ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL–6450–5]

RIN 2040–AD27

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: Final rule.

SUMMARY: The Clean Water Act (CWA) requires States to adopt numeric criteria for priority toxic pollutants for which EPA has published criteria guidance if the discharge or presence of such pollutants could reasonably be expected to interfere with the designated uses of the State's 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 issuing 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. The revised criteria will apply in: Alaska, District of Columbia, Kansas, Michigan, Nevada, New Jersey, Puerto Rico, Rhode Island, Vermont and Washington.

EFFECTIVE DATE: This rule shall be effective December 9, 1999.

ADDRESSES: The public may inspect the administrative record for this rulemaking and all public comments received on the proposed rule at the Water Docket, East Tower Basement, USEPA, 401 M St., S.W., Washington, D.C. The record is available for inspection from 9:00 to 4:00 p.m., Monday through Friday, excluding legal holidays. 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.

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A. Who Is Potentially Affected by the National Toxics Rule?

Dischargers of PCBs to waters of the United States in States and jurisdictions subject to the National Toxics Rule (NTR) could be affected by this rule. National Toxics Rule States include: Alaska, District of Columbia, Kansas, Michigan, Nevada, New Jersey, Puerto Rico, Rhode Island, Vermont and Washington. These dischargers may be affected since water quality criteria are part of water quality standards that, in turn, are used in developing National Pollutant Discharge Elimination System (NPDES) permit limits. Categories of pollutant dischargers that may ultimately be affected include:

Category	Examples of potentially affected entities
Industry	Industries discharging to waters of 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 if PCBs are found in their pollutant discharges. To determine whether your facility, company, business, or organization 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. 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. What Is the National Toxics Rule?

The Clean Water Act (CWA) requires States to adopt numeric criteria for priority toxic pollutants if EPA has published criteria guidance and if the discharge or presence of these pollutants could reasonably be expected to interfere with the designated uses of the State's waters. In 1992, EPA ''promulgated'' or put into force of law, 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 (57 FR 60848, December 22, 1992, incorporated in the Code of Federal Regulations at 40 CFR 131.36). These States and jurisdictions had not adopted adequate numeric criteria for pollutants necessary to comply with the Clean Water Act.

C. Why Is EPA Revising the National Toxics Rule?

Among the criteria promulgated in the NTR were PCB criteria to protect human health. These criteria were based on procedures 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 (GE) 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. (*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 a number of activities underway that could have led to a revision of the criteria, 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. EPA and the plaintiffs entered into a partial settlement agreement in which EPA agreed, among other things, to a schedule for completing the cancer reassessment. See ''Partial Settlement Agreement,'' Consolidated Case No. 93–0694 RMU, D.D.C, signed November 7, 1995.

EPA also agreed that within 18 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 cancer reassessment in September 1996, (''PCBs: Cancer Dose-Response Assessment and Applications to Environmental Mixtures'' (EPA 600/P–96/001F). This report shows how information on toxicity, tendencies and environmental processes can be used together to evaluate health risks from PCBs in the environment. EPA also considered several issues identified by the plaintiffs. In accordance with the terms outlined in the partial settlement agreement, EPA proposed revisions to the NTR human health criteria for PCBs on March 27, 1998 (63 FR 16182, April 2, 1998). In today's document, EPA is amending the PCBs human health criteria in the NTR.

D. Why Did EPA Change the Human Health Criteria for PCBs?

What Are PCBs and Why are They a Problem in the Environment?

Polychlorinated biphenyls or PCBs are a group of chemicals that contain 209 individual compounds known as ''congeners.'' Commercial PCBs are mixtures of congeners 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 also contribute to the slow degradation 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 continue in use, primarily in electrical capacitors and transformers.

In the environment, PCBs 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. Partitioning is the separation of a chemical into different environmental media, such as fish tissue or sediments. Preferential bioaccumulation is the affinity for a congener to accumulate in one type of environmental media over another. Some PCB congeners can accumulate in living organisms. PCBs are widespread in the environment because of past contamination, and humans are exposed through multiple pathways including ambient air, drinking water, and diet.

How Were the Criteria for PCBs Developed?

The PCBs criteria included in the NTR were based on a single dose-response slope factor (7.7 per mg/kg-d average lifetime exposure); this was the value included in EPA's Integrated Risk Information System (IRIS, www.epa.gov/ngispgm3/iris/irisdat) at that time. A slope factor is a means of indicating the relevant potency of a cancer causing chemical. This slope factor value was derived from a rat feeding study by Norback and Weltman (1985), one of several studies of a commercial mixture called Aroclor 1260. Because there was no agreed-upon basis for reflecting differences among environmental mixtures, the 7.7 per mg/kg-d slope factor was used for all PCBs and PCB mixtures. As noted above, GE challenged the PCB criteria, disagreeing with 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 agreed to complete a reassessment of the cancer potency factor for PCBs .

What's Different About the New Cancer 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 that can decrease or increase toxic potency of an environmental mixture. EPA's new assessment considered all cancer studies (which used commercial mixtures only) including a new study of four different commercial mixtures (Aroclors) that strengthens the case that all PCBs mixtures can 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 range 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 guidance matches slope values from the range to exposure pathway (*e.g.*, food chain) by using a ''tiered approach'' which attributes higher risk to exposure through the food chain compared to other exposures. 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 toxicity (Safe, 1994). 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). Because it considers consumption of contaminated fish to be the dominant source of PCB exposure, EPA proposed and has decided to use 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 cancer risks associated with early life exposure to PCBs.

The cancer reassessment was subject to peer review by a group of experts from outside the Agency. See ''Report on Peer Review Workshop on PCBs: Cancer-Dose Response Assessment and Application to Environmental Mixtures,'' May 1996.

How Are Today's Human Health Criteria for PCBs Calculated?

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

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

Where:
RF = Risk Factor = 1×10 (−6)
BW = Body Weight = 70 kg
q1* = Cancer slope factor = 2 per mg/kg-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 total PCBs. See ''PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures'' (EPA 600/9–96–001F). The body weight and water consumption factors are discussed in 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). The BCF is discussed in the 304(a) criteria guidance document for PCBs (''Ambient Water Quality Criteria for Polychlorinated Biphenyls,'' EPA 440/5–80–068) (1980).

In developing today's criteria EPA relied on the currently available Human Health Guidelines (45 FR 79347, November 28, 1980). However, EPA recently proposed revisions to the methodology it uses to derive water quality criteria for human health (63 FR 43755, August 14, 1998). When the proposed revisions are finalized, EPA expects to recommend the use of bioaccumulation factors (BAFs) in place of bioconcentration factors (BCFs). For certain chemicals including PCBs, the revised methodology would emphasize the assessment of bioaccumulation (*i.e.*, uptake from water, food, sediments) over bioconcentration (*i.e.*, uptake from water only). The change outlined above may result in a significant numeric change in the ambient water quality criteria for PCBs. For PCBs and other bioaccumulative chemicals, BAFs may be developed which are orders of magnitude greater than the BCFs developed in 1980. This would likely result in a criterion which is orders of magnitude more stringent, if all other parameters (such as q1*s) remain constant.

Why Are the Criteria Now Expressed as Total PCBs?

In its 1998 proposal, EPA offered a different approach for expressing human health criteria for PCBs. Human health criteria would no longer be based on individual Aroclors, but rather on total PCBs concentrations. In the environment, PCBs occur as mixtures of congeners but these are different in composition than commercial mixtures (Aroclors). This is because PCB mixtures can change over time through partitioning among different environmental media (*e.g.*, water, sediment), by chemically transforming or preferentially bioaccumulating. Therefore, it can be imprecise and inappropriate to characterize environmental mixtures in terms of Aroclors (EPA, 1996). It is the Agency's view that expressing the criteria in terms of total PCBs rather than individual Aroclors better reflects current scientific thought (See: ''PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures,'' ''Assessing the cancer risks from environmental PCBs'' (Cogliano, 1998) and the proposed PCBs criteria in the California Toxics Rule, 62 FR 42160, August 5, 1997).

