees that Congress has required it to collect for fiscal year 1998. Section 9 of the Communications Act of 1934, as amended, provides for the annual assessment and collection of regulatory fees. For fiscal year 1998