

Dated: June 12, 2003.

James W. Newsom,

Acting Regional Administrator, EPA Region III.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

[OPPT-2003-0029; FRL-7314-2]

RIN 2070-AC01

Polychlorinated Biphenyls; Use of Porous Surfaces; Amendment in Response to Court Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revising the language of the regulations affecting the use of polychlorinated biphenyls (PCBs) in the Code of Federal Regulations (CFR) to conform to a court decision vacating an amendment to these regulations. EPA's 1998 amendments to the PCB disposal regulations added a use authorization for porous materials contaminated by spills of liquid PCBs. Due to an editing error, the regulation referred to a unit of measurement inapplicable to the concentration of PCBs in liquids. In 1999, EPA issued a final rule correcting a number of errors in the 1998 action, including the porous surfaces use authorization. On January 30, 2001, the United States Court of Appeals for the District of Columbia Circuit (the Court) vacated the portion of the 1999 amendment which pertained to the porous materials use authorization. This document revises the CFR to conform to the court decision, and requires no notice and public comment.

DATES: This final rule is effective on June 20, 2003.

FOR FURTHER INFORMATION CONTACT: For general information contact: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Sara McGurk, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(202) 566-0480; e-mail address: mcgurk.sara@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, distribute in commerce, use, or dispose of PCBs or materials containing PCBs. Potentially affected entities may include, but are not limited to:

- Oil and Gas Extraction (NAICS 2111), e.g., Facilities with surfaces contaminated by PCBs
- Electric Power Generation, Transmission and Distribution (NAICS 2211), e.g., Facilities with surfaces contaminated by PCBs
- Construction (NAICS 23), e.g., Facilities with surfaces contaminated by PCBs
- Food Manufacturing (NAICS 311), e.g., Facilities with surfaces contaminated by PCBs
- Paper Manufacturing (NAICS 322), e.g., Facilities with surfaces contaminated by PCBs
- Petroleum and Coal Products Manufacturing (NAICS 324), e.g., Facilities with surfaces contaminated by PCBs
- Chemical Manufacturing (NAICS 325), e.g., Facilities with surfaces contaminated by PCBs
- Primary Metal Manufacturing (NAICS 331), e.g., Facilities with surfaces contaminated by PCBs
- Rail Transportation (NAICS 48211), e.g., Facilities with surfaces contaminated by PCBs
- Lessors of Real Estate (NAICS 5311), e.g., Facilities with surfaces contaminated by PCBs
- Waste Treatment and Disposal (NAICS 5622), e.g., Facilities with surfaces contaminated by PCBs
- Public Administration (NAICS 92), e.g., Facilities with surfaces contaminated by PCBs

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR part 761. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT-2003-0029. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566-0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 761 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml/00/Title_40/40cfr761_00.html, a beta site currently under development.

To access information about PCBs, go directly to the PCB Home Page for the Office of Pollution Prevention and Toxics at <http://www.epa.gov/pcb>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background

A. What Action is the Agency Taking?

EPA is amending the regulation at 40 CFR 761.30(p) that governs the continued use of porous surfaces contaminated by spills of liquid PCBs to reflect a decision from the Court in

Utility Solid Waste Activities Group v. EPA, 236 F3d 749 (D.C. Cir. 2001).

B. What is the Agency's Authority for Taking this Action?

The authority for issuing 40 CFR 761.30(p) was section 6(e)(2) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(2). This amendment is issued pursuant to a decision of the Court.

Section 6(e) of TSCA, 15 U.S.C. 2605(e), specifically regulates PCBs. It bans the manufacture, processing, distribution in commerce, or use of PCBs in other than a "totally enclosed manner," unless the activity is specifically authorized by EPA through rulemaking. In order to authorize any of these activities, EPA must make an affirmative finding that the activity does not pose an unreasonable risk of injury to health or the environment. Comprehensive regulations addressing the manufacture, processing, distribution in commerce, use, and disposal of PCBs were promulgated by EPA in 1979 and codified at 40 CFR part 761.

