



**John G. Haggard**  
Engineering Project Manager  
Hudson River

General Electric Company  
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January 25, 1996

Douglas J. Tomchuk  
Emergency and Remedial Response Division  
U. S. Environmental Protection Agency  
290 Broadway 20th Floor  
New York, NY 10007-1866

RE: UTILIZATION OF PCB TOXICITY INFORMATION

Dear Mr. Tomchuk:

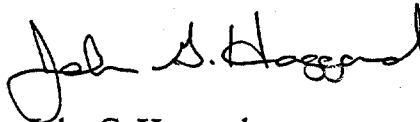
As you may recall, the General Electric Company has requested that the U. S. EPA Region II, evaluate the results of the 1991 Institute for Environmental and Health Research (IEHR) re-read of the rat liver slides from PCB feeding studies as part of the Hudson River Reassessment Remedial Investigation Feasibility Study (RRI/FS). The findings in the IEHR report have important implications for the PCB Cancer Slope Factor employed by regulating agencies for estimating potential human health risks. The only official response to this request from EPA Region II was published in the July 1992 Responsiveness Summary for the Phase I Report: Hudson River PCB Reassessment RI/FS. On page B.6-9 of the Responsiveness Summary, it states: "The Cancer Slope Factor (CSF) of  $7.7 \text{ (ug/kg-d)}^{-1}$  will continue to be used by Region II in evaluating the potential carcinogenic risks posed by human exposure to PCBs until this value is updated by USEPA." However, at our meeting in May, considerable interest was shown by EPA personnel in both the re-read and the rat feeding study, which GE has initiated.

Enclosed for your information is a copy of an agreement between the General Electric Company, the American Forest and Paper Association, and U. S. EPA that addresses issues in the litigation over the National Toxics Rule and the reliability of the present IRIS cancer slope fact (CSF) for PCBs, in particular. Pursuant to the agreement EPA has issued a guidance memorandum (attached) to the EPA Regional Water Management Division Directors that allows states to "assess the available data on PCBs and chose a CSF different from that in IRIS". Further, EPA is committed by the agreement to a prompt reassessment of the cancer potency of PCBs. In the very near future, EPA will make available a draft report on the reassessment of the cancer potency of PCB's. The reassessment should be complete by September 1, 1996. We also understand that the results of the GE sponsored rat feeding study are being evaluated by EPA as part of the required reassessment of the PCB cancer slope factor.

Based on the above, it appears that the U.S. EPA cancer potency reevaluation will be complete well before the Record of Decision (ROD) is issued for the Hudson River site. Therefore, GE believes that the human health risk assessments issued for the project will need to incorporate the revised cancer slope factors.

Please let me know if you have any questions or comments. We will keep you informed of developments.

Very truly yours,

A handwritten signature in black ink, appearing to read "John G. Haggard", written in a cursive style.

John G. Haggard  
Engineering Project Manager

cc: Walter Demick, NYSDEC  
Dorothy Canter, U. S. EPA  
Bob Montione, NYSDOH  
Bill McCabe, U.S. EPA  
Paul Simon, U.S. EPA  
Douglas Fischer, U.S. EPA  
Marion Olsen, U.S. EPA

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

AMERICAN FOREST AND PAPER  
ASSOCIATION, INC.,

Plaintiff,

v.

UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY,

Defendant.

Consolidated Case  
No. 93-0694 RMU

GENERAL ELECTRIC COMPANY

Plaintiff,

v.

UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY, and CAROL M. BROWNER, ADMINISTRATOR

Defendants.

PARTIAL SETTLEMENT AGREEMENT

WHEREAS, on December 22, 1992, the United States Environmental Protection Agency ("EPA" or the "Agency"), pursuant to the Clean Water Act, promulgated a final rule adding 40 C.F.R. 131.36 to the Code of Federal Regulations, which rule is commonly referred to as the "National Toxics Rule" or "NTR;"

WHEREAS, the General Electric Company ("GE"), the American Forest and Paper Association ("AFPA") (collectively "Plaintiffs") and other entities filed timely actions seeking review of the NTR, which actions were consolidated as reflected in the above caption;

WHEREAS, all parties to the consolidated actions other than Plaintiffs have dismissed their actions pursuant to settlements with EPA;

WHEREAS, the NTR promulgated numeric water quality criteria for numerous chemicals and classes of chemicals, including polychlorinated biphenyls ("PCBs") for specific States and jurisdictions;

