ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 132

[FRL–5907–4]

RIN 2040–AC08

Revocation of the Polychlorinated Biphenyl Human Health Criteria in the Water Quality Guidance for the Great Lakes System

AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial revocation of final rule.

SUMMARY: As a result of the recent decision in *AISI* v. *EPA*, D.C. Cir. No. 95–1448 (decided June 6, 1997), EPA is today removing the human health criteria for polychlorinated biphenyls (PCBs) promulgated for the final Water Quality Guidance for the Great Lakes System (Guidance) in March 1997. EPA plans to propose replacement criteria in 1998. In the interim, EPA has calculated a Tier I value for PCBs for human health of 2.6 E–5 micrograms per liter (ug/L) for both drinking water and nondrinking water uses. EPA is recommending that States and Tribes either adopt a human health criterion for PCBs that is no less stringent than this value or use their Guidance based Tier I methodologies for human health, together with appropriate data, to derive an ambient value to be used in setting permit limits. EPA anticipates these Tier I values to be no less stringent than EPA's interim value of 2.6 E–5 ug/L (unless site-specific data are used). EPA is not removing the wildlife criterion for PCBs of 1.2 E–4 ug/L promulgated in March of 1997. EPA expects States and Tribes to adopt and submit PCB wildlife criteria consistent with this criterion.

EFFECTIVE DATE: October 9, 1997.

ADDRESSES: The public docket for this and earlier rulemakings concerning the Water Quality Guidance for the Great Lakes System, 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. Discussion

A. Potentially Affected Entities

Entities potentially affected by today's action 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. Other types of entities not listed in the table could also be regulated. 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. Overview

As a result of the recent decision in *AISI* v. *EPA*, D.C. Cir. No. 95–1448 (decided June 6, 1997), EPA is today removing the human health criteria for polychlorinated biphenyls (PCBs) promulgated for the final Water Quality Guidance for the Great Lake System (Guidance) in March 1997. EPA plans to propose replacement criteria in 1998. In the interim, EPA has calculated Tier I values for PCBs for human health of 2.6 E–5 micrograms per liter (ug/L) for both drinking water and nondrinking water uses. EPA is recommending that States and Tribes either adopt a human health criterion for PCBs that is no less stringent than this value or use their Guidance based Tier I methodologies for human health, together with appropriate data, to derive an ambient value to be used in setting permit limits. EPA anticipates these Tier I values to be no less stringent than EPA's interim value of 2.6 E–5 ug/L (unless site-specific data are used). EPA is not removing the wildlife criterion for PCBs of 1.2 E–4 ug/L promulgated in March of 1997. EPA expects States and Tribes to adopt and submit PCB wildlife criteria consistent with this criterion.

C. Background

In March 1995 (60 FR 15366–15425, March 23, 1995), EPA promulgated the final Water Quality Guidance for the Great Lakes System (the Guidance) required under section 118(c)(2) of the Clean Water Act, 42 U.S.C. 1268(c)(2). The Guidance included ambient water quality criteria setting maximum ambient concentrations for pollutants to be met in all waters of the Great Lakes Basin (unless site-specific criteria are derived and approved). States and Tribes were required to adopt regulations consistent with EPA's Guidance criteria and implementation procedures by March 23, 1997. Once the criteria take effect, permits for discharges of the pollutants they cover must include limits needed to attain the criteria.

EPA promulgated human health and wildlife criteria for a class of closely related toxic chemicals known as PCBs. Various industries and trade associations challenged the human health and wildlife criteria for PCBs. They alleged that EPA had improperly computed a ''composite'' bioaccumulation factor (BAF) for the class of PCBs. The BAF played a role in the derivation of both the human health and wildlife criteria. They also alleged that EPA used an inappropriate cancer potency factor of 7.7 milligrams per kilogram per day ((mg/kg)/d) in deriving the human health criteria.

EPA decided in the summer of 1996 that it wished to revise its method for calculating composite BAFs for the two types of criteria. It requested the U.S. Court of Appeals for the District of Columbia Circuit to remand the human health and wildlife criteria for further rulemaking related to this issue. The Court granted the motion, and EPA proposed a new approach for calculating composite BAFs on October 22, 1996. (61 FR 54748). In March 1997, EPA promulgated its revised mathematical method for deriving composite BAFs for PCBs. (62 FR 11724, March 12, 1997). EPA also promulgated revised human health and wildlife criteria for Tables 3 and 4 of 40 CFR part 132 that were based on the new mathematical approach. See 62 FR 11731.

Also in 1996, EPA announced in a guidance document that it would approve PCB criteria for human health submitted by States or Tribes that used a revised, Agency-approved cancer

potency factor of 2 (mg/kg)/d. It explained that it would consider such criteria to be ''consistent with'' the final Guidance. See Questions and Answers on Implementing the Great Lakes Guidance, March 20, 1996.

