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IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL DEFENSE FUND, INC.,

Petitioner,

v.

ENVIRONMENTAL PROTECTION AGENCY,

Respondent,

AD HOC COMMITTEE ON LIQUID DIELECTRICS OF THE
ELECTRONIC INDUSTRIES ASSOCIATION, et al.,

EDISON ELECTRIC INSTITUTE, et al., and

ALUMINUM COMPANY OF AMERICA,

Intervenors.

Civ. No. 79-1580

EPA REPORT IN ACCORDANCE WITH THIS COURT'S
APRIL 13, 1981 ORDER CONCERNING EPA PROPOSAL FOR
ACTION ON POLYCHLORINATED BIPHENYLS IN CONCENTRATIONS BELOW
50 PARTS PER MILLION RESULTING FROM "UNCONTROLLED ~~RELEASES~~ PCBs"
AND MOTION FOR EXTENSION OF STAY OF MANDATE AS TO EPA
ACTION ON UNCONTROLLED ~~RELEASES~~ UNTIL DECEMBER 1, 1982

(PCBs)

In accordance with paragraph 2.B. of this Court's order
of April 13, 1981, the Environmental Protection Agency ("EPA"),
hereby reports its plans for further regulatory action with
respect to manufacturing, processing, distribution in commerce
and use of polychlorinated biphenyls (PCBs) at concentrations
less than 50 parts per million (ppm), in other than closed

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manufacturing processes ("closed processes") and processes producing only controlled wastes ("controlled processes"). ^{for the purposes of this document,} We have referred to this aspect of the PCB rulemaking as dealing with "uncontrolled ^{PCBs} releases."

After ^{a preliminary evaluation of the} evaluating information submitted to EPA in response to requests published in the Federal Register and other relevant data and consulting with all parties to this case, EPA determines that completion of PCB rulemaking for uncontrolled ^{PCBs} releases ^{maybe} is largely dependent ^{upon} on the resolution of issues in the rulemaking on "closed" and "controlled" processes. A final PCB rule on "closed" and "controlled" processes is scheduled for October 13, 1982. Therefore, EPA will need a short time after that date to further report to the Court on final plans for completing rulemaking on ^{the} uncontrolled releases of PCBs. EPA suggests that the further report of plans be made by November 1, 1982. Since the Court's present stay of its mandate expires on October 13, 1982, with respect to all PCBs at concentrations less than 50 ppm, EPA also suggests that the stay be extended until December 1, 1982, with respect to uncontrolled ^{PCBs} releases at those levels. During this extension of the stay, EPA can report its plans for such ^{uncontrolled PCBs} releases on November 1, 1982 and the Court will have sufficient time to review these plans before the stay of the mandate expires.

defined by the "absence" of PCBs in either final product or in certain releases, such as air emissions or water discharges. EPA is evaluating how to define "absence" of PCBs. (see page 11)

for purposes of this document,

A "closed manufacturing process" is ^{one which generates} PCBs but from which no PCBs are released. In a "controlled waste process," PCBs are released only as constituents of wastes which are incinerated or disposed of in EPA approved landfills, or held for such disposal.

The reasons for EPA's determination to suggest this course of action for further rulemaking on uncontrolled ^{PCBs} ~~release~~ is explained below.

I. BACKGROUND

A. GENERAL BACKGROUND.

Section 6(e) of TSCA, 15 U.S.C. §2605(e), required EPA, among other things, to adopt rules governing the manufacturing, processing, distribution in commerce, and use of PCBs. On May 31, 1979, EPA promulgated such rules, called the "PCB Ban Regulations," 44 Fed. Reg. 31542-58, 40 CFR Part 761. The Environmental Defense Fund, Inc. ("EDF") obtained judicial review of the PCB Ban Regulations. On October 30, 1980, this Court held, inter alia, that two aspects of the PCB Ban Regulations were invalid. EDF v. EPA, 636 F.2d 1267.

This Court set aside the portion of the PCB Ban Regulations that, generally, had limited the applicability of those rules to materials containing PCBs in concentrations of at least 50 ppm. 636 F.2d at 1279-1284. In addition, the Court set aside EPA's determination that certain uses of PCBs were "totally enclosed" uses and, therefore, exempt from regulation under Section 6(e). 636 F.2d at 1284-6.*/ The rules were then remanded for further rulemaking by EPA, consistent with the Court's opinion. 636 F.2d at 1284.