WHEREAS, the NTR water quality criteria consist of criteria intended to protect aquatic life and criteria intended to protect human health;

WHEREAS, Plaintiffs maintain, among other things, that the NTR water quality criteria for PCBs intended to protect human health are based on an arbitrary and capricious application of EPA's cancer risk assessment methodology to its evaluation of the alleged carcinogenicity of PCBs and an arbitrary and capricious evaluation by EPA of the various scientific studies relevant to the alleged cancer risk posed by PCBs;

WHEREAS, EPA maintains, among other things, that in developing the NTR human health water quality criteria for PCBs EPA appropriately applied the Agency's cancer risk assessment methodology and appropriately evaluated the various scientific studies relevant to the cancer risk posed by PCBs;

WHEREAS, EPA has underway a number of activities, including: reassessment of the cancer potency of PCBs (the "cancer reassessment"), revision of the methodology to derive human health water quality criteria, and revision of the cancer

guidelines, that could lead the Agency to decide to amend the human health water quality criteria for PCBs in the NTR;

THEREFORE IT IS AGREED THAT:

1. Promptly upon execution of this Partial Settlement Agreement, EPA and the Plaintiffs shall submit a joint motion to the Court seeking a stay of this litigation and transfer of the relevant part of the case to the Court's inactive docket.

2. Within 60 days after execution of this Partial Settlement Agreement, EPA shall:

(a) Include in the IRIS entry for PCBs the following statement: "EPA is currently reassessing the cancer potency factor for PCBs. Following a scientific external peer review and public review, EPA will revise the IRIS summary for PCBs to reflect the results of the reassessment. Requests for EPA's memorandum describing the reassessment of the IRIS cancer potency factor for PCBs and questions concerning the reassessment can be directed to the Human Health Assessment Group in the National Center for Environmental Assessment (202-260-3814)."

(b) Issue a memorandum to the EPA Regions and the states announcing the PCBs cancer reassessment and explaining that, for the purpose of promulgating and seeking EPA approval of human health water quality standards for PCBs, a State may base its standards on a cancer potency factor less stringent than  $7.7 \text{ (mg/kg/day)}^{-1}$  (the current cancer potency factor in IRIS), if the State complies with 40 CFR 131.11 with respect to development of water quality criteria, and EPA, in approving or disapproving the criteria, will review the State's assumptions and overall

rationale, to determine if they are scientifically defensible, protective of public health, and in compliance with the CWA. Such memorandum shall be in a form substantially similar to Attachment A.

3. EPA's reassessment of the cancer potency factor for PCBs will: (a) take into consideration the impact of biodegradation and other processes that change commercial PCB mixtures after release into the environment; (b) consider, among other things, the studies and issues identified by Plaintiffs and listed in Attachment B; and (c) describe the Agency's work, including the scientific issues considered and the scientific studies and related technical issues reviewed (including progression from benign to malignant tumors, reevaluation of liver pathology, and application of cross-species scaling factors), and the basis for EPA's findings and recommendations.

4. With regard to its reassessment of the cancer potency factor for PCBs, EPA will: complete the draft cancer reassessment and provide a copy of the draft to plaintiffs by December 29, 1995, and convene the external scientific peer review by March 29, 1996. By mid-May, 1996, EPA will determine what additional work needs to be done to issue the final cancer reassessment. If the Agency concludes (a) that it is only necessary to revise the draft cancer reassessment in relatively minor ways, EPA will complete the final cancer reassessment by September 1, 1996. If the Agency concludes (b) that it is necessary to undertake a fundamentally different approach to the cancer reassessment or to conduct significant new analyses before revising the draft cancer

reassessment, EPA will meet with Plaintiffs by September 1, 1996 to discuss the Agency's schedule for the final cancer reassessment. EPA shall include the final cancer reassessment in the Agency's Integrated Risk Information System (IRIS) in the month following issuance of the final reassessment.

5. EPA will propose an amendment to the NTR to revise the human health water quality criteria for PCBs (the "proposed rule"), or publish a Federal Register notice stating its reasons for not revising the human health water quality criteria for PCBs, within 18 months of issuance of the final reassessment. In developing the proposed rule or Federal Register notice, as the case may be, EPA will consider, among other things, the issues identified by Plaintiffs and listed in Attachment C. If EPA issues the proposed rule, the Agency will provide for a public comment period of no less than 60 days, and will promulgate a final rule within 18 months from the date of proposal.

