ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 132

[FRL–5708–8]

RIN 2040–AC94

Final Revisions to the Polychlorinated Biphenyl Criteria for Human Health and Wildlife for the Water Quality Guidance for the Great Lakes System

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is publishing final revisions to the polychlorinated biphenyl (PCB) ambient water quality criteria for human health and wildlife for the final Water Quality Guidance for the Great Lakes System that was published in March 1995 (the 1995 Guidance). The final revisions are limited to the method for calculating a composite baseline bioaccumulation factor (BAF) for PCBs and the method for calculating a composite octanol-water partition coefficient (K_{ow}) for PCBs. After reviewing all public comments, EPA concluded that the approach it proposed in October 1996 for calculating a composite baseline BAF, using the second alternative proposed for calculating a composite K_{ow}, for PCBs would be preferable to the approach used in the 1995 Guidance because it would more appropriately relate the concentrations of the PCB congeners in tissue to the concentrations of the PCB congeners in water. Consequently, EPA is today revising the human health cancer criterion for PCBs from 3.9E–6 ug/L to 6.7E–6 ug/L, and the wildlife criterion for PCBs from 7.4E–5 ug/L to 1.2E–4 ug/L. EPA believes that these revisions more accurately represent the numerical limits necessary to protect human health and wildlife in the Great Lakes System.

EFFECTIVE DATE: March 12, 1997.

ADDRESSES: The public docket for this rulemaking, including the proposal, public comments in response to the proposal, other major supporting documents, and the index to the docket are available for inspection and copying at U.S. EPA Region 5, 77 West Jackson Blvd., Chicago, IL 60604 by appointment only. Appointments may be made by calling Mary Willis Jackson (telephone 312–886–3717).

FOR FURTHER INFORMATION CONTACT: Mark Morris (4301), U.S. EPA, 401 M Street, SW, Washington, D.C. 20460 (202–260–0312).

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Potentially Affected Entities

Entities potentially affected by this final rule are those discharging pollutants to waters of the United States in the Great Lakes System. Potentially affected categories and entities include:

Category	Examples of potentially affected entities
Industry	Industries discharging PCBs to waters in the Great Lakes System as defined in 40 CFR 132.2.
Municipalities	Publicly-owned treatment works discharging PCBs to waters of the Great Lakes System as defined in 40 CFR 132.2.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this final rule. This table lists the types of entities that EPA is now aware could potentially be affected by this action. To determine whether your facility may be affected by this final rule, you should examine the definition of ''Great Lakes System'' in 40 CFR 132.2 and examine 40 CFR 132.2 which describes the purpose of water quality standards such as those established in this rule. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Great Lakes Water Quality Guidance

In March 1995, EPA promulgated the final Water Quality Guidance for the Great Lakes System (the 1995 Guidance) required under section 118(c)(2) of the Clean Water Act, 33 U.S.C. 1268(c)(2). See 60 FR 15366–425 (March 23, 1995). The ambient water quality criteria (AWQC) included in the 1995 Guidance to protect human health and wildlife set maximum ambient concentrations for harmful pollutants to be met in all waters in the Great Lakes System unless site-specific criteria are derived and approved. See 40 CFR Part 132, Tables 3 and 4. Great Lakes States and Tribes must adopt criteria consistent with EPA's criteria by March of 1997. CWA section 118(c)(2). If any State or Tribe fails to meet that deadline, EPA must promulgate criteria that will apply in that State's or Tribe's jurisdiction. *Id.* Once the criteria take effect, permits for discharges of such pollutants into the Great Lakes System must include limits as necessary to attain the criteria.

EPA promulgated human health and wildlife criteria for a class of closely related toxic pollutants known as polychlorinated biphenyls (PCBs). The PCB criteria for human health and wildlife incorporate bioaccumulation factors (BAFs) which reflect the fact that PCBs magnify at several steps in aquatic food chains, so that humans and wildlife that eat fish from the Great Lakes may be exposed to PCB concentrations many times higher than the PCB concentration in the waters of the Lakes. Different members of the class of PCBs (called ''congeners'') have different potentials to bioaccumulate. In the 1995 Guidance, EPA derived a single baseline BAF for PCBs for each trophic level by computing a weighted geometric mean baseline BAF from the baseline BAFs for each trophic level for approximately 50 PCB congeners.