E. Can an NTR State Develop Site-Specific Criteria

EPA prefers that States maintain primacy, revise their own standards, and achieve full compliance, but in order to achieve primacy, States must first be removed from the NTR. Removal of a State from the NTR requires rulemaking by EPA according to the requirements of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). For example, both Rhode Island and Vermont have adopted criteria, including criteria for PCBs, required by CWA 303(c)(2)(b). EPA approved the state adoptions and will be initiating action to remove both Rhode Island and Vermont from the NTR in the near future. Pending completion of this action, nothing in this rule preempts these States' authority to implement any more stringent State criteria for PCBs. (See section 510 of CWA).

A State cannot derive site-specific criteria for pollutants for which EPA has established standards in the National Toxics Rule. Promulgation of the NTR removed most of the flexibility available to the affected States for modifying their standards on a discharger-specific or stream-specific basis. For example, site-specific criteria for human health are precluded for NTR States unless there is a Federal rulemaking in that State to change the Federal rule for that State, or unless the State adopts a more stringent criteria pursuant to CWA section 510, which as a practical matter would override the less stringent NTR criteria.

EPA will withdraw the promulgated criteria in the NTR by rule without a notice and comment, when a State adopts standards no less stringent than the NTR (*i.e.*, standards which provide, at least, equivalent environmental protection). However, if a State adopts standards for toxics which are less stringent than the Federal rule but, in the Agency's judgment fully meet the requirements of the Act, EPA will propose to withdraw the NTR criteria with a notice of proposed rulemaking and provide for public participation. Thereafter the Agency will issue a final rule.

A State may want to develop site-specific human health criteria for PCBs when exposure information indicates that an alternate cancer slope factor is appropriate. As mentioned above, EPA's 1996 cancer assessment for PCBs uses information on environmental processes to provide guidance on choosing an appropriate cancer slope factor from a range of slope factors. An ''upper bound'' potency factor, such as the 2 per mg/kg-d used in this rule, is appropriate for food chain exposure, sediment or soil ingestion, and dust or aerosol inhalation pathways. These are exposure pathways where environmental processes tend to increase risk. Lower potencies are appropriate for ingestion of water-soluble congeners or inhalation of evaporated congeners. These are pathways where environmental processes tend to decrease risk (EPA, 1996).

F. Response to Public Comments

As noted above, EPA published proposed revisions of the PCB human health criteria in 1998. EPA received several comments from the public and significant comments are addressed in this section.

1. One commenter asked for more time in which to prepare additional materials for submission.

Response: EPA did not agree that revisions of the PCB criteria should be delayed based upon the expectations of future analyses of epidemiological data. EPA realizes that scientific information is constantly evolving. Additional research is always being done and test

methods and theories improve. There can be a long lag time between conducting the research, analyzing data, issuing a criteria or risk assessment for peer review, incorporating peer review comments and working through the State or Federal administrative processes to adopt water quality standards. There comes a point in this process, where the administering agencies, both EPA and the States, have to act using the existing criteria recommendations based on the methodology by which they are derived, and put standards into place to assist the implementation of control programs to protect the health of the public and the environment.

In this instance, EPA has completed a cancer reassessment for PCBs and has subjected that analysis to extensive scientific analysis and debate, including an external peer review. EPA believes this reassessment provides a strong scientific basis for revision of the PCBs human health criteria. Commenters have not provided EPA with epidemiological data or other information sufficiently compelling for EPA to delay amending the NTR to incorporate the revised criteria. Accordingly, it is EPA's view that the promulgation process should go forward.

2. Two commenters did not agree that the proposed rule results in ambient water quality criteria for human health that are less stringent than those currently in the NTR.

Response: The Agency does not believe that the new criteria based on total PCBs are more stringent. As discussed above, and in the 1998 proposed rule, the new human health criteria specify concentration limits of 0.00017 µg/L for total PCBs, in contrast to the old criterion of 0.000044 µg/L for each of seven different Aroclors. The old criteria would, in theory, have allowed 0.000308 µg/L total PCBs if each of the seven Aroclors were at its limit. EPA does not believe this is a reasonable assumption. The new criterion is not more stringent than the old because several of the 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 accounted for over 90 percent. Thus, it is highly unlikely that all seven Aroclors would be present in similar concentrations. Further, from what we know about how PCBs degrade and partition into different environmental media and bioaccumulate in living organisms, environmental PCBs do not look like the seven industrial Aroclors at their limits. For example, PCBs in fish or sediment would contain PCB congeners of high chlorine content and be characterized as ''like'' Aroclor 1254 or 1260. PCBs in water would contain PCB congeners of lower chlorine content and be characterized as ''like'' one or two Aroclors of lower chlorine content. This conclusion is confirmed when environmental samples are characterized in terms of Aroclor mixtures; experience shows that no more than two or three Aroclors are used. Accordingly, it is unlikely that an environmental sample could be characterized in terms of similar concentrations of the seven different Aroclors.

3. Several commenters prefer criteria for individual Aroclors stating that the proposed criteria based on total PCBs were inappropriate. Their objections include:

(a) Only one slope factor and one BCF were used to derive the criteria rather than different slope factors and BCFs for each individual Aroclor;

(b) Environmental samples are likely to contain the four most common Aroclors and the proposed criterion is equal to the sum of these four most common Aroclors;

(c) Criteria based on total Aroclors are inaccurate because formulations in different lots can differ by 2–5 fold for many PCB congeners, making even Aroclor estimated PCB levels inconsistent with each other if different lots of a formulation are used in different labs;

(d) Differences between environmental samples and commercial mixtures make accurate summations of Aroclors difficult and therefore it is unlikely that an accurate estimation can be made of total PCBs (*i.e.*, total Aroclors);

(e) Criteria based on sum of PCBs are too stringent because monitoring programs and analytical labs quantify PCBs as multiple Aroclor formulations, and the sum of PCBs would exceed the proposed total criteria;

(f) PCB congeners are shared by several Aroclors, thus, measuring total Aroclors could double or triple count some congeners leading to inaccurately high total PCB levels;

(g) It is not possible to characterize PCB congeners as ''like'' Aroclors and it is unlikely that an accurate estimate can be made of total PCBs; and

(h) It is not appropriate to develop a single criterion because the Agency does not expect to find all seven Aroclors in significant quantities in samples.

Response: The Agency does not agree that individual criteria for each Aroclor should be maintained. The revised PCB criteria were derived using a single cancer potency factor and a single bioconcentration factor (BCF) because as discussed below, in the Agency's view, this approach protects against the major exposure pathway of concern, consumption of contaminated fish and shellfish.

The Agency adopted an approach in its new cancer reassessment, ''PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures'' (EPA, 1996) (EPA 600/P–96/001F), that distinguishes among PCB mixtures by using information on environmental processes to provide guidance in choosing appropriate slope factors for representative classes of environmental mixtures and different exposure pathways. In this methodology, exposure through the food chain is associated with higher risks than other exposures. Preferential bioaccumulation through the food chain tends to concentrate certain highly chlorinated congeners which are often among the most toxic and persistent. Thus, EPA chose a cancer potency factor of 2 per mg/kg-d, the upper bound slope factor, to calculate the revised human health criteria. Humans can be exposed to PCBs through the food chain which is an exposure pathway where environmental processes are likely to increase risk.

EPA uses a single bioconcentration factor (BCF), from the 1980 criteria guidance document, ''Ambient Water Quality Criteria for Polychlorinated Biphenyls,'' (EPA 440/5–80–068), to derive the criteria for today's rule. This BCF, 31,200 L/kg, was derived from data from 21 studies of several different Aroclors and two specific congeners and in the Agency's view represents an average bioaccumulation factor for PCBs in all freshwater fish and shellfish.