6. If EPA fails to meet any of the schedules set forth above, Plaintiffs may reactivate this litigation, and such right shall constitute their exclusive remedy. Plaintiffs may, after providing EPA thirty days notice, reactivate this litigation by filing a motion to lift the stay provided in Paragraph 1, if (a) EPA fails to meet any of the schedules in Paragraphs 4 or 5; or (b) Plaintiffs and EPA do not agree on a schedule for issuing the final reassessment as discussed in Paragraph 4(b), above. EPA shall not oppose such motion, and, at Plaintiffs' request, EPA shall agree to a schedule providing that all dispositive motions

be filed and briefed no later than 120 days after reactivation of the litigation.

7. Within 30 days of EPA's publication of the cancer reassessment in IRIS, and in accordance with the terms of Paragraph 6 relating to scheduling of dispositive motions and briefs, Plaintiffs may reactivate this litigation. Nothing in this Paragraph shall be construed to mean that the cancer reassessment is subject to challenge upon entry in IRIS or that any information in IRIS is subject to challenge unless and until such information is included in an Agency rulemaking or other final Agency action where it becomes reviewable.

8. The parties acknowledge that this Partial Settlement Agreement is based on requirements of the law on the date the Agreement was executed. If the legal requirements to which the Agency is subject are altered, the Agency may be unable to meet the commitments in this Agreement. Notwithstanding any change in the law, however, Plaintiffs shall have the right to reactivate this litigation as provided in Paragraphs 6 and 7.

9. In the event that EPA promulgates a final rule amending the NTR by revising the human health water quality criteria for PCBs, Plaintiffs and EPA shall promptly stipulate to the dismissal with prejudice of Plaintiffs' complaints in this litigation (each party bearing its own costs and attorneys' fees). Plaintiffs shall be entitled to seek judicial review of such final rule.



10. The current fiscal year for the federal government ended on September 30, 1995. Congress has not yet enacted a full year appropriation for EPA for fiscal year 1996. In the event that EPA employees necessary to complete the draft cancer risk assessment in Paragraph 4 of this Partial Settlement Agreement are furloughed due to the absence of such appropriation, the parties agree that the schedule to complete that draft shall be extended by a period equal to the number of days the EPA employees are furloughed. Any extension provided under this paragraph shall not apply to any other schedules in Paragraphs 4 or 5.

11. EPA shall provide prompt notice to Plaintiffs of any proposed, and any final, settlement in NRDC v EPA, Dkt. No. 92-2369 (D.N.J.), and provide prompt notice to Plaintiffs of the establishment of any briefing schedule in that proceeding.

12. Except as expressly provided in this Partial Settlement Agreement, none of the parties waives or relinquishes any legal rights, claims or defenses it might have, including but not limited to Plaintiffs' rights to contest EPA's use in other proceedings of the NTR water quality criteria for PCBs.

13. Nothing in this Partial Settlement Agreement shall be construed to limit or modify EPA's discretion to alter, amend, or revise the NTR water quality criteria for PCBs from time to time or to promulgate superseding criteria, nor to limit any rights that Plaintiffs may have to challenge any such alterations, amendments, revisions, or superseding criteria.

14. Nothing in this Partial Settlement Agreement shall be construed to limit or modify the discretion accorded EPA under the Clean Water Act or by general principles of administrative law.

15. No provision of this Partial Settlement Agreement shall be interpreted as or constitute a commitment or requirement that EPA obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. §1341.

16. The undersigned representatives of each party certify that they are fully authorized by the party they represent to bind such party to the terms of this Partial Settlement Agreement. This Partial Settlement Agreement shall be effective when it has been signed by the representatives of the parties set forth below.