Based on issues raised as part of a lawsuit on the 1995 Guidance, in 1996 EPA proposed a different approach for calculating a single BAF for the class of PCBs. EPA also decided to call this single BAF a ''composite baseline BAF.'' The new approach also required EPA to calculate a composite K_{ow} for PCBs. EPA proposed two different approaches for this calculation. EPA, however, presented calculations of revised BAFs and revised ambient water quality criteria based on only one of the two K_{ow} alternatives. For a more complete discussion of the 1995 Guidance and the revised approach in the 1996 proposal, refer to 60 FR 15366 (March 23, 1995) and 61 FR 54748 (October 22, 1996).

After considering all comments, EPA has decided to follow the proposed approach. EPA selected the second of the two alternatives to calculating a composite K_{ow}. As a result, the numerical values for the final BAFs and the final criteria differ very slightly from those that EPA presented in the proposal. The discussion below explains the reasons for the changes.

II. Background

The BAFs in the 1995 Guidance relate the concentration of a chemical measured in water to the concentration of the same chemical measured in fish tissue. Under the methodology for the 1995 Guidance, the calculation of a BAF that is to be used for calculating AWQC for a non-polar organic chemical involves three steps for each trophic level. First, EPA obtains a ''total'' BAF based on the total concentrations of the chemical in the water and in the aquatic biota, based on field measurements. Second, EPA converts this initial total BAF into a ''baseline'' BAF that reflects the amount of lipid (fat) in the aquatic biota that was assessed and the amount

of freely dissolved chemical that was estimated in the water. This permits better extrapolation of data from one species to another and from one water body to another. Third, EPA computes a final ''total'' BAF based on the total concentration of the chemical in the water and the organisms at the site to be protected. In this notice, EPA will refer to the first ''total'' BAF as the ''initial total'' BAF, and the final as the ''final total'' BAF. The initial and final total BAFs generally differ because they usually apply to different bodies of water.

An important factor in the calculation of the baseline BAF and both total BAFs for a chemical is the K_{ow} for that chemical. The K_{ow} is a measure of the affinity of a chemical to partition between octanol and water and is used as an estimate of the partitioning between the lipids (fatty tissues) of an aquatic organism and water. The higher the K_{ow}, all other factors being constant, the greater the affinity of the chemical to concentrate in fish tissue. Each chemical has a K_{ow} value. The K_{ow} value for a chemical is usually reported as the log K_{ow} for the chemical. When calculating total and baseline BAFs for a chemical, the chemical-specific K_{ow} is used to estimate the freely dissolved fraction of the chemical in the water.

When this methodology is used to derive human health and wildlife AWQC for a class of chemicals, the normal ''single'' values for baseline and total BAFs for an individual chemical are replaced by composite baseline and composite total BAFs for the class to simplify the equations. Using a composite value in a calculation for the class gives the same result as summing the results of calculations for each member of the class. When calculating a composite baseline BAF or a composite total BAF for all of the chemicals in a class at a trophic level, it is necessary to use a composite K_{ow}. This composite K_{ow} is used to estimate the composite freely dissolved fraction of the class of chemicals in the Great Lakes waters.

EPA based the PCB BAFs in the 1995 Guidance on a field study conducted in the Great Lakes by Oliver and Niimi (1988). The study collected data on numerous PCB congeners, and EPA calculated a separate baseline BAF for each congener using separate, congener-specific K_{ow}s. EPA, however, needed to calculate composite baseline BAFs and composite total BAFs representing all congeners at a trophic level in order to calculate AWQC for human health and wildlife, because there is a single ''cancer potency factor'' which is used for evaluating human health cancer risk for all PCBs. Similarly, for wildlife, there is a single toxicity factor which is used in the derivation of the wildlife criterion. Consequently, composite baseline and total BAFs were needed in order to be consistent with the toxicity data available to derive human health and wildlife criteria.

In the 1995 Guidance, EPA calculated a composite baseline BAF for PCBs for trophic level 3 and a composite baseline BAF for trophic level 4 by computing a weighted geometric mean of the baseline BAFs for individual PCB congeners at each trophic level. The weighted geometric mean baseline BAF was 55,281,000 for trophic level 3 and 116,553,000 for trophic level 4. As explained above, when calculating a composite baseline BAF for PCBs, EPA must also use a composite K_{ow}. In the 1995 Guidance, EPA calculated a weighted geometric mean K_{ow} of 3,885,000 (mean log K_{ow} of 6.589) by weighting the log K_{ow}s for the individual PCB congeners by the concentrations of the PCB congeners in fish. The weighted mean log K_{ow} of 6.589 was then used to estimate the freely dissolved fraction of the PCB congeners in the study of Oliver and Niimi (1988). The log K_{ow}s for the individual PCB congeners used in the final Guidance came from Hawker and Connell (1988).