EPA recently proposed revisions to the methodology it uses to derive water quality criteria for human health (63 FR 43755, August 14, 1998). In the revised human health methodology, EPA expects to recommend the use of bioaccumulation factors (BAFs) in place of BCFs. However, until the proposed changes to the human health methodology are finalized, EPA will continue to rely on existing criteria or components (*e.g.*, BCFs or q1*s) of existing criteria as the basis for regulatory and non-regulatory decisions. Until EPA revises and reissues the criteria or component using the revised human health methodology the existing criteria or components are viewed as scientifically acceptable by EPA.

The fact that the Agency changed its approach from one where each Aroclor had its own criterion to one where a single criterion applies to total PCBs does not stem from the fact that not all Aroclors are likely to be present in the environment at significant concentrations as a commenter would suggest. As mentioned above, the Agency changed its approach for regulating PCBs because PCBs degrade, partition, transform and selectively bioaccumulate in living organisms. The Agency agrees it is unlikely that an environmental sample characterized in terms of Aroclors would resemble an original Aroclor mixture in any definable way. This is why the Agency stated that if an environmental sample was characterized in terms of Arolors it could only be characterized as ''like'' a particular Aroclor. It is difficult to characterize environmental samples in terms of Aroclors.

The Agency agrees that characterizing environmental samples in terms of Aroclors can result in under or overestimating PCBs. In measuring PCB concentrations in terms of Aroclors, certain ratios of characteristic congeners are considered representative of a particular Aroclor. When these characteristic congeners are detected in appropriate ratios, they are quantified as a certain Aroclor. Because some congeners are present in more than one Aroclor, there is a possibility of double (or triple) counting a particular congener in quantifying an Aroclor. There are techniques available to minimize double counting though, such as use of two different gas chromatograph (GC) columns or adjusting instrument conditions to get sufficient separation of peaks. These techniques allow an analyst to view samples on different chromatographs at slightly different retention times in order to minimize interference from overlapping peaks. Analysts also exercise ''Best Professional Judgment'' in selecting the appropriate peaks for use in quantifying samples in order to minimize quantification errors.

The possibility of underestimating total PCB concentrations using Aroclor analyses also exists. In cases where congeners are detected in environmentally altered mixtures but not in characteristic ratios, the congeners detected may not be quantified because they do not resemble a particular Aroclor. In this case Aroclor measurements would underestimate concentrations of total PCBs present.

EPA agrees that Aroclor formulations may vary substantially by lot (*e.g.*, percent of a particular congener present). Measuring congener concentrations rather than Aroclor concentrations eliminates problems associated with congener weight percent variations between different lots of a particular Aroclor formulation. Congener analyses are not impacted by variations between formulations. Aroclor analyses can be influenced by lot-to-lot variations due to the difference in using specific congeners as calibration standards versus using Aroclors for calibration standards.

4. One commenter states that EPA bases the new PCB criteria on only one or a couple of unspecified, highly chlorinated Aroclors, and not all Aroclors. The commenter believes that EPA should apply the criteria to individual Aroclors or the combination most like that which is found in the samples.

Response: The Agency does not agree that the new PCB criteria are based on only one or a couple of unspecified, highly chlorinated Aroclors. The risk-assessment used as the basis for this rulemaking, ''PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures,'' is based on a range of potency estimates, developed using studies for a range of mixtures (commercial mixtures only), instead of focusing only on the highest-potency mixture. Section 2 of the risk assessment provides brief summaries on the studies used in developing the dose-response assessment.

Again, as discussed above in Response #3, it is the Agency's view that human health water quality criteria for PCBs should be expressed in terms of total PCBs rather than on individual Aroclors.

5. One commenter disagrees with EPA's statement that, ''Some PCBs congeners can accumulate selectively in living organisms'' (63 FR 16184.) The commenter considers this statement an unfair generalization and asks EPA to identify the specific congeners that selectively accumulate in various classes of living organisms and those that do not.

Response: Accumulation patterns can vary by species and location. One compilation of bioaccumulation information cited in the reassessment was done by McFarland and Clarke (1989). EPA's reassessment also cites other studies that show retention and bioaccumulation of specific congeners.

6. The commenter asks EPA to clarify its use of the term ''toxic'' in the statement, ''It is noteworthy that bioaccumulated PCBs appear to be more toxic than commercial PCBs . . .'' (63 FR 16184). If the reference is to carcinogenicity, the commenter states that this statement is speculation and has not been scientifically demonstrated in human or animal studies.

Response: Recent animal studies (Mayes, 1998) with commercial mixtures have demonstrated that every PCB mixture tested poses a risk of cancer. The commercial mixtures tested by Brunner *et al.*, (1996, later published by Mayes (1998)), Aroclor 1016, 1242, 1254 and 1260, together accounted for over 90 percent of the U.S. PCB production. These four commercial mixtures contain overlapping groups of congeners that, together span the range of congeners most often found in environmental mixtures (Cogliano, 1998). Commercial mixtures of PCBs can cause cancer and environmental mixtures contain subsets of congeners from commercial mixtures.

Preferential bioaccumulation of PCBs can occur in humans, fish and wildlife. PCBs are highly soluble in lipids and are absorbed by organisms. Different species in the food chain retain persistent congeners that prove resistant to metabolism and elimination (Oliver and Niimi, 1988). While persistence is not synonymous with toxicity, in the absence of testing on most congeners, it is reasonable to suppose some correlation between persistence and toxicity (EPA, 1996), because persistence of PCBs in the body can enhance the opportunity for congeners to express tumor promoting activity (Safe, 1994).

7. A commenter disagrees with Dr. Wiltse's (EPA) statement that ''cancer risk assessment for PCBs is beyond the scope of this rulemaking.''

Response: The actual statement Dr. Wiltse made in replying to a request for an extension to the comment period for this rulemaking (see comment #1 above), based on the expectation of the future availability of an analysis of epidemiological data was:

> Revisions to the cancer risk assessment used as the basis for this proposed rule (''PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures,'' September 1996) may be considered in the future based on the epidemiological data provided by The General Electric Company or other new data on PCBs. However, revising the entire cancer risk assessment for PCBs is beyond the scope of this rulemaking action and is not feasible prior to

promulgation of this specific action on the NTR.

As noted in its response to comment #1 above, the Agency recently completed a major reassessment of all the available data for PCBs (EPA 1996) which was satisfactory to independent peer reviewers. The Agency believes this reassessment provides a strong scientific basis for revising the human health criteria for PCBs. In this rulemaking, EPA is amending the NTR to include the revised criteria as provided in the Settlement Agreement discussed above. A commenter has suggested that EPA should defer this promulgation pending analyses of new scientific information concerning risk to human health from occupational exposure to PCBs. The commenter informed the Agency that they are in the process of analyzing epidemiological data for capacitor workers exposed to PCBs and expected to have that analyses available in the near term.

EPA believes its cancer risk assessment provides a strong scientific basis for the revised PCB human health criteria. The Agency must make decisions based on the available, scientifically defensible, data. EPA does not agree that revisions of the PCB criteria should be delayed based upon the expectations of future analyses of epidemiological data.

Scientific information is constantly evolving and there can be a long lag time from conducting research and analyzing data, to preparing risk assessments and obtaining peer review, and developing human health criteria. When the commenter's analysis has been made available to the Agency, EPA will of course consider this information and any other new information. Indeed, EPA anticipates that its next assessment of PCB risks will again examine closely whether the current criteria are sufficiently protective of children given continuing research by the Agency for Toxic Substance and Disease Registry.