AGREED:

Attorney for Plaintiff  
American Forest and  
Paper Association:

Russell S. Frye  
Russell S. Frye, Esq.  
CHADBOURNE & PARKE  
1101 Vermont Ave. N.W.  
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(202) 289-3000

DATED: 2 November 1995

Attorney for Plaintiff  
General Electric Company

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~~Marion D. Herrington, Esq.~~  
GENERAL ELECTRIC COMPANY  
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(203) 373-3899

DATED: November 3, 1995

ROBERT W. FRANTZ

Attorneys for Defendants

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Environment and Natural  
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DATED: November 7 1995

Karen H. Clark  
Karen H. Clark  
U.S. Environmental Protection  
Agency  
Office of General Counsel  
401 M Street, S.W.  
Washington, D.C. 20460  
(202) 260-4138

DATED: 11/7/95

## ATTACHMENT A

MEMORANDUM

SUBJECT: Reassessment of IRIS Cancer Potency Factor for  
Polychlorinated Biphenyls (PCBs) and Setting State  
Water Quality Standards for PCBs

FROM: William H. Farland, Director  
National Center for Environmental Assessment

Tudor T. Davies, Director  
Office of Science and Technology

TO: Water Management Division Directors, Regions I-X

The purpose of this memorandum is to announce the Agency's reassessment of the cancer potency factor (CPF) for polychlorinated biphenyls (PCBs) entered in the Agency's Integrated Risk Information System (IRIS), and to review the Agency's policy concerning the flexibility of states in promulgating water quality standards for PCBs.

Cancer Risk Reassessment

The current CPF for PCBs set forth in IRIS is 7.7 (mg/kg/day)<sup>-1</sup>. That value was derived from a rat feeding study by Norback & Weltman (1985), one of several studies of Aroclor 1260. Other animal feeding studies using PCB mixtures other than Aroclor 1260 indicate that other PCBs may have cancer potencies lower than Aroclor 1260. It is also significant that the original tissue slides from the Norback & Weltman (1985) study, as well as original tissue slides from other PCB cancer studies,

were reevaluated using new criteria for evaluating liver pathology by a pathology working group (PWG) convened by the Institute for the Evaluation of Health Risks (IEHR). The PWG found tumor incidences somewhat lower than those reported by the original authors of these studies.

Taking this information into account, as well as the Agency's belief that there is a need to establish a procedure for estimating the cancer risk of mixtures of PCBs found in the environment, EPA has begun to reassess the cancer potency of PCBs. EPA expects that the reassessment will result in a range of CPFs for PCBs and guidance for the application of those factors to PCB mixtures found in the environment. EPA expects that the reassessment will be completed in draft form by the end of 1995 and, after peer review, will be finalized by September 1996. Upon completion of this process, the IRIS entry for PCBs will then be amended.

In view of this reassessment of the cancer potency of PCBs, it seems appropriate to review the Agency's policy on the degree of flexibility available to the states in adopting water quality criteria for PCBs.

#### Setting Water Quality Criteria for PCBs

Several of the states are in the process of developing water quality criteria, including criteria for PCBs, to replace federal criteria that EPA promulgated in the "National Toxics Rule" (40 CFR §131.36, 57 Fed. Reg. 60848 (Dec. 22, 1992)). Other states are in the process of performing their triennial reviews of water

quality criteria. While the states have primary authority for establishing levels of protection under the Clean Water Act (CWA), they must submit their new or revised water quality standards to EPA for review and approval or disapproval. CWA Section 303(c)(2). The states must document their decisions to provide adequate information for EPA's review of the state's decision, and any subsequent administrative or judicial review. 40 CFR 131.6.

EPA reviews new or revised water quality standards adopted by the states for consistency with the requirements of the CWA. EPA regulations explain that numerical water quality criteria must be based on EPA's criteria guidance developed under CWA Section 304(a), EPA's criteria guidance modified to reflect site-specific conditions, or other scientifically defensible methods. 40 CFR §131.11(b).

EPA's policy is that any human health criterion for a carcinogen is based on at least three inter-related considerations: potency, exposure, and risk characterization. States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments must be clear and in the public record.

If a State relies on EPA's Section 304(a) criteria document (or other EPA documents), the State may reference and rely on the data in these documents and need not create duplicative or new material for inclusion in their records. However, where site-specific issues arise or the State decides to adopt an approach

to any one of these three factors which is different from that in EPA's criteria document, the State must provide an explanation of its reasons which is sufficient for a reviewer to determine that the approach chosen is based on sound scientific rationale.

In accordance with this policy, states may "make their own judgments" on the cancer potency of PCBs. States may continue to rely on the current Section 304(a) criteria guidance for PCBs pending any possible revisions of the criteria guidance or IRIS values. EPA believes the cancer potency factor on IRIS is protective of public health. States may also, in light of EPA's announced reassessment of the cancer risk of PCBs or other considerations, assess the available data on PCBs and choose a CPF different from that in IRIS. The Agency recognizes that other reasonable assumptions can be used to set water quality criteria for PCBs in accordance with 40 CFR §131.11(b).