Using the composite baseline BAF for each trophic level and the weighted mean log K_{ow} of 6.589, EPA calculated composite final total BAFs of 520,900 for trophic level 3 and 1,871,000 for trophic level 4 for use in calculating human health criteria. The PCB human health cancer criterion calculated using these BAFs was 3.9E–6 ug/L. For wildlife, the composite final total BAFs were 1,850,000 for trophic level 3 and 6,224,000 for trophic level 4. The PCB wildlife criterion derived using these BAFs was 7.4E–5 ug/L.

Various industries and trade associations challenged the human health and wildlife criteria for PCBs. *AISI v. EPA*, D.C. Cir. No.95–1348 and consolidated cases. Among the issues they raised was the calculation of the composite baseline BAF as the weighted geometric mean for PCBs. The AISI petitioners alleged that the equation was mathematically inappropriate for a variety of reasons. As a result of this challenge, EPA re-examined the basis for the calculation of the composite baseline BAF as the weighted geometric mean. For a more complete discussion of bioaccumulation and the approach used in the 1995 Guidance, refer to 58 FR 20803 (April 16, 1993), and the Procedure to Determine Bioaccumulation Factors (''TSD for BAFs'')(EPA–820–B–95–005).

III. Revised Method for Calculating Composite Baseline BAFs for PCBs

A. The Proposed Approach

On October 22, 1996, EPA proposed a revised approach for calculating the composite baseline BAF for PCBs for each trophic level. The revised approach uses the sum of all concentrations of PCB congeners in tissue and the sum of all concentrations of PCB congeners in the ambient water, as reported in Oliver and Niimi (1988), to calculate a composite initial total BAF for PCBs at each trophic level. This approach is equivalent to using a weighted arithmetic mean of all the measured initial total BAFs from the PCB congeners, where the weights are the concentrations of the PCB congeners in water. EPA believes this approach is consistent with the definition of bioaccumulation factor and appropriately relates the sum of the concentrations of the PCB congeners in tissue to the sum of the concentrations of the PCB congeners in water. EPA further believes that this approach will provide an accurate composite initial total BAF for the class of PCBs.

As part of the October 22, 1996 proposal, EPA also proposed to revise its approach for calculating the composite K_{ow} used in the calculation of the composite baseline and total BAFs. EPA proposed two alternatives: the first alternative used the median log K_{ow} of the PCB congeners to derive a composite K_{ow}; the second used the sum of the concentrations of the K_{ow}s for all congeners together with the sum of all of the freely dissolved concentrations of the congeners in water. For a more complete discussion of the revised approach for calculating composite BAFs and K_{ow}s, refer to 61 FR 54748 (October 22, 1996).

B. Comments on the Proposed Approach

EPA received three comments on the proposal. Two commenters opposed the revised approach for calculating composite BAFs for PCBs. One of the commenters who opposed the proposal argued that the revised approach yielded less stringent criteria for PCBs and that this action was contradictory to the principle of zero discharge, and inconsistent with what the public had been told about the 1995 Guidance methodology being a superior method yielding more stringent criteria. This commenter also argued that the resulting higher criteria would allow backsliding for pollution prevention scenarios currently established and

operating for existing permitted discharges of PCBs. The other commenter who opposed the proposal was concerned that data (congener specific K_{ow}s, tissue and water PCB concentrations) used in the revised approach were taken from reports that were published a decade ago and that more recent data on the behavior of PCBs in the environment, their activity as carcinogenic promoters, and the tendency of ''weathered'' PCBs to be more toxic than the parent compounds, have not been considered. This commenter argued that the revised approach did not provide as much protection against the tendency for PCBs to become more toxic over time. In addition, the commenter argued that, if EPA were to revise the 1995 approach, it should not use the median value because the median ignores extremely high or low values, disregards population trends, and does not weigh skewness, which is a characteristic of the PCBs. In fact, the commenter recommended that EPA compute and use a BAF at the 90 percent confidence level. Finally, the commenter also noted that, since a higher K_{ow} also affects the amount of pollutant that is freely dissolved, the change in the K_{ow} value has a large impact on the final criterion. For these reasons the commenter argued that the 1995 approach, which produces the lowest composite K_{ow} was preferable. However, the commenter concluded that, if EPA revised its approach, it should use the second of the two alternatives proposed, because it produces a lower K_{ow} than the first alternative.