8. Several comments were received regarding the use of epidemiological data to generate a cancer potency factor for PCBs. The comments include the following:

(a) Cancer slope factors from epidemiological studies can be used to establish environmental standards. A cancer slope factor is calculated using the negative results of Taylor (1988), the positive results of Brown (1987), the measured cancer incidence rate, and the 95% upper confidence limit on the incremental risk rate. This results in cancer slope factors ranging from 7.7E–4 (measure, Taylor) to 1.9E–2 (95% UCL, Brown). The cancer slope factor for the Taylor study (7.7E–4) is conservatively assumed to equal the cancer slope factor for Aroclor 1242 (workers were exposed to Aroclor 1242, 1254 and 1016). Using an animal study of cancer risk (Mayes 1998) which concluded that Aroclor 1260 is 5 times as potent as 1242, the suggested environmental standard would be 3.8E–3 per mg/kg/day (5 * 7.7E–4). This standard is 519 times greater than the proposed value.

(b) Any cancer slope factor calculated from epidemiological studies which reported air concentrations would overestimate cancer risk of PCBs. Air concentrations would significantly underestimate exposure since dermal exposure and incidental ingestion also form significant exposure routes. Dermal exposure studies, despite uncertainty in quantifying dermal absorption of PCBs, can be used to estimate PCB exposure if conservative assumptions are used as in the Terra (1993) analysis.

(c) EPA has not thoroughly reviewed the epidemiological studies performed to date or considered how they can be used in risk assessment. Specifically, EPA should consider the numerous epidemiological studies performed on populations with extensive workplace exposure to PCBs which do not support the proposition that PCBs cause cancer in humans or lead to increased mortality from cancer. Also, given the uncertainty in cancer dose response modeling, the Agency should reexamine the evidence for carcinogenic risk that can be derived from human epidemiological studies.

(d) It has been stated that epidemiological studies are not as statistically robust as animal studies, however, the commenter states, in many cases human epidemiological data should be used to validate, confirm, or set upper bound estimates of carcinogenic potency. In general when epidemiological data are available, it is not appropriate to accept only the result of mathematical models that analyze rodent data without serious consideration to the human experience (Cook, 1982; Dinman and Sussman, 1983; Layard and Silvers, 1989). Animal studies (rat feeding studies) may indicate cancer in rats, but there may not be a direct transfer of cancer incidence in humans, particularly at environmental or occupational exposure levels. Many instances exist of chemicals that are potent rodent carcinogens but do not pose an equivalent cancer hazard in humans.

Response: The commenters' arguments and studies they cite were available at the time EPA drafted its reassessment. EPA as well as the external panel that reviewed EPA's reassessment concluded that epidemiological data are inadequate for use in a quantitative risk assessment. The external panel strongly recommended that EPA base its reassessment on the Brunner *et. al.,* (1996) study, that was later published by Mayes (1998). EPA's quantitative assessment reflects the advice of the external panel in this regard. (See: ''Report on Peer Review Workshop on PCBs: Cancer-Dose Response Assessment and Application to Environmental Mixtures,'' May 1996.)

9. The commenter suggests that EPA use state-of-the-art methodology for interpreting the results of epidemiological studies, particularly a weight-of-the-evidence test and ''causation analysis.'' Additionally, the commenter notes that studies which have larger cohorts and numbers of cancer deaths are inherently more important than are studies with smaller cohorts and fewer deaths when applying the weight-of-the-evidence test.

Response: The Agency uses the weight-of-evidence approach for interpreting the results of the epidemiological studies. The epidemiological studies have been found to provide limited (IARC, 1987) to inadequate (EPA, 1988) evidence of carcinogenicity. The overall conclusion, however, uses the weight-of-evidence approach on the entire data base, human and animal. Recent animal tests, Mayes (1998), have demonstrated that every PCB mixture tested poses a risk of cancer.

The Agency does note that cohort size is one of the many factors that goes into a weight-of-evidence analysis. Weight-of-evidence analyses also include exposure factors such as exposure level, exposure duration and lack of confounding exposure.

10. The commenter notes that it is unclear how the inclusion of noncarcinogenic Aroclors (1016 and 1254) in the total PCB criteria affects compliance determinations as human health criteria are based on cancer potential. The commenter suggests that their inclusion would over-estimate the risk to human health. This issue supports the argument for the development of individual criteria for individual Aroclors rather than for total PCBs.

Response: The Agency does not agree with the commenter that Aroclors 1016 and 1254 are non-carcinogenic. The 1996 cancer dose-response assessment for PCBs includes new data from Brunner *et al.,* (1996) in which rats fed

diets containing Aroclors 1260, 1254, 1242 or 1016 were found to have statistically significant, dose-related, increased incidences of liver tumors from each mixture. The Mayes (1998) data indicate that Aroclor 1254 was the most potent of the four mixtures tested.

As previously discussed, the 1996 cancer dose-response assessment does acknowledge that overall, human studies are considered to provide limited (IARC, 1987) to inadequate (EPA, 1988) evidence of carcinogenicity. This notwithstanding, animal studies are considered to provide sufficient evidence of carcinogenicity and thus some commercial PCB mixtures have been characterized as probably carcinogenic to humans based on these findings (IARC, 1987; EPA, 1988) (EPA, 1996). The Agency does not agree that inclusion of Aroclors 1016 and 1256 in the total PCB determinations over-estimates the risk posed to humans.

Although there is sufficient evidence of carcinogenicity for Aroclor 1016 and 1254, Aroclor 1016 was found to have a several-fold lower potency compared to Aroclor 1242 (Brunner *et al.*, 1996). The approach adopted in the 1996 cancer reassessment for PCBs does account for differences in potency by establishing a range of dose-response slopes. Information on environmental processes is then used to provide guidance on choosing the appropriate slope factor to apply. Likewise, the Agency recognizes that not all environmental mixtures are regarded as equally potent; environmental mixtures differ from commercial mixtures and from each other (EPA, 1996).

11. EPA acknowledges that the mode of action of PCBs is promotional. Therefore, PCBs should be considered as epigenetic carcinogens and assessed with a margin of exposure approach rather than by the linear 95th%ile carcinogenicity modeling appropriate for genetic toxins.

Response: Although genetic activity testing for PCBs is generally negative, the mode of action of PCBs has not been established. In such a case, it is appropriate to use a linear extrapolation under EPA's existing 1986 cancer guidelines. This would also be the case under the Agency's 1996 proposed cancer guidelines. Moreover, at low doses, some PCB congeners add to the considerable background of human exposure to dioxin-like compounds and augment processes associated with dioxin toxicity, providing an expected linear component to the dose-response curve. There is also considerable background exposure to nondioxin-like congeners, so additional PCB exposure can augment other carcinogenic processes that may be operating.

12. The commenter believes that the linear method for estimating the carcinogenic potency of PCBs is likely to overestimate the low-dose carcinogenic risk of PCBs. The commenter refers to a study by Ottobonni (1984) which suggests that genotoxic agents may exhibit thresholds at low doses, thus there is considerable uncertainty in the assumption of low dose linearity for carcinogens. EPA's proposed cancer guidelines (EPA, 1996) allow for non linear low dose extrapolation in cases where the available data support a nonlinear mode of action.

Response: Linear low-dose extrapolation does, indeed, yield an upper bound on the potential risk, albeit a plausible upper bound. As discussed in the response to comment #11, there is not sufficient information available at this time to support a non linear extrapolation under the existing 1986 cancer guidelines, nor would there be under the 1996 proposed cancer guidelines.

13. The mode of action data for PCBs as tumor promoters and not initiators was not given appropriate considerations, thus EPA's reassessment completed in September 1996 was not consistent with the proposed cancer risk assessment guidelines. EPA should delete its statements claiming that the 1996 reassessment was consistent with proposed EPA cancer risk assessment guidelines.