Therefore, a state may base its water quality criteria for PCBs on a cancer potency factor less stringent than  $7.7 \text{ (mg/kg/day)}^{-1}$  (the CPF for PCBs currently in IRIS), if the state complies with 40 CFR §131.11 and provides sound scientific reasoning for its estimate of cancer risk for humans and documents its judgments. EPA will review the state's assumptions and overall rationale, to determine if they are scientifically defensible, protective of public health, and in compliance with the CWA.

If you have questions related to EPA approval of state water quality criteria for PCBs based on assumptions different from

those used by the Agency, please call Edward Ohanian of the Office of Water's Health and Ecological Criteria Division at 202-260-7574. If you have questions related to EPA's reassessment of cancer risk of PCBs, please call Jim Cogliano of the Office of Research and Development's Human Health Assessment Group at 202-260-3814.

Lastly, we would ask that you distribute this memorandum to the appropriate officials in the states within your Regions.



## ATTACHMENT B

### STUDIES

IEHR. 1991. Reassessment of Liver Findings in Five PCB Studies in Rats. Institute for Evaluating Health Risks, Washington, D.C. July 1.

Kimbrough, R.D., R.A. Squire, R.E. Linder, J.D. Strandberg, R.J. Montali, and V.W. Burse. 1975, Induction of Liver Tumors in Sherman Strain Female Rats by Polychlorinated Biphenyls 1260. J. Natl. Cancer Inst. 55:1453-1459.

NCI. 1978. Bioassay of 1254 for Possible Carcinogenicity. NCI-GC-TR-38. Bethesda, MD: National Cancer Institute. NTIS PB279624.

Norback, D.H. and R.H. Weltman. 1985. Polychlorinated Biphenyl Induction of Hepatocellular Carcinoma in the Sprague-Dawley Rat. Environ. Health Persp. 60:97-105.

Schaeffer, E., H. Greim, and W. Goessner. 1984. Pathology of Chronic Polychlorinated Biphenyl (PCB) Feeding in Rats. Toxicol. Appl. Pharmacol. 75:272-288.

Delaware Department of Natural Resources and Environmental Control, Summary and Assessment of Polychlorinated Biphenyls and Selected Pesticides in Striped Bass for the Delaware Estuary (March 1994).

### ISSUES

The appropriateness of using data from both sexes of laboratory animals in evaluating the cancer risk of PCBs.

The appropriateness of using data from various tested species and strains of laboratory animals in evaluating the cancer risk of PCBs.

The appropriateness of using averages or means of data from more than one study in evaluating cancer risk.

The choice of an appropriate "species scaling factor" in converting cancer potency in animals to cancer potency in humans consistent with the draft report entitled "A Cross-Species Scaling Factor for Carcinogen Risk Assessment Based on Equivalence of mg/kg<sup>3/4</sup>/Day," published at 57 Fed. Reg. 24152 (June 5, 1992).

Assignment of a range of CPFs to environmental mixtures of PCBs based on the average percent chlorinations (by weight) of the mixtures in relationship to levels of chlorination of PCB mixtures tested in bioassays.

Assignment of the reassessed CPFs for 60% chlorinated mixtures to environmental mixtures having approximately 60% chlorination or greater. For mixtures having lesser percent chlorination, assignment of a CPF of zero.

Assignment of a CPF to an environmental mixture based on the CPF of a tested mixture that has the closest chlorination pattern. Alternatively, when the environmental mixture appears to contain more than one commercial mixture, assignment of a CPF that reflects the proportional composition of the environmental mixture.

#### ATTACHMENT C

1. The effect that the reduction in PCB concentrations in fish due to cooking and cleaning has on the human intake of PCBs through fish consumption.
2. Statistical analysis, including Monte Carlo analysis, of studies to determine average daily human fish consumption.
3. The impact of biodegradation of PCBs in the environment in determining an appropriate water quality criteria for PCBs.
4. The scientific basis of proposed models for establishing bioaccumulation factors (BAFs), including: (a) the extent to which such models account for the sources of PCBs to fish tissue, including the water column and various strata of sediment, and dissolved, undissolved and adsorbed PCBs; and (b) the variability of field-calculated BAFs for PCBs among various water bodies and the reasons for such variations.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC 6 1995

MEMORANDUM

SUBJECT: Reassessment of IRIS Cancer Potency Factor for Polychlorinated Biphenyls (PCBs) and Setting State Water Quality Standards for PCBs

FROM: William H. Farland, Director *William H. Farland*  
National Center for Environmental Assessment

Tudor T. Davies, Director *Tudor T. Davies*  
Office of Science and Technology

TO: Water Management Division Directors, Regions I-X

The purpose of this memorandum is to announce the Agency's reassessment of the cancer potency factor (CPF) for polychlorinated biphenyls (PCBs) entered in the Agency's Integrated Risk Information System (IRIS), and to review the Agency's policy concerning the flexibility of states in promulgating water quality standards for PCBs.