Finally, one commenter supported the revised approach stating that the proposed modifications to the equation used to calculate the composite BAFs for PCBs are scientifically and mathematically appropriate. However, the commenter further stated that it disagrees with many other issues arising from the 1995 Guidance and EPA's derivation of BAFs for PCBs, which are issues outside the scope of this rulemaking.

C. Response to Comments

EPA appreciates those who provided comments on this rulemaking. In regard to the first comment, EPA disagrees that it has misinformed the public concerning either the 1995 Guidance methodology or the 1996 revised methodology. EPA also disagrees with the prediction that the revised criteria will result in backsliding. Although the revised criteria are less stringent than the 1995 criteria, they are not less stringent than the PCB criteria currently in effect in the Great Lakes States. Currently, the range of water quality criteria being implemented in the Great Lakes Basin to protect human health from PCBs is 0.1 to 0.00008 ug/L. EPA's revised methodology produces a human health criterion for PCBs that is about 10 to 10,000 times more stringent than those currently being implemented. For the protection of wildlife the disparity is even more dramatic because many of the Great Lakes States do not have criteria for PCBs to protect wildlife. For the three Great Lakes States that do have criteria for PCBs to protect wildlife, EPA's revised approach produces a wildlife criterion that is approximately 10 to 1,000 times more stringent than those currently being implemented. Given this information, EPA does not believe that permit limits for PCBs based on criteria for human health and wildlife produced by the revised methodology will result in less protection or backsliding. Further, EPA interprets the concept of zero discharge in the Great Lakes Agreement as a goal toward which it is working. The revised PCB criteria, which are still more stringent than criteria currently in effect in the Great Lakes States, are a reasonable and substantial step toward that goal.

EPA also disagrees with the comment that asserts that EPA should chose an approach to calculating a composite K_{ow} that leads to a more conservative PCB criterion because the current criteria may not sufficiently take into account the effects of ''weathering'' or data from new studies suggesting that PCBs might cause reproductive and developmental toxicity effects. EPA believes that the BAF should estimate bioaccumulation as accurately as possible. EPA believes it is more appropriate to account for the commenter's concerns—if warranted—by adjusting its estimate of PCB's toxicity. Further, EPA believes that it has adequately accounted for weathering. PCBs were first introduced into the Great Lakes Basin in the 1930s. Researchers in the Great Lakes have spent a significant amount of time gathering data and studying the fate and effects of PCBs in this system. Given the length of time some of the PCBs have resided in the Great Lakes Basin, any increased toxicity due to ''weathering'' would be reflected in the data collected in 1986. Therefore, EPA does not agree that it needs to retain the 1995 approach to ensure protection against the possible impacts of weathering.

EPA agrees that some recent data indicate that PCBs, particularly co-planar PCBs, might cause reproductive and developmental toxicity through processes such as endocrine disruption. Because concentrations associated with such potential adverse effects are under evaluation, EPA can not yet predict whether such effects might occur at concentrations above or below those associated with the cancer risks modeled by the 1995 Guidance. EPA does not believe that it has enough information concerning these additional, potential effects to revise the criteria at this time. As stated in the 1995 Guidance, EPA is committed to improving the science supporting its methodologies and criteria, and will continue to evaluate and revise them in future rulemakings in light of new information, as appropriate.

EPA agrees with the comment that the median K_{ow} of the PCB congeners should not be used as the composite K_{ow} and that the second alternative set forth in the proposal is more appropriate. EPA also agrees with some of the limitations identified by the commenter that are associated with using a median. However, EPA's reason for adopting the second alternative to calculate a composite K_{ow} as part of this final rule is not because it introduces, as the commenter suggests, a more protective value, but because EPA believes that the second alternative more accurately reflects how PCBs behave in the Great Lakes System. The second alternative provides the same result as would be obtained by performing the relevant calculations for each congener and then summing the results.

D. Final Action

As described above, the approach for this final rule uses the sum of the concentrations of all PCB congeners in tissue and the sum of the concentrations of all PCB congeners in the ambient water to calculate a composite initial total BAF for PCBs at each trophic level. The approach also uses individual PCB congener K_{ow} to calculate the composite K_{ow}. The calculations of the composite baseline BAFs for PCBs, the composite final total BAFs to be used in the calculation of AWQC for wildlife and human health, and the PCB criteria for wildlife and humans using the new PCB BAFs are presented below. EPA is not revising the data used in the calculation of the composite BAFs or composite K_{ow}s or other aspects related to the derivation of the human health and wildlife criteria for PCBs. The fish tissue data, water column data, and log K_{ow} values used to calculate the new composite BAFs and composite K_{ow} are identical to those used in the 1996 proposal.