Response: As discussed in the responses to comment #11 above, EPA did consider the mode-of-action data, concluding that there was not sufficient information available at this time to support non linear extrapolation. Moreover, several features of the 1996 reassessment were clearly motivated by the 1996 proposed cancer guidelines: developing a range of potency estimates instead of focusing on the highest-potency mixture, using the LED10/ED10 approach instead of the linearized multistage procedure, and using the cross-species scaling factor based on the ¾ power of relative body weight. Most important, however, is the reassessment's emphasis on discussing circumstances that affect cancer risks, in this case, how environmental processes alter the composition and toxicity of PCB mixtures.

14. The commenter notes difficulties in estimating human cancer risks from rodent bioassays, particularly that tumor promoters often produce rodent liver tumors in long term bioassays, but are not generally known to cause cancer in humans. Tumor promoters like PCBs selectively increase the growth of cancerous cells but do not interact to cause the initial heritable change which begins the multi-stage process of cancer.

Response: Although noting that there are uncertainties in estimating human cancer risks from any animal study, it is not correct to suggest that EPA is concerned only about substances that cause the initial heritable genetic change in cancer development. Because cancer development is a multistage process, any substance that brings about or accelerates any of these stages can increase the risk of ultimately developing cancer.

15. EPA's statement that the major pathway of exposure to PCBs is through food (63 FR 16184) is not supported by human epidemiological studies which show very similar burdens of total PCBs and congener profiles between consumers and nonconsumers of fish. Other major sources for PCBs exist and, additionally, fish consumption may not be the primary route of exposure. EPA's statement should be revised or deleted.

Response: EPA notes in its cancer risk assessment for PCBs, that PCBs are widespread in the environment and that humans are exposed to PCBs through multiple pathways. Nonetheless, recent multimedia studies indicate that the major exposure pathway to persistent toxic substances such as PCBs is through food (*i.e.*, contaminated fish and shellfish consumption). Birmingham *et al.*, (1989), Newhook (1988) and Fitzgerald *et al.*, (1996) found that fish consumption appears to be the major pathway of exposure for PCBs. The majority of peer reviewers for the PCB Cancer Dose-Response Assessment agreed that consumption of contaminated fish is considered to be the predominant source of PCB contamination for humans. Exposure to PCBs through fish consumption is associated with high risk in the revised cancer assessment for PCBs.

16. EPA's statement (63 FR 16184) that ''all PCBs cause cancer'' implies a fact that has not yet been demonstrated. EPA considered all cancer studies which used commercial mixtures only. There is still no strong supporting evidence of carcinogenicity in humans and the PCBs tested in animals were commercial formulations, but that is not conclusive evidence that all PCB congeners are cancer-causing. Many PCB congeners are unlikely to cause cancer. The suggested revision of the statement would be ''all commercial Aroclor formulations can cause cancer in animals.''

Response: EPA's new assessment considered all cancer studies (which used commercial mixtures only) including a new study (Brunner, 1996) of four Aroclor's that strengthen the case that all PCBs cause cancer. The four mixtures used in the Brunner study contain overlapping groups of congeners that, together, span the range of congeners most often found in environmental mixtures (Cogliano, 1998). EPA used this information to develop a range of dose response slopes, changing from a single dose-response cancer potency factor to a range of slope factors. Even though the Agency developed a range of slope factors in its reassessment, a single slope factor is selected from the range, based on the likely exposure pathway, to develop a criterion.

Although animal feeding studies demonstrate the carcinogenicity of commercial PCB preparations, as discussed previously, it is not known which of the PCB congeners in such preparations are responsible for these effects, or if decomposition products, contaminants or metabolites are involved in the toxic response. In the absence of information ruling out the possibility that certain PCB isomers are not carcinogenic EPA believes it is a prudent public health policy to be conservative and regulate as if all PCBs are carcinogenic.

17. The use of a risk factor of 10^{-6} may be overly stringent. Virginia has sufficiently protective human health standards that use a risk factor of EPA 10^{-5}.

Response: EPA recognizes the primary authority of States to adopt water quality standards; and Agency policy generally allows States to select an appropriate risk level within the general range of 10^{-4} to 10^{-6}. EPA uses a 10^{-6} risk level in setting its human health water quality criteria. In order for the human health criteria to be implemented in water quality programs, a single risk level must be chosen so that a specific numeric limit is established for a pollutant. Some States use a different risk factor, and in the NTR, EPA applied the State's risk factor in calculating the criteria promulgated for that State.

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

18. EPA is using a database dated 1980 or earlier for items such as bioconcentration factor and fish consumption rate. As the revised criteria will serve as the basis for regulatory actions, the criteria should reflect the current state-of-the-science.

Response: In this rulemaking, EPA did rely on existing bioconcentration and fish consumption data. Until proposed revisions to the methodology the Agency used to derive human health criteria is finalized, the Agency will continue to rely on the existing criteria or components which are still scientifically defensible. As discussed in #1, scientific information is always evolving and EPA believes it is not in the public interest to defer action on criteria awaiting new methodology or data.

19. The proposed water quality standards for human health protection are in the part per quadrillion range and proposed aquatic standards are 14 part per trillion (ppt), but the lowest detectable concentration which the ''best'' technique has been able to measure is 40 ppt. EPA must refrain from establishing restrictive limits without providing the analytical methodology capable of achieving these levels.

Response: EPA's water quality standards regulation at 40 CFR 131.11 requires that criteria be adopted by States at concentrations necessary to protect designated uses. EPA has determined that consideration of analytical detect ability would not be an appropriate factor to consider when calculating the water quality criteria component of water quality standards. EPA's human health criteria are developed from protocols generally using toxicity studies on laboratory animals such as mice and rats. Thus, EPA criteria are effect-based without regard to chemical analytical methods or techniques. This has been the Agency's position since the inception of the water quality standards' program in 1965.

Because water quality standards developed pursuant to section 303(c) of the Clean Water Act are not self-enforcing, the measurement of these chemicals in a regulatory sense is generally in the context of an NPDES permit limitation. Although the sensitivity of analytical methods is not an appropriate basis for setting water quality criteria or water quality-based effluent limitations, analytical methods are needed for monitoring and assessing compliance with water quality-based permit limits. The permit issuing authority, either a State or EPA, establishes the analytical methodology to be used in assessing compliance with the permit limit.

20. Fin fish must be exposed to PCBs in the water column for extended periods of time to attain the levels of bioconcentration represented by the BCFs used to calculate human health criteria. Exceedance of criteria values in the water column will only result in human health impact if the tissue of the fish being consumed has reached equilibrium with the water column PCBs. Species traveling in and out of waters believed to exceed the criteria may actually contain little or no PCBs.

Response: EPA agrees that for certain highly hydrophobic congeners of PCBs, extended exposure periods are required to achieve steady-state between fish and the water column. However, the Agency does not agree that human health impacts can only occur in cases where the criteria were exceeded and fish tissue reached equilibrium with the water column. Specifically, bioaccumulation of a chemical to harmful levels in aquatic organisms can occur even if steady-state conditions have not been reached. For high log K_{OW} compounds such as certain PCB congeners, chemical concentrations in fish and other higher trophic level aquatic organisms are a function of the long-term average concentration in their environment (water exposure in the case of bioconcentration factor-based criteria). Therefore, achieving unacceptable tissue concentrations can result under non-steady conditions if the long-term average exceeds the human health criterion, which would occur if the exposures above the criterion level are not completely offset by exposures below the criterion.

In cases where chemicals and organisms require relatively long time periods to reach steady-state (such as for certain highly hydrophobic PCB congeners), the Agency would agree that migrating organisms may not be

exposed to pollutant concentrations in the water column for sufficient periods of time for tissues to reach equilibrium conditions. Under some circumstances, migration of fish in and out of marginally contaminated areas (*i.e.*, defined as those areas with water concentrations at or slightly above criteria levels) may result in tissue levels of certain highly hydrophobic PCB congeners that are below levels represented by the BCF in the human health criterion. However, this circumstance may not hold true for all organisms, PCB congeners, and exposure conditions that can exist in the United States. Moreover, in cases where organisms accumulate highly hydrophobic compounds (*i.e.*, high log K_{OW} compounds), pollutants may be retained after organisms leave an exposure area due to slow depuration. In this case, an organism could travel out of an exposure area, but retain a contaminant in its tissue.