Cancer Risk Reassessment

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Taking this information into account, as well as the Agency's belief that there is a need to establish a procedure for estimating the cancer risk of mixtures of PCBs found in the environment, EPA has begun to reassess the cancer potency of PCBs. EPA expects that the reassessment will result in a range of CPFs for PCBs and guidance for the application of those

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factors to PCB mixtures found in the environment. EPA expects that the reassessment will be completed in draft form by the end of 1995 and, after peer review, will be finalized by September 1996. Upon completion of this process, the IRIS entry for PCBs will then be amended.

In view of this reassessment of the cancer potency of PCBs, it seems appropriate to review the Agency's policy on the degree of flexibility available to the states in adopting water quality criteria for PCBs.

#### Setting Water Quality Criteria for PCBs

Several of the states are in the process of developing water quality criteria, including criteria for PCBs, to replace federal criteria that EPA promulgated in the "National Toxics Rule" (40 CFR §131.36, 57 Fed. Reg. 60848 (Dec. 22, 1992)). Other states are in the process of performing their triennial reviews of water quality criteria. While the states have primary authority for establishing levels of protection under the Clean Water Act (CWA), they must submit their new or revised water quality standards to EPA for review and approval or disapproval. CWA Section 303(c)(2). The states must document their decisions to provide adequate information for EPA's review of the state's decision, and any subsequent administrative or judicial review. 40 CFR 131.6.

EPA reviews new or revised water quality standards adopted by the states for consistency with the requirements of the CWA. EPA regulations explain that numerical water quality criteria must be based on EPA's criteria guidance developed under CWA Section 304(a), EPA's criteria guidance modified to reflect site-specific conditions, or other scientifically defensible methods. 40 CFR §131.11(b).

EPA's policy is that any human health criterion for a carcinogen is based on at least three inter-related considerations: potency, exposure, and risk characterization. States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments must be clear and in the public record.

If a State relies on EPA's Section 304(a) criteria document (or other EPA documents), the State may reference and rely on the data in these documents and need not create duplicative or new material for inclusion in their records. However, where site-specific issues arise or the State decides to adopt an approach to any one of these three factors which is different from that in EPA's criteria document, the State must provide an explanation of its reasons which is sufficient for a reviewer to determine that the approach chosen is based on sound scientific rationale.

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In accordance with this policy, states may "make their own judgments" on the cancer potency of PCBs. States may continue to rely on the current Section 304(a) criteria guidance for PCBs pending any possible revisions of the criteria guidance or IRIS values. EPA believes the cancer potency factor on IRIS is protective of public health. States may also, in light of EPA's announced reassessment of the cancer risk of PCBs or other considerations, assess the available data on PCBs and choose a CPF different from that in IRIS. The Agency recognizes that other reasonable assumptions can be used to set water quality criteria for PCBs in accordance with 40 CFR §131.11(b). Therefore, a state may base its water quality criteria for PCBs on a cancer potency factor less stringent than  $7.7 \text{ (mg/kg/day)}^{-1}$  (the CPF for PCBs currently in IRIS), if the state complies with 40 CFR §131.11 and provides sound scientific reasoning for its estimate of cancer risk for humans and documents its judgments. EPA will review the state's assumptions and overall rationale, to determine if they are scientifically defensible, protective of public health, and in compliance with the CWA.

If you have questions related to EPA approval of state water quality criteria for PCBs based on assumptions different from those used by the Agency, please call Edward Ohanian of the Office of Water's Health and Ecological Criteria Division at 202-260-7574. If you have questions related to EPA's reassessment of cancer risk of PCBs, please call Jim Coglianor of the Office of Research and Development's Human Health Assessment Group at 202-260-3814.

Lastly, we would ask that you distribute this memorandum to the appropriate officials in the states within your Regions.