*/ The Court also upheld the PCB Ban Regulations' authorization of eleven non-enclosed uses of PCBs. 636 F.2d at 1275-9.

The Court's decision placed industries that had relied upon the PCB Ban Regulations in a difficult position. EPA and EDF believed that issuance of the Court's mandate would have activated Section 6(e)'s broad prohibitions on the manufacture, processing, distribution in commerce and use of PCBs. The parties, therefore, filed a series of joint motions with the Court to seek a stay of the Court's mandate. During the period encompassed by the proposed stay: (1) EPA would conduct new rulemaking with respect to PCBs; (2) industry groups would undertake activities related to the new rulemaking; and (3) users of transformers containing PCBs would institute an interim inspection and reporting program.

On February 12, 1981, this Court entered an order in response to the joint motion of January 21, 1981 ("February 12 Order"). This order is not relevant to the matters discussed in the instant report, but is described in a separate document submitted to the Court today titled "Joint Motion For One Week Extension Of Stay Of This Court's Mandate."

On April 13, 1981, the Court entered a second order in EDF v. EPA, in response to a joint motion that was submitted on February 20, 1981 (the "April 13 Order"). The April 13 Order stayed issuance of the Court's mandate with respect to activities relating to PCBs in concentrations below 50 ppm. The order also adopted a plan for further actions by EPA and

industry groups leading toward new EPA rulemaking on the regulation of PCBs in concentrations below 50 ppm. The April 13 Order required EPA: (1) to publish two Advance Notices of Proposed Rulemaking ("ANPR") on developing rules to cover PCBs in concentrations below 50 ppm; (2) within 18 months from the date of the order (i.e., October 13, 1982), to promulgate a final rule with respect to the exclusion from the prohibitions of Section 6(e)(3) of the generation of PCBs in "closed manufacturing processes" or only as constituents of "controlled wastes," or to explain the reasons for not proceeding with such a rule; and (3) within eleven months after the date of the order (i.e., March 13, 1982), to advise the Court of EPA's plans and schedule for further action on PCBs in concentrations below 50 ppm generated other than either in "closed manufacturing processes" or as constituents of "controlled wastes," i.e., for "uncontrolled ^{PCBs} ~~release~~."

For these "uncontrolled ^{PCBs} ~~releases~~," described in item 3, EPA needed to collect a range of additional factual information in order to develop an adequate rulemaking record consistent with the Court's opinion of October 30, 1980. This need for collection and evaluation of additional data accounts for the relatively greater difficulties EPA will face in completing rulemaking on "uncontrolled ^{PCBs} ~~release~~" as compared with the "closed" and "controlled" processes.

B. INFORMATION RELATING TO PCBs IN CONCENTRATIONS
LESS THAN 50 PPM.

1. Publication of ANPR's and Related Notices

In deciding what further action it will take with respect to PCBs in concentrations less than 50 ppm, EPA has ^{and will rely} ~~relied~~ heavily on information received in response to the two ANPRs published in the Federal Register on May 20, 1981, 46 Fed. Reg. 27614, in accordance with the Court's April 13 Order.

As set out above, the ANPRs established bifurcated rulemaking proceedings with respect to PCBs in concentrations below 50 ppm. The first ANPR announced activities that EPA believed may lead to rulemaking on PCBs generated in the "closed manufacturing processes" and "controlled waste" processes. The second ANPR announced the framework for the Agency's exploration of the scope of the problem presented by PCBs in concentrations below 50 ppm in uncontrolled ^{PCBs} ~~releases~~. EPA there stated that it needed to develop a substantial factual basis to support rulemaking on these PCBs.*/ 46 Fed. Reg. 27619.

The comment period for both ANPRs expired on November 16, 1981. Approximately 50 public comments were submitted in response to the two ANPRs published on May 20th. The most significant submission was filed by the Chemical Manufacturers Association ("CMA") -- a trade association whose membership

*/ On May 20, 1981, EPA also had published in the Federal Register a summary and the full text of the April 13 Order. 46 Fed. Reg. 27615.

consists of nearly 200 companies, including the nation's principal manufacturers of primary chemicals. ~~most important chemical manufacturers.~~ As explained further below, EPA ^{will rely} ~~relied~~ on CMA's submission ^{to a significant extent,} because ^{CMA has collected} ~~it is~~ the most comprehensive set of data gathered to date on generation of PCBs in concentrations below 50 ppm.