1. Calculation of Composite Baseline BAFs for PCBs

The equation used to calculate a baseline BAF for an individual chemical for each individual trophic level in this final rule is the same as was used in the 1995 Guidance and the 1996 proposal (61 FR 54748). The equation to calculate a baseline BAF when a field-measured BAF is available for a chemical, as is the case with PCBs, is (each of the three components for calculating a baseline BAF is discussed below):

$$\text{Baseline BAF} = \left[\frac{\text{Measured BAF}_T^t}{f_{fd}} - 1\right]\left(\frac{1}{f_l}\right)$$

Where:

Measured BAF^t_T = BAF based on total concentration in tissue and water (i.e., a total BAF).

f_l = fraction of the tissue that is lipid.

f_{fd} = fraction of the total chemical in the ambient water that is freely dissolved.

By comparison, the equation for calculating a composite baseline BAF is:

$$\text{Composite Baseline BAF} = \left[\frac{\text{Composite Initial Total BAF}}{\text{Composite } f_{fd}} - 1\right]\left(\frac{1}{f_l}\right)$$

a. Composite Initial Total BAF

To calculate a composite initial total BAF for trophic level 4, the data needed are the total concentration of the chemical in the tissue of a trophic level 4 species and the total concentration of the chemical in ambient water at the site of sampling. The trophic level 4 species used in the 1995 Guidance, the 1996 proposal and this final rule are salmonids. To calculate a composite initial total BAF for trophic level 3, the data needed are the total concentration of the chemical in the tissue of a trophic level 3 species and the total concentration of the chemical in ambient water at the site of sampling. The trophic level 3 species used in the 1995 Guidance, the 1996 proposal and this final rule are sculpins and alewives. The average of the values for the sculpins and alewives is used to represent the trophic level 3 values. The equation to calculate a composite total BAF is:

$$\text{Composite Total BAF} = \frac{\text{Total concentration of chemical in tissue}}{\text{Total concentration of chemical in ambient water}}$$

For trophic level 4, the total concentration of PCB congeners in fish tissue (salmonids) is 4057.3 ng/g and the total concentration of PCB congeners in ambient water is 1006.1 pg/L. For trophic level 3, the average of the total concentrations of PCB congeners in tissue from sculpins and alewife is 1393.15 ng/g. These values were derived in the 1996 proposal from Oliver and Niimi (1988).

$$\text{Composite Initial Total BAF} - \text{Trophic Level 4} = \frac{(4057.3\ \text{ng/g})(1000\ \text{pg/ng})(1000\ \text{g/L})}{1006.1\ \text{pg/L}} = 4{,}033{,}000$$

$$\text{Composite Initial Total BAF} - \text{Trophic Level 3} = \frac{(1393.15\ \text{ng/g})(1000\ \text{pg/ng})(1000\ \text{g/L})}{1006.1\ \text{pg/L}} = 1{,}385{,}000$$

The resulting composite initial total BAF is 4,033,000 for trophic level 4 and 1,385,000 for trophic level 3 (rounded to four significant figures as discussed on page G–2 of the TSD for BAFs).

b. Composite Fraction Freely Dissolved

To estimate the fraction of PCBs that are freely dissolved in the ambient water requires information on the particulate organic carbon (POC) and dissolved organic carbon (DOC) in the ambient water where the samples were collected and the K_{ow} of the chemical. As in the 1995 Guidance and the 1996 proposal, the equation for calculating the fraction freely dissolved for an individual chemical is:

$$f_{fd} = \frac{1}{\left[1 + (\text{POC} \times K_{ow}) + (\text{DOC} \times K_{ow}/10)\right]}$$

Where:

POC=concentration of particulate organic carbon (kg/L).

DOC=concentration of dissolved organic carbon (kg/L).

K_{ow}=n-octanol water partition coefficient for the chemical.

By comparison, to calculate a composite fraction freely dissolved for a group of chemicals, the equation is:

$$\text{Composite } f_{fd} = \frac{1}{\left[1 + (\text{POC} \times \text{Composite } K_{ow}) + (\text{DOC} \times \text{Composite } K_{ow} / 10)\right]}$$

The log K_{ow}s used for the individual PCB congeners come from Hawker and Connell (1988), which were included in the 1996 proposal. To calculate the composite K_{ow}, as explained above, EPA will not employ the first alternative that uses the median log K_{ow} from the log K_{ow}s presented in Table 1 of the 1996 proposal (61 FR 54752), but will instead use the second alternative for calculating a composite K_{ow}. As proposed, the formula for calculating the second alternative composite K_{ow} is:
Where:

$$\text{Composite } K_{ow} = \left(\frac{1}{\frac{\text{DOC}}{10} + \text{POC}}\right)\left(\frac{\sum_{i=1}^{n} C_w^t}{\sum_{i=1}^{n} C_w^{fd}} - 1\right)$$