At oral argument in the *AISI* litigation EPA told the Court that it planned to propose new human health criteria for PCBs that would utilize the new cancer potency factor of 2 (mg/kg)/d. When the Court issued its opinion on June 6, 1997, it vacated the March 1995 criteria for human health and wildlife, citing the decisions to replace the mathematical method for composite BAFs and the cancer potency factor.

D. Decision To Remove Human Health Criteria

EPA believes that the Court's decision did not affect the March 1997 human health criteria incorporating the revised mathematical approach to deriving composite BAFs. No challenge to those criteria were before the Court, so it did not have jurisdiction to vacate or remand them. EPA, however, acknowledges that it did not use the revised cancer potency factor of 2 (mg/kg)/d in deriving the March 1997 human health criteria. Because the issue vacated by the Court clearly overlaps with the scope of the 1997 rule, EPA has decided to withdraw the March 1997 human health criteria for PCBs.

EPA still intends to propose revised human health criteria using both the new potency factor and the new mathematical approach. It currently anticipates signing this proposal in March of 1998.

E. Consequences of Today's Action

As a result of today's action, States and Tribes need not adopt or submit to EPA for review human health criteria for PCBs for waters of the Great Lakes Basin. EPA, however, recommends that States and Tribes adopt a human health criterion for PCBs based on the revised BAFs and the revised cancer potency factor of 2 (mg/kg)/d. EPA has calculated a revised value of 2.6 E–5 ug/L for both drinking and nondrinking water uses. States and Tribes that chose not to adopt criteria must, at a minimum, provide protection of human health from risk of exposure to PCBs on a permit-by-permit basis using their Guidance based Tier I methodologies for human health criteria and best available data. EPA anticipates these Tier I values to be no less stringent than 2.6 E–5 ug/L (unless site-specific factors are used).

EPA does not intend to withdraw the March 1997, PCB criterion for wildlife of 1.2 E–4 ug/L. That rule replaced the challenged mathematical approach to deriving composite BAFs. The cancer potency factor at issue in the *AISI* litigation is an estimate of human health impacts. It played no role in the development of either the 1995 or 1997 wildlife criteria. There is no need to conduct further rulemaking to incorporate that potency factor into the wildlife criterion. States and Tribes must submit wildlife criteria for PCBs that are consistent with the March 1997 criterion.

II. ''Good Cause'' Under the Administrative Procedure Act

EPA has determined that it has ''good cause'' under section 553(b)(3) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3), to promulgate this final rule without prior opportunity for notice and comment. EPA finds it ''unnecessary'' to provide an opportunity to comment on the strictly legal issue of the impact of the *AISI* decision on the March 1997 PCB criteria.

Moreover, all interested members of the public had an opportunity to comment on the revised method for computing composite BAFs when EPA proposed them in October of 1996. The public will have a new opportunity to comment on that method when EPA issues its new proposal for human health criteria for PCBs in the Great Lakes System. The public will also have an opportunity to comment on the cancer potency factor at that time.

EPA also believes the public interest is best served by reacting as quickly as possible to the Court's decision. For this reason, EPA has also determined that it has ''good cause'' under 5 U.S.C. 553(d) to make the rule effective upon publication.

III. 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.

IV. 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).

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

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et. seq.), whenever a Federal agency promulgates a final rule after being required to publish a general notice of proposed rulemaking under section 553 of the Administrative Procedures Act (APA), the agency generally must prepare a final regulatory flexibility analysis describing the economic impact of the regulatory action on small entities. EPA has not prepared a final regulatory flexibility analysis for this action because the Agency was not required to publish a general notice of proposed rulemaking for this rule.

As explained above, section 553 of the APA provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary and contrary to the public interest, an agency may first issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without notice and opportunity for comment for the reasons spelled out above. In these circumstances, the RFA does not require preparation of a final regulatory flexibility analysis. Today's final rule establishes no requirements applicable to small entities.

VI. Unfunded Mandates Reform Act

This action will not result in the annual expenditures of $100 million or more for State, local, and Tribal

governments, in the aggregate, or to the private sector, and is not a Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (UMRA) (P.L. 104–4), nor does it uniquely affect small governments in any way. As such, the requirements of sections 202, 203, and 205 of Title II of the UMRA do not apply to this action.

VII. 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.*

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: October 2, 1997.

Carol M. Browner,

Administrator.

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

PART 132—[AMENDED]

2. Table 3 to part 132 is amended by removing the entry for PCBs (class).

[FR Doc. 97–26864 Filed 10–8–97; 8:45 am]

BILLING CODE 6560–50–P