2. Information-Gathering by the Chemical Manufacturers Association

On April 24, 1981, CMA distributed detailed questionnaires to its membership -- nearly two hundred companies. These questionnaires were designed to provide a data base to ^{in Standard Industrial Code (SIC) 28} ~~determine the extent and nature of the generation of~~ PCBs in concentrations below 50 ppm in chemical manufacturing processes. ^{with permission for late filing} After collecting and evaluating the data, CMA submitted its final ^{survey and comments} report to EPA on November 30, 1981. The report is titled, A Report of A Survey on the Incidental Manufacturing, Processing, Distribution, and Use of Polychlorinated Biphenyl at Concentrations Below 50 PPM [hereafter CMA ^{Survey} REPORT -- a copy of the CMA Report is attached as Appendix A].

Insert Attachment A

Among other things, the questionnaires asked CMA members to describe the quantity and the environmental fate of PCBs generated in each process of each facility in which there was reason to believe PCBs were generated. The questionnaires also requested information with respect to potential human and environmental exposure to the PCBs generated and to controls employed to reduce the generation of PCBs. A copy of the questionnaire CMA distributed in connection with this survey was appended to the joint motion filed with the Court on February 20, 1981.

ATTACHMENT A

In addition, CMA submitted the following reports to EPA:

- 1.) The Analysis of Chlorobiphenyls, submitted August 21, 1981 (An analytical narrative on the problems and costs associated with analyzing low level PCBs.)
- 2.) Summary of the Health Effects of PCBs by Ecology and Environment, Inc., and associated reference material which contained five unpublished reviews, draft report submitted November 16, 1981; final report submitted November 25, 1981.
- 3.) Comments In Response to two Advance Notices of Proposed Rulemaking Relating to the Manufacture of PCBs below 50 parts per million published May 20, 1981 by the Environmental Protection Agency (46 Fed. Reg. 27617, 27619), submitted November 25, 1981.
- 4.) Statistical Analysis of Data From A Round Robin Experiment On PCB Samples by Reiden Pittaway Associates, draft report. (Report of an analytical round robin with EPA and industrial participants.)

C. PROBLEMS WITH DATA AND ANALYTICAL CAPABILITIES

~~first responded to the CMA Incidental Generation Survey.~~ ^{firms}
~~Eighty-five CMA members reported.~~ ^{Twenty-six of them}

believed that one hundred and thirty-five processes generate PCBs in concentrations below 50 ppm. CMA reports these companies generate 13,800 pounds of PCBs, of which 13,100 pounds are disposed of as controlled wastes.

EPA has used the data presented by CMA and available data from some other sources to project PCB generation for the entire chemical industry. Although the CMA data has been very helpful, as explained below it has not entirely put to rest certain questions about the generation of PCBs and the quantities being formed.

~~Because responding to the Survey~~ ^{principal manufacturers of primary}
~~firms reporting to CMA represent approximately 35 percent~~
~~chemicals, CMA believes that the poundage reported is representative of the total amount of~~
~~of all chemical industry sales, based on 1978 sales data.~~ ^{PCBs generated by the chemical industry (see CMA Survey Report, page}

~~However,~~
~~CMA in its report admits that accurate projections of the~~
~~number of individual processes which incidentally generate PCBs to the~~
~~industry as a whole cannot be made on this basis without~~
~~a high level of~~ ^{Theoretically,}
~~substantial uncertainty.~~ ^{PCBs may be formed when carbon,}
~~high temperature~~
chlorine and a source of heat are present, and may therefore

be present in many processes fundamental to the organic chemicals industry. The ^{number of individual processes incidentally generating}
~~65 respondents to the CMA survey~~
~~reported 135 processes generating PCBs. If this approximate~~
~~ratio holds for the 11,000 chemical firms in the U.S., the~~
~~number of chemical processes generating PCBs could be between~~
10,000 and 20,000.