C. What is the History of this Action?

On December 6, 1994, EPA proposed extensive revisions to the PCB regulations. Some of the commenters on this proposal asked EPA to consider including an authorization for the use of porous surfaces that had been contaminated by old PCB spills. EPA considered the information submitted by the commenters and decided to include such a use authorization in the final amendments to the PCB regulations published in the **Federal Register** issue of June 29, 1998 (63 FR 35384) (FRL-5726-1) EPA determined that the continued use of porous surfaces cleaned, sealed, and marked in accordance with the requirements of 40 CFR 761.30(p) does not pose an unreasonable risk of harm to human health and the environment.

EPA had intended to apply the cleaning, sealing, and marking requirements in this new provision of the regulations to use of all porous surfaces that had been contaminated by spills of liquids containing PCBs at levels greater than or equal to 50 parts per million (ppm), regardless of the residual contamination level on the surface of the material. This is the standard EPA historically has used to trigger the regulation of PCB disposal. Unfortunately, due to an editing error, the 1998 version of 40 CFR 761.30(p) referred to a unit of measurement inapplicable to the concentration of PCBs in liquids. Instead of the 50 ppm standard for this use authorization, the

1998 final rule referred to ">10 µg/100 cm²." Shortly after the 1998 final rule was published, EPA discovered this and several other errors. EPA posted a list of the errors and appropriate corrections on its Internet site and, on June 24, 1999, in the **Federal Register** (64 FR 33755) (FRL-6072-4), promulgated these corrections in a final rule without prior notice and comment.

The Utility Solid Waste Activities Group and others challenged the 1999 amendment to 40 CFR 761.30(p), arguing that EPA had failed to follow requisite procedures by issuing the amendment without notice and comment.

D. What is the Basis for this Action?

On January 30, 2001, the Court vacated the correction to 40 CFR 761.30(p). *Utility Solid Waste Activities Group v. EPA*, 236 F3d 749 (D.C. Cir., 2001) The Court determined that EPA was required to promulgate the correction through full notice and comment rulemaking procedures consistent with section 553 of the Administrative Procedures Act (APA) (5 U.S.C. 553).

Accordingly, EPA is issuing this document to revise the language of 40 CFR 761.30(p) to conform to the Court's decision. The regulation at 40 CFR 761.30(p) will now read as published in 1998. However, EPA continues to believe that the 1999 amendment of 40 CFR 761.30(p) is the appropriate approach for the continued use of porous surfaces contaminated by spills of liquid PCBs. The Agency intends to issue a proposal in the near future to amend 40 CFR 761.30(p).

III. Statutory and Executive Order Reviews

This action amends 40 CFR part 761 to conform to a decision by the Court. Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). This action does not involve special consideration of environmental justice-related issues as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). Because this action is not subject

to notice and comment requirements under the APA or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This action also is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Executive order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish any environmental standards intended to mitigate health or safety risks. This action does not involve technical standards and therefore is not subject to section 12(d) of the National Technology Transfer and Advancement Act of 1995, 15 U.S.C. 272 note. This final rule does not have federalism implications and, therefore, Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), does not apply. This action does not involve or impose any requirements that affect Indian Tribes, so the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 62749, November 6, 2000), are not applicable. This final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866. Finally, this action is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, because it does not impose any monitoring, reporting, or recordkeeping requirements. EPA's compliance with the statutes and Executive orders for the underlying Disposal Amendments rule is discussed in the June 29, 1998, **Federal Register** (63 FR 35384).

IV. 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 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**. This rule conforms 40 CFR part 761 to a decision by the Court and is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 761

Environmental protection, Hazardous substances, Labeling, Polychlorinated biphenyls (PCBs), Reporting and recordkeeping requirements.

Dated: June 13, 2003.

Stephen L. Johnson,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 761—[AMENDED]

■ 1. The authority citation for part 761 continues to read as follows:

Authority: 15 U.S.C. 2605, 2607, 2611, 2614, and 2616.