Where:
i=1, 2, * * * *n congeners.*
C^t_w=total concentration of the congener in water.
C^{fd}_w=freely dissolved concentration of the congener in water.
The second alternative for calculating the composite K_{ow} was derived algebraically from the following definition of the fraction freely dissolved, f_{fd}, for a single congener, as given in the 1995 Guidance and the 1996 proposal :

$$f_{fd} = \frac{C_w^{fd}}{C_w^t} = \frac{1}{1 + (\text{POC})(K_{ow}) + \frac{(\text{DOC})(K_{ow})}{10}}$$

In the second alternative for the composite K_{ow}, the ratio of the sum of the total concentrations of all of the congeners in water over the sum of the freely dissolved concentrations of all of the congeners in water is substituted for the ratio of the total over freely dissolved concentration of a single congener in water. Using the data provided in Table 1 of the 1996 proposal, these equations yield a composite K_{ow} of 2,189,000 (rounded to four significant figures).

$$\text{Composite } K_{ow} = \left(\frac{1}{\frac{2.0 \times 10^{-6}}{10} + 0}\right)\left(\frac{1006.1}{699.72} - 1\right) = 2{,}189{,}000$$

This differs slightly from the composite K_{ow} value of 2,238,721 derived in the proposal using the median log K_{ow} approach.

In the 1995 Guidance and the 1996 proposal, the POC value used was 0.0 kg/L and the DOC value used was 2.0×10^{-6} kg/L for the study of Oliver and Niimi (1988). In this final rule, EPA is not changing these values. Using these values and the revised composite K_{ow} value of 2,189,000 the composite fraction freely dissolved in this final rule is 0.6955, as shown below:

$$\text{Composite } f_{fd} = \frac{1}{\left[1 + (0 \times 2{,}189{,}000) + \left(2.0 \times 10^{-6} \times 2{,}189{,}000 / 10\right)\right]} = 0.6955$$

Again, this differs slightly from the fraction freely dissolved presented in the 1996 proposal. The difference stems from the use of the second alternative for calculating a composite K_{ow}.

c. Fraction Lipid

In addition, EPA is not changing the fraction lipid content of the salmonids (0.11) or sculpin (0.08) or alewife (0.07) that were used in the 1995 Guidance and the 1996 proposal for the study of Oliver and Niimi (1988). The average fraction lipid for sculpin and alewife is 0.075.

d. Composite Baseline BAF

Based on the information presented above and using the equation for calculating composite baseline BAFs, EPA calculates for this final rule a new composite baseline BAF for PCBs for trophic level 4 of 52,720,000 and a new composite baseline BAF for PCBs for trophic level 3 of 26,550,000 (rounded to four significant figures). Composite Baseline BAF TL4

$$\text{Composite Baseline BAF TL3} = \left[\frac{1{,}385{,}000}{0.6955} - 1\right]\left(\frac{1}{0.075}\right) = 26{,}550{,}000$$

2. Calculation of Composite Final Total BAFs for Use in AWQC

The data required to calculate a composite final total BAF for use in deriving a AWQC for PCBs are the composite baseline BAF, the fraction lipid of the aquatic species consumed by the population of interest whether that is humans or wildlife and the composite fraction freely dissolved in the ambient water for the area of interest.

Composite Total BAF for AWQC = [(Composite Baseline BAF)(Fraction Lipid of Aquatic Species Consumed) + 1](Composite f_{fd})

a. Composite Baseline BAF

The new composite baseline BAFs derived above in section III.D will be used: 52,720,000 for trophic level 4 and 26,550,000 for trophic level 3.

b. Composite Freely Dissolved Fraction

The equation for calculating the composite freely dissolved fraction is presented above. EPA is using the same values for POC and DOC used in the 1995 Guidance and the 1996 proposal (4.0 x 10–8 kg/L for POC and 2.0 x 10^{-6} kg/L for DOC). These values represent POC and DOC concentrations in Lake Superior and were used to calculate all of the final total BAFs that were used to derive the AWQC in the 1995 Guidance. Both the composite K_{ow} and the composite freely dissolved fraction must be calculated using the Lake Superior values for POC and DOC. The relative total concentrations of the PCB congeners in Lake Superior will be assumed to be the same as in Oliver and Niimi (1988). The resulting composite K_{ow} is 2,107,000 and the composite f_{fd} is 0.6642 (both rounded to four significant figures).