Specifically, EPA's ambient human health water quality criteria are national in scope, they are designed to be protective of the vast majority of exposure conditions that can occur in U.S. waters. These conditions include exposure via consumption of aquatic organisms that are sedentary and do not migrate (*e.g.*, clams, oysters, mussels) in addition to consumption of other shellfish and finfish which may reside for long periods of time at a specific site (*e.g.*, bottom dwelling finfish such as flounder and catfish). Furthermore, EPA's national criteria must be protective of both open (*e.g.*, riverine) and closed (*e.g.*, reservoirs, lakes) aquatic ecosystems. In relatively closed systems such as lakes and reservoirs, migration of fish from a contaminant-influenced site may be restricted such that even highly mobile organisms can achieve unacceptable tissue burdens of PCBs as a result of marginal exceedences of EPA's PCB criteria. Finally, EPA notes that its PCB criteria apply to total PCBs which represents a mixture of PCB congeners with K_{OW}s that vary up to three orders of magnitude. Thus, some moderately hydrophobic PCB congeners can reach steady state in substantially shorter exposure periods than other highly hydrophobic congeners. Thus, the commenters' assumption that long time periods are required to reach steady state does not apply to all PCB congeners to which EPA's PCB criteria apply. Therefore, EPA believes that its national ambient water quality criteria for PCBs are set at an appropriate level of protection considering the variety of exposure conditions which may arise in U.S. waters.

21. Criteria expressed solely as fish tissue concentrations only examine the after-effects of pollution rather than ensure that designated uses are adequately protected from pollution.

Response: When proposed revisions to the human health methodology (63 FR 43756, August 14, 1998) are finalized, the Agency expects to allow ambient water quality criteria to be expressed in terms of fish tissue concentrations as an alternative to water concentrations in some cases. Particularly for substances that are expected to exhibit substantial bioaccumulation, the water quality criteria may be a very low value. Consequently, 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 substances that bioaccumulate. Even so, these fish tissue criteria would still correspond to an ambient water quality criteria (AWQC), expressed as a water concentration, calculated by multiplying the AWQC (water concentration) by the bioaccumulation factor (BAF) used to develop the AWQC. Whether concentration limits are based on a fish tissue concentration or water column concentrations will therefore make little or no difference. It could be argued that either a fish tissue concentration or water column concentration is derived to be protective, or only examines the after-effects of pollution. Both water column concentrations and fish tissue concentrations are intended to prevent harmful accumulations from occurring.

EPA may allow ambient water quality criteria for certain compounds to be expressed in terms of fish tissue concentrations when the proposed human health methodology is finalized. However, no final decisions will be made by the Agency regarding the expression of criteria in terms of fish tissue concentrations until the proposed revisions to the human health methodology are finalized.

22. The commenter suggests the use of fish tissue concentrations together with ambient criteria. While it is true that some criteria are below levels which can be reliably measured, such criteria serve a valuable purpose to prevent build-up of pollutants in fish tissues.

Response: As stated above, the Agency expects to allow ambient water quality criteria for protection of human health to be expressed in terms of fish tissue concentrations as an alternative to water concentrations when it finalizes the proposed human health methodology revisions. Expressing criteria in terms of fish tissue concentrations would allow for measurements of pollutants that would otherwise be difficult. The Agency's approach does not include both a water concentration and a fish tissue concentration, but rather, relates the water concentration to an appropriate fish tissue concentration as outlined in the proposed revisions to the human health methodology (63 FR 43756, August 14, 1998).

Again, as mentioned above, EPA may allow ambient water quality criteria for certain compounds to be expressed in terms of fish tissue concentrations when the proposed human health methodology is finalized. However, no final decisions will be made by the Agency regarding the expression of criteria in terms of fish tissue concentrations until the proposed revisions to the human health methodology are finalized.

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H. Regulatory Assessment Requirements

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

Under Executive Order 12866, (58 Federal Register 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.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action'' within the meaning of the Executive Order. As such this action was submitted to OMB for review. No changes were made as a result of OMB review.

2. The Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 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 final 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 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 rule imposes no enforceable duty on any State, local or Tribal governments or the private sector; rather, this rule establishes ambient water quality criteria which, when combined with State-adopted designated uses, will create water quality standards for those water bodies with such adopted uses. The State may use the resulting water quality standards in implementing their water quality control programs and in issuing National Pollutant Discharge Elimination System Permits. 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. As stated above, the rule imposes no enforceable requirements on any party, including small governments. Moreover, any water

quality standards, including those promulgated here, apply broadly to those dischargers and are not uniquely applicable to small governments. Thus, this rule is not subject to the requirements of section 203 of UMRA.

3. Executive Orders on Federalism

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 funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, any written communications from the governments, and a 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 H.2, EPA has determined this rule does not impose federal mandates on State, local or Tribal governments. Thus, today's rule is not subject to E.O. 12875.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, (64 FR 43255 (August 10, 1999) which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685 (October 30, 1987) on federalism still applies. This rule will not have a substantial direct effect on 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 12612.

This final rule amends the National Toxic Rule (NTR) to revise the human health water quality criteria for PCBs. EPA adopted the NTR in 1992 for those States and jurisdictions that had not established adequate numeric water quality criteria to comply with the Clean Water Act. States that adopt their own criteria will no longer be subject to the federal regulation.

4. 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 provided 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 costs on them. No Indian tribal governments are subject to the NTR and therefore are not affected by this rule. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act, EPA generally is required to conduct a regulatory flexibility analysis (RFA) describing the impact of the regulatory action on small entities as part of rulemaking. However, under section 605(b) of the RFA, if the Administrator certifies that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare a regulatory flexibility analysis. The Administrator is today certifying, pursuant to section 605(b) of the RFA, that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, the Agency did not prepare a regulatory flexibility analysis.

The RFA requires analysis of the impacts of a rule on the small entities *subject to the rules' requirements. See United States 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.

Under the Clean Water Act, 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 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 rule imposes obligations on States included in the NTR but, as explained above, does not itself establish any requirements that are directly 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 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 rule results in ambient water quality criteria for human health that are not more stringent than those formerly promulgated in the NTR. Therefore, application of today's criteria on dischargers should not impose any adverse economic impact on small entities.

6. The Paperwork Reduction Act

The final rule includes no new or additional information collection activities, therefore, no information collection request was submitted to OMB for review under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

7. National Technology Transfer and Advancement Act (NTTAA)

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Pub. L. No. 104–113 § 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, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

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

8. E.O. 13045—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 E.O. 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 reasonablely feasible alternatives considered by the Agency.

This final rule is not subject to the Executive Order because it is not economically significant as defined in E.O. 12866. Further, the Agency does not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. We have evaluated current data regarding the environmental health effects of PCBs on children. While there are no available data showing that children have an increased risk of cancer from PCBs, the Agency did consider the fact that children are a highly exposed population in the risk assessment used as the basis for this rule. Based on estimates of average daily intake for nursing infants, an average daily intake of PCBs for a 5-kg nursing infant would be about triple the average adult intake and approximately 50-fold higher when adjusted for body weight. Thus, the Agency considers nursing infants to be an important potentially highly exposed population. However, since the Agency considers carcinogenicity a function of total dose over a lifetime of 70 years the increased intake for nursing infants should not result in a disproportionate lifetime risk. Furthermore, the final water quality criteria in this rule are based on an upper bound cancer potency factor to be protective of sensitive subpopulations, including children.