■ 2. Amend § 761.30(p)(1) by revising the introductory text to read as follows:

§ 761.30 Authorizations.

* * * * *

(p) * * * *

(1) Any person may use porous surfaces contaminated by spills of liquid PCBs at concentrations >10 µg/100 cm² for the remainder of the useful life of the surfaces and subsurface material if the following conditions are met:

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[FR Doc. 03-15668 Filed 6-19-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.

ACTION: Final action on waiver.

SUMMARY: In a document published in the **Federal Register** on October 7, 2002 (67 FR 62432), the Secretary of Health and Human Services sought public comment on a proposed waiver of the applicability of certain requirements of

the Department of Health and Human Services (DHHS or Department) regulations for the protection of human subjects, 45 CFR part 46, to allow DHHS to conduct or support certain important and necessary epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects. Pursuant to his authority under 45 CFR 46.101(i), the Secretary proposed the waiver of §§ 46.305(a)(1) and 46.306(a)(2) of the DHHS regulations for the protection of human subjects, which sections set forth specific requirements for any research involving prisoners that is conducted or supported by DHHS. After consideration of the public comments received, the Secretary is granting this waiver.

DATES: The waiver is effective June 20, 2003.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections (OHRP), The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone 301-496-7005; e-mail istithco@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION:

Regulatory Background

The Department of Health and Human Services (DHHS) regulates research involving human subjects conducted or supported by DHHS through regulations codified at 45 CFR part 46. Subpart C of 45 CFR part 46, entitled "Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects," provides additional regulatory protections to prisoners who are research subjects.

Subpart C sets forth specific requirements for any research involving prisoners as subjects that is conducted or supported by DHHS. Subpart C lists four categories of research involving prisoners as subjects that may be conducted or supported by DHHS. Sections 45 CER 46.305(a)(1) and 46.306(a)(2) require that the institutional review board (IRB) reviewing the research and the Secretary, respectively, determine that the research involving prisoners represent one of these four categories. The first three categories, §§ 46.306(a)(2)(i), (ii), and (iii), require that the research target either (i) the possible causes, effects, or processes of incarceration and of criminal behavior; (ii) the prison as an institution or prison life; or (iii) conditions particularly affecting prisoners as a class. The fourth category, § 46.306(a)(2)(iv), permits research on practices which have the intent and reasonable probability of

improving the health or well-being of the prisoner-subject.

DHHS Conducted or Supported Epidemiologic Research

DHHS conducts or supports certain epidemiologic studies in which the purposes are as follows: (1) To describe the prevalence or incidence of a disease by identifying all cases, and (2) To study potential risk factor associations for a disease. For most such studies, the institutional review board (IRB) reviewing the study determines that the research at issue involves no more than minimal risk and no more than inconvenience to the subjects. The human participants in this type of public health research may include prisoners in the study population. State health agencies are most commonly the conduits for this type of research. Because certain epidemiologic studies conducted or supported by DHHS focus on a particular condition or disease that might affect prisoners as it would any other members of the general population, such studies do not meet any of the four categories of permissible research under subpart C, 45 CFR part 46.

Proposed Waiver

Pursuant to 45 CFR 46.101(i), the Secretary of DHHS has the authority to waive the applicability of some or all of the provisions of the DHHS regulations for the protection of human subjects to specific research activities or classes of research activities otherwise covered by the regulations. In a document published in the **Federal Register** on October 7, 2002 (67 FR 62432), the Secretary of DHHS sought public comment on a proposed waiver of the applicability of certain requirements of subpart C, 45 CFR part 46, to allow DHHS to conduct or support certain important and necessary epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects. The Secretary of DHHS specifically proposed waiving the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

(1) In which the sole purposes are (i) To describe the prevalence or incidence of a disease by identifying all cases, or

(ii) To study potential risk factor associations for a disease, and (2) Where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of