$$\text{Composite } K_{OW} = \left(\frac{1}{\frac{2.0\times10^{-6}}{10} + 4.0\times10^{-8}} \right) \left(\frac{1006.1}{668.2} - 1 \right) = 2{,}107{,}000$$

$$\text{Composite } f_{fd} = \frac{1}{\left[1 + \left(4.0\times10^{-8} \times 2{,}107{,}000\right) + \left(2.0\times10^{-6} \times 2{,}107{,}000 / 10\right)\right]} = 0.6642$$

The freely dissolved fraction of 0.6642 differs slightly from the value of 0.6505 presented in the 1996 proposal. The difference is due to the change in the method for calculating the composite K_{ow}.

c. Lipid Fraction

EPA is not changing the lipid values used in the 1995 Guidance and the 1996 proposal. The lipid fraction of the aquatic species consumed by humans in the Great Lakes region is 1.82 for trophic level 3 and 3.10 for trophic level 4. For wildlife, the lipid fraction for trophic level 3 is 6.46 and for trophic level 4 is 10.31.

d. Composite Final Total BAFs for Calculating AWQC

Using the above values for the composite baseline BAFs, composite freely dissolved fraction for Lake Superior and fraction lipid, EPA today is promulgating the following composite final total BAFs (rounded to four significant figures) to be used in deriving the human health and wildlife AWQC for PCBs:

Human Health BAF for Trophic Level 4 = [(52,720,000)(0.0310) +1] 0.6642 = 1,086,000

Human Health BAF for Trophic Level 3 = [(26,550,000)(0.0182) +1] 0.6642 = 321,000

Wildlife BAF for Trophic Level 4 = [(52,720,000)(0.1031) +1] 0.6642 = 3,610,000

Wildlife BAF for Trophic Level 3 = [(26,550,000)(0.0646) +1] 0.6642 = 1,139,000

3. Human Health Cancer Criteria

Based on the BAFs presented above, EPA today is revising the human health cancer criteria for PCBs in Table 3 of the 1995 Guidance from 3.9E–6 µg/L to 6.7E–6 µg/L. The equations used to calculate the human health cancer criteria for PCBs in this final rule are the same as were used in the 1995 Guidance and the 1996 proposal (61 FR 54753).

4. Wildlife Criterion

For wildlife, EPA today is revising the PCB criterion from 7.4E–5 µg/L to 1.2E–4 µg/L based on using the BAFs presented above. The equations used to calculate the wildlife criterion for PCBs in this final rule are the same as were used in the 1995 Guidance and the 1996 proposal (61 FR 54754).

IV. Effective Date

Section 553(d)(3) of the Administrative Procedure Act requires Federal agencies to publish final rules at least 30 days before they take effect unless they find that they have ''good cause'' to waive the notice requirement. EPA finds that it has good cause to waive the 30-day notice requirement for these revisions to the PCB criteria. EPA needs to make this rule effective as soon as possible to maximize the ability of the States and Tribes to use the new criteria in their Guidance submissions that are due in March 23, 1997. Also, in this case an immediate effective date does not conflict with the goal of the notice requirement (giving the public the opportunity to adjust behavior before the rule imposes penalties). The revised criteria will not affect any member of the public until they are adopted by a Great Lakes State or Tribe (or promulgated by EPA where a State or Tribe fails to submit adequate criteria). EPA anticipates that these processes will take at least 30 days, so that the public will receive adequate notice of the revised requirements before they become binding.

V. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA 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 final rule is not a ''significant regulatory action'' and is therefore not subject to OMB review.

VI. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

VII. Regulatory Flexibility Act as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996

The Regulatory Flexibility Act (RFA) provides that, whenever an agency promulgates a final rule under 5 U.S.C. 553, after being required to publish a general notice of proposed rulemaking, an agency must prepare a final regulatory flexibility analysis unless the head of the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 604 & 605.

Under the CWA, EPA's promulgation of water quality standards establishes standards that the States implement through the National Pollutant Discharge Elimination System (NPDES) permit process. 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 standards may result in new or revised discharge limits being placed on small entities, the standards themselves do not apply to any discharger, including small entities.