Peer reviewed data on the developmental toxicity of PCBs to Rhesus monkeys is available in EPA's Integrated Risk Information System (IRIS) (available at: www.epa.gov/ngispgm3/iris/irisdat). Reference doses (RfDs) for non-cancer effects for particular Aroclors are available on IRIS, but criteria based on these RFDs would be less stringent than those promulgated today based on carcinogenicity.

The Agency is also aware of other human studies concerning the effects of PCBs on child development in locations where the mothers are consumers of fish contaminated with PCBs. However, the currently available data on children's risks to PCBs have not to date been sufficient to make full quantitative assessments of risk and preliminary analyses have not shown effects at levels that would suggest that the criteria in this rule are not protective. (Johnson *et. al., 1*999).

9. 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 action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective December 9, 1999.

List of Subjects in 40 CFR Part 131

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

Dated: September 27, 1999.

Carol M. Browner,

Administrator.

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

PART 131—WATER QUALITY STANDARDS

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

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

2. Section 131.36 is amended as follows:

a. By revising paragraph (b)(1):

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

c. Paragraph (d)(9)(ii) is amended by revising entry ''B2'' under the heading ''Applicable Criteria'' as set forth below.

The revisions read as follows:

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

* * * * *

(b)(1) EPA's Section 304(a) criteria for Priority Toxic Pollutants.

A			B Freshwater		C Saltwater		D Human Health (10^{-6} risk for carcinogens) For consumption of:	
(#)	Compound	CAS Number	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] (µg/L) C2	Water & Organisms (µg/L) D1	Organisms Only (µg/L) D2
1	Antimony	7440360					14 a	4300 a
2	Arsenic	7440382	360 m	190 m	69 m	36 m	0.018 abc	0.14 abc
3	Beryllium	7440417					n	n
4	Cadmium	7440439	3.7 e	1.0 e	42 m	9.3 m	n	n
5a	Chromium (III)	16065831	550 e	180 e			n	n
b	Chromium (VI)	18540299	15 m	10 m	1100 m	50 m	n	n
6	Copper	7440508	17 e	11 e	2.4 m	2.4 m		
7	Lead	7439921	65 e	2.5 e	210 m	8.1 m	n	n
8	Mercury	7439976	2.1 m	0.012 ip	1.8 m	0.025 ip	0.14	0.15
9	Nickel	7440020	1400 e	160 e	74 m	8.2 m	610 a	4600 a
10	Selenium	7782492	20 p	5 p	290 m	71 m	n	n
11	Silver	7440224	3.4 e		1.9 m			
12	Thallium	7440280					1.7 a	6.3 a
13	Zinc	7440666	110 e	100 e	90 m	81 m		
14	Cyanide	57125	22	5.2	1	1	700 a	220000 aj
15	Asbestos	1332214					7,000,000 fibers/L k	
16	2,3,7,8-TCDD (Dioxin)	1746016					0.000000013 c	0.000000014 c
17	Acrolein	107028					320	780
18	Acrylonitrile	107131					0.059 ac	0.66 ac
19	Benzene	71432					1.2 ac	71 ac
20	Bromoform	75252					4.3 ac	360 ac
21	Carbon Tetrachloride	56235					0.25 ac	4.4 ac
22	Chlorobenzene	108907					680 a	21000 aj
23	Chlorodibromomethane	124481					0.41 ac	34 ac
24	Chloroethane	75003						
25	2-Chloroethylvinyl Ether	110758						
26	Chloroform	67663					5.7 ac	470 ac
27	Dichlorobromomethane	75274					0.27 ac	22 ac
28	1,1-Dichloroethane	75343						
29	1,2-Dichloroethane	107062					0.38 ac	99 ac
30	1,1-Dichloroethylene	75354					0.057 ac	3.2 ac
31	1,2-Dichloropropane	78875						
32	1,3-Dichloropropylene	542756					10 a	1700 a
33	Ethylbenzene	100414					3100 a	29000 a
34	Methyl Bromide	74839					48 a	4000 a
35	Methyl Chloride	74873					n	n
36	Methylene Chloride	75092					4.7 ac	1600 ac
37	1,1,2,2-Tetrachloroethane	79345					0.17 ac	11 ac
38	Tetrachloroethylene	127184					0.8 c	8.85 c
39	Toluene	108883					6800 a	200000 a
40	1,2-Trans-Dichloroethylene	156605						
41	1,1,1-Trichloroethane	71556					n	n
42	1,1,2-Trichloroethane	79005					0.60 ac	42 ac
43	Trichloroethylene	79016					2.7 c	81 c
44	Vinyl Chloride	75014					2 c	525 c
45	2-Chlorophenol	95578						
46	2,4-Dichlorophenol	120832					93 a	790 aj
47	2,4-Dimethylphenol	105679						
48	2-Methyl-4,6-Dinitrophenol	534521					13.4	765
49	2,4-Dinitrophenol	51285					70 a	14000 a
50	2-Nitrophenol	88755						
51	4-Nitrophenol	100027						
52	3-Methyl-4-Chlorophenol	59507						
53	Pentachlorophenol	87865	20 f	13 f	13	7.9	0.28 ac	8.2 acj
54	Phenol	108952					21000 a	4600000 aj
55	2,4,6-Trichlorophenol	88062					2.1 ac	6.5 ac
56	Acenaphthene	83329						
57	Acenaphthylene	208968						
58	Anthracene	120127					9600 a	110000 a
59	Benzidine	92875					0.00012 ac	0.00054 ac
60	Benzo(a)Anthracene	56553					0.0028 c	0.031 c
61	Benzo(a)Pyrene	50328					0.0028 c	0.031 c
62	Benzo(b)Fluoranthene	205992					0.0028 c	0.031 c
63	Benzo(ghi)Perylene	191242						
64	Benzo(k)Fluoranthene	207089					0.0028 c	0.031 c
65	Bis(2-Chloroethoxy)Methane	111911						
66	Bis(2-Chloroethyl)Ether	111444					0.031 ac	1.4 ac
67	Bis(2-Chloroisopropyl)Ether	108601					1400 a	170000 a
68	Bis(2-Ethylhexyl)Phthalate	117817					1.8 ac	5.9 ac
69	4-Bromophenyl Phenyl Ether	101553						
70	Butylbenzyl Phthalate	85687						
71	2-Chloronaphthalene	91587						
72	4-Chlorophenyl Phenyl Ether	7005723						
73	Chrysene	218019					0.0028 c	0.031 c

A			B Freshwater		C Saltwater		D Human Health (10^{-6} risk for carcinogens) For consumption of:	
(#)	Compound	CAS Number	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] (µg/L) C2	Water & Organisms (µg/L) D1	Organisms Only (µg/L) D2
74	Dibenzo(ah)Anthracene	53703	.....	.....	.....	.....	0.0028 c	0.031 c
75	1,2-Dichlorobenzene	95501	.....	.....	.....	.....	2700 a	17000 a
76	1,3-Dichlorobenzene	541731	.....	.....	.....	.....	400	2600
77	1,4-Dichlorobenzene	106467	.....	.....	.....	.....	400	2600
78	3,3′-Dichlorobenzidine	91941	.....	.....	.....	.....	0.04 ac	0.077 ac
79	Diethyl Phthalate	84662	.....	.....	.....	.....	23000 a	120000 a
80	Dimethyl Phthalate	131113	.....	.....	.....	.....	313000	2900000
81	Di-n-Butyl Phthalate	84742	.....	.....	.....	.....	2700 a	12000 a
82	2,4-Dinitrotoluene	121142	.....	.....	.....	.....	0.11 c	9.1 c
83	2,6-Dinitrotoluene	606202	.....	.....	.....	.....	.....	.....
84	Di-n-Octyl Phthalate	117840	.....	.....	.....	.....	.....	.....
85	1,2-Diphenylhydrazine	122667	.....	.....	.....	.....	0.040 ac	0.54 ac
86	Fluoranthene	206440	.....	.....	.....	.....	300 a	370 a
87	Fluorene	86737	.....	.....	.....	.....	1300 a	14000 a
88	Hexachlorobenzene	118741	.....	.....	.....	.....	0.00075 ac	0.00077 ac
89	Hexachlorobutadiene	87683	.....	.....	.....	.....	0.44 ac	50 ac
90	Hexachlorocyclopentadiene	77474	.....	.....	.....	.....	240 a	17000 aj
91	Hexachloroethane	67721	.....	.....	.....	.....	1.9 ac	8.9 ac
92	Indeno(1,2,3-cd)Pyrene	193395	.....	.....	.....	.....	0.0028 c	0.031 c
93	Isophorone	78591	.....	.....	.....	.....	8.4 ac	600 ac
94	Naphthalene	91203	.....	.....	.....	.....	.....	.....
95	Nitrobenzene	98953	.....	.....	.....	.....	17 a	1900 aj
96	N-Nitrosodimethylamine	62759	.....	.....	.....	.....	0.00069 ac	8.1 ac
97	N-Nitrosodi-n-Propylamine	621647	.....	.....	.....	.....	.....	.....
98	N-Nitrosodiphenylamine	86306	.....	.....	.....	.....	5.0 ac	16 ac
99	Phenanthrene	85018	.....	.....	.....	.....	.....	.....
100	Pyrene	129000	.....	.....	.....	.....	960 a	11000 a
101	1,2,4-Trichlorobenzene	120821	.....	.....	.....	.....	.....	.....
102	Aldrin	309002	3 g	.....	1.3 g	.....	0.00013 ac	0.00014 ac
103	alpha-BHC	319846	.....	.....	.....	.....	0.0039 ac	0.013 ac
104	beta-BHC	319857	.....	.....	.....	.....	0.014 ac	0.046 ac
105	gamma-BHC	58899	2 g	0.08 g	0.16 g	.....	0.019 c	0.063 c
106	delta-BHC	319868	.....	.....	.....	.....	.....	.....
107	Chlordane	57749	2.4 g	0.0043 g	0.09 g	0.004 g	0.00057 ac	0.00059 ac
108	4-4′-DDT	50293	1.1 g	0.001 g	0.13 g	0.001 g	0.00059 ac	0.00059 ac
109	4,4′-DDE	72559	.....	.....	.....	.....	0.00059 ac	0.00059 ac
110	4,4′-DDD	72548	.....	.....	.....	.....	0.00083 ac	0.00084 ac
111	Dieldrin	60571	2.5 g	0.0019 g	0.71 g	0.0019 g	0.00014 ac	0.00014 ac
112	alpha-Endosulfan	959988	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a
113	beta-Endosulfan	33213659	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a
114	Endosulfan Sulfate	1031078	.....	.....	.....	.....	0.93 a	2.0 a
115	Endrin	72208	0.18 g	0.0023 g	0.037 g	0.0023 g	0.76 a	0.81 aj
116	Endrin Aldehyde	7421934	.....	.....	.....	.....	0.76 a	0.81 aj
117	Heptachlor	76448	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00021 ac	0.00021 ac
118	Heptachlor Epoxide	1024573	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00010 ac	0.00011 ac
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)	.....	.....	.....	.....	.....	0.00017 q	0.00017 q
126	Toxaphene	8001352	0.73	0.0002	0.21	0.0002	0.00073 ac	0.00075 ac
	Total Number of Criteria (h) =	.....	24	29	23	27	85	84

Footnotes

a. Criteria revised to reflect current agency q_1* or RfD, as contained in the Integrated Risk Information System (IRIS). The fish tissue bioconcentration factor (BCF) from the 1980 criteria documents was retained in all cases.

b. The criteria refers to the inorganic form only.

c. Criteria in the matrix based on carcinogenicity (10^{-6} risk). For a risk level of 10^{-5}, move the decimal point in the matrix value one place to the right.

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

e. Freshwater aquatic life criteria for these metals are expressed as a function of total hardness (mg/L as $CaCO_3$), the pollutant's water effect ratio (WER) as defined in § 131.36(c) and multiplied by an appropriate dissolved conversion factor as defined in § 131.36(b)(2).

For comparative purposes, the values displayed in this matrix are shown as dissolved metal and correspond to a total hardness of 100 mg/L and a water effect ratio of 1.0.

f. Freshwater aquatic life criteria for pentachlorophenol are expressed as a function of pH, and are calculated as follows. Values displayed above in the matrix correspond to a pH of 7.8.

$$CMC = \exp(1.005(pH) - 4.830)$$
$$CCC = \exp(1.005(pH) - 5.290)$$

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

h. These totals simply sum the criteria in each column. For aquatic life, there are 31 priority toxic pollutants with some type of freshwater or saltwater, acute or chronic criteria. For human health, there are 85 priority toxic pollutants with either ''water + fish'' or ''fish only'' criteria. Note that these totals count chromium as one pollutant even though EPA has developed criteria based on two valence states. In the matrix, EPA has assigned numbers 5a and 5b to the criteria for chromium to reflect the fact that the list of 126 priority toxic pollutants includes only a single listing for chromium.

i. If the CCC for total mercury exceeds 0.012 µg/l more than once in a 3-year period in the ambient water, the edible portion of aquatic species of concern must be analyzed to determine whether the concentration of methyl mercury exceeds the FDA action level (1.0 mg/kg). If the FDA action level is exceeded, the State must notify the appropriate EPA Regional Administrator, initiate a revision of its mercury criterion in its water quality standards so as to protect designated uses, and take other appropriate action such as issuance of a fish consumption advisory for the affected area.

j. No criteria for protection of human health from consumption of aquatic organisms (excluding water) was presented in the 1980 criteria document or in the 1986 Quality Criteria for Water. Nevertheless, sufficient information was presented in the 1980 document to allow a calculation of a criterion, even though the results of such a calculation were not shown in the document.

k. The criterion for asbestos is the MCL (56 FR 3526, January 30, 1991).

l. [Reserved: This letter not used as a footnote.]

m. Criteria for these metals are expressed as a function of the water effect ratio, WER, as defined in 40 CFR 131.36(c).

$$CMC = \text{column B1 or C1 value} \times WER$$
$$CCC = \text{column B2 or C2 value} \times WER$$

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

o. [Reserved: This letter not used as a footnote.]

p. Criterion expressed as total recoverable.

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

General Notes

1. This chart lists all of EPA's priority toxic pollutants whether or not criteria recommendations are available. Blank spaces indicate the absence of criteria recommendations. Because of variations in chemical nomenclature systems, this listing of toxic pollutants does not duplicate the listing in Appendix A of 40 CFR Part 423. EPA has added the Chemical Abstracts Service (CAS) registry numbers, which provide a unique identification for each chemical.

2. The following chemicals have organoleptic based criteria recommendations that are not included on this chart (for reasons which are discussed in the preamble): copper, zinc, chlorobenzene, 2-chlorophenol, 2,4-dichlorophenol, acenaphthene, 2,4-dimethylphenol, 3-methyl-4-chlorophenol, hexachlorocyclopentadiene, pentachlorophenol, phenol.

3. For purposes of this rulemaking, freshwater criteria and saltwater criteria apply as specified in 40 CFR 131.36(c).

Note to paragraph (b)(1): On April 14, 1995, the Environmental Protection Agency issued a stay of certain criteria in paragraph (b)(1) of this section as follows: the criteria in columns B and C for arsenic, cadmium, chromium (VI), copper, lead, nickel, silver, and zinc; the criteria in B1 and C1 for mercury; the criteria in column B for chromium (III); and the criteria in column C for selenium. The stay remains in effect until further notice.

* * * * * * *

(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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