Today's rule imposes obligations on the Great Lakes States but, as explained above, does not itself establish any requirements that are applicable to small entities. As a result of EPA's action here, the Great Lakes States will need to ensure that permits they issue include any limitations on discharges necessary to comply with the criteria in today's rule. Until actions are taken to implement the 1995 Guidance, there will be no economic effect of the 1995 Guidance on any entities, large or small. States and Tribes must both adopt their own criteria and implement them before impacts are felt. The implementation regulations provide States and Tribes with a variety of flexible alternatives which can affect the burden felt by any small entity as a result of State or Tribal action to implement this final rule, including total maximum daily load (TMDL) calculations and waste load allocations (WLAs). Impacts will not be felt until States and Tribes select and put in place implementation measures.

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.

Furthermore, today's final rule results in human health cancer criteria and wildlife criteria less stringent than those currently in the 1995 Guidance. If States or Tribes adopt criteria consistent with today's final rule, they should reduce any adverse economic impact that might have been imposed by State or Tribal adoption of the 1995 criteria. Consequently, the economic effect of today's final rule relative to the 1995 Guidance should be positive. Any adverse economic impact on small entities associated with measures taken to implement the current provisions of the 1995 Guidance should be reduced by adoption of the final revisions.

VIII. Unfunded Mandates Reform Act

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

As noted above, this final rule is limited to the method for deriving a composite BAF for PCBs and for deriving a composite K_{ow} for PCBs, which will result in human health cancer criteria and wildlife criteria for PCBs less stringent than those currently in the 1995 Guidance. If States or Tribes adopt criteria consistent with today's final rule, they will reduce any adverse economic impact that might have been imposed by State or Tribal adoption of

the 1995 criteria. Consequently, EPA has determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small governments. EPA has also determined that this final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Thus, today's final rule is not subject to the requirements of sections 202 and 205 of the UMRA.

IX. Paperwork Reduction Act

There are no information collection requirements in this final rule and therefore there is no need to obtain OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

X. References

Great Lakes Water Quality Technical Support Document for the Procedure to Determine Bioaccumulation Factors (EPA–820–B–95–005). NITS Number: PB95187290. ERIC Number: D049.

Great Lakes Water Quality Initiative Criteria Documents for the Protection of Human Health (EPA–820–B–95–006). NITS Number: PB95187308. ERIC Number: D050.

Great Lakes Water Quality Initiative Criteria Documents for Protection of Wildlife: DDT; Mercury; 2,3,7,8–TCDD; PCBs (EPA–820–B–95–008). NITS Number: PB95187324. ERIC Number: D052.

Hawker D.W. and D.W Connell. 1988. Octanol-Water Partition Coefficients of Polychlorinated Biphenyl Congeners. Environ. Sci. Technol., 22(4):382–387.

Oliver, B.G. and A.J Niimi. 1988. Trophodynamic Analysis of Polychlorinated Biphenyl Congeners and Other Chlorinated Hydrocarbons in the Lake Ontario Ecosystem. Environ. Sci. Technol., 22(4):388–397.

U.S. Environmental Protection Agency. Water Quality Guidance for the Great Lakes System and Correction; Proposed Rules. Vol. 58, No.72. April 16, 1993. pp.20802–21047.

U.S. Environmental Protection Agency. Water Quality Guidance for the Great Lakes System; Notice of Data Availability. Vol. 59. August 30, 1994. pp.44678–44685.

U.S. Environmental Protection Agency. Final Water Quality Guidance for the Great Lakes System; Final Rule. Vol. 60, No.56. March 23, 1995. pp.15366–15425.

U.S. Environmental Protection Agency. Proposed Revisions to the Polychlorinated Biphenyl Criteria for Human Health and Wildlife for the Water Quality Guidance for the Great Lakes System; Proposed Rule. Vol. 61, No.205. October 22, 1996. pp.54748–54756.

List of Subjects in 40 CFR Part 132

Environmental protection, Administrative practice and procedure, Great Lakes, Indians—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 6, 1997.

Carol M. Browner,

Administrator.

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

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

1. The authority citation for Part 132 continues to read as follows:

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

2. Table 3 to Part 132 is amended by revising the entry for PCBs(class) to read as follows:

TABLE 3.—WATER QUALITY CRITERIA FOR PROTECTION OF HUMAN HEALTH

Chemical	HNV (ug/L)		HCV (ug/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
* * * * * * *				
PCBs(class)			6.7E–6	6.7E–6
* * * * * * *				

3. Table 4 to Part 132 is amended by revising the entry for PCBs(class) to read as follows:

TABLE 4.—WATER QUALITY CRITERIA FOR PROTECTION OF WILDLIFE

Chemical	Criteria (ug/L)
* * * * *	
PCBs(class)	1.2E–4
* * * * *	

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