Of these 13,100 pounds, 9100 pounds (66 percent) are incinerated, 1800 pounds (13 percent) are in salt water wash discharged to a salt water reservoir surface water system, 1600 pounds (12 percent) go to landfill and 600 pounds (2 percent) go to ground injection. (See CMA Survey Report at page 16)

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As a result, EPA faces substantial uncertainty in determining how many of these processes ^{could be regulated as} ~~may~~ generate ⁱⁿ "uncontrolled ~~wastes~~ ^{PCBs}." The potential number of such processes could be relatively few or more than 10,000. Where the likely actual number falls will seriously affect how EPA can manage a rulemaking on "uncontrolled ~~releases~~ ^{PCBs}." If there are relatively few ~~"uncontrolled" processes~~ ^{in this category}, EPA could formulate PCB rules employing procedures that are simple, and the time needed for rulemaking will be relatively short. If the actual projected number of "uncontrolled ~~releases~~ ^{PCBs}" ~~generating~~ processes is very large (i.e., several thousand or more), resources for formulating and administering PCB rules could be severely strained. Larger numbers of processes will make it more difficult to develop definitions of terms or recordkeeping and reporting requirements that can uniformly apply to the persons subject to the rule. Moreover, the larger the number of processes covered by an "uncontrolled ~~releases~~ ^{PCBs}" rule, the more difficult it will be to fashion a rational exemption procedure under section 6(e)(3) of TSCA, 15 U.S.C. §2605(e)(3). EPA will have to perform considerable analyses to reduce the large number of individual processes into manageable categories for purposes of determining exposure to PCBs, availability of substitutes ^(manufacturing, processing and distribution) and, ultimately, whether the ~~processes~~ present unreasonable risks. See §6(e)(3)(B) of TSCA, 15 U.S.C. §2605(e)(3)(B).

EPA might find it administratively impossible to make such findings on an individual plant or even process basis, if the

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number of processes covered by a rule is large. Resolution of technical and legal issues for formulating the rules would require a considerable effort on EPA's part. Particularly, care must be taken to fashion a scheme that would ^{direct focus} regulating those available EPA resources ~~and public attention~~ on ^{which present the} processes ~~of~~ greatest environmental or health concern.

After completion of the rulemaking on "closed" and "controlled" processes, EPA can better estimate the number of the remaining, "uncontrolled ^{PCBs,} ~~release,~~" processes. When EPA refines the estimate of "uncontrolled ^{PCBs,} ~~release,~~" it will be able to submit to the Court a plan reflecting the expenditure of resources and time needed to complete additional rulemaking.

Until then EPA will continue to evaluate and eventually resolve, in the context of the "closed" and "controlled" process rulemaking, issues necessary to decide what qualifies a process as "closed" or "controlled." Among these issues are: (1) how wastes from a process must be handled; (2) whether there will be a limit to the amount of PCBs generated within, but not released from, a system considered "closed" or "controlled;" ^{*}/ (3) what, if any, worker protection requirements are necessary; ~~what~~ (4) what analytical techniques should be used to determine that a process is "closed" or "controlled;" and (5) an evaluation of the health and environmental concerns.*

^{*}/ This issue will have a bearing on the risks associated with accidental release of PCBs.

The problem of choosing analytical techniques is a particularly good example of the problems EPA faces in determining the number of processes that will be considered "closed" and "controlled" and, consequently, the scope of the rulemaking on "uncontrolled" ^{PCBs} releases of PCBs in concentrations below 50 ppm. There is substantial uncertainty in the accuracy of PCB analytical techniques at low concentrations. These questions stem from the fact that controlled and closed processes are defined by the "absence" of PCBs either in the final product or in certain releases, such as air emissions or water discharges. Because of scientific and other practical limitations on the detection and quantification of PCBs in these releases, the "absence" of PCBs cannot mean literally zero molecules. Consequently, the Agency must specify how the absence of PCBs is to be determined in various releases.

The ^{analytical system} instrument most often used to monitor ^{includes} for PCBs is a gas chromatograph (GC). There are 209 different chemical ^{congeners} forms (isomers) of PCBs which can be present in various processes, products, and releases in differing proportions. The identification of total amounts of PCBs is complicated by difficulties in determining which of the 209 forms are present. Further, the sensitivity of analysis for PCBs by

(A gas chromatograph is part of a system to)

By ^{measuring the length of time it takes for each chemical compound to travel through a packed tube of small diameter, the identification of individual components of the mixture is accomplished by comparing the retention time of the compound in the sample being analysed to the retention time of a known standard solution.} provides qualitative analysis

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GC methods may be adversely affected by the presence of other organic compounds in several ways.^{2/}

To deal with these problems the analytical chemist must find appropriate procedures to extract the PCBs and to remove the interfering compounds. Different procedures are suitable for solving these problems in air emissions, in water discharges, in waste streams and in end products. Moreover, differences in the physical and chemical nature of processes add complexity to the analytical chemistry issues. Accordingly, a number of procedures of varying complexity will have to be evaluated before EPA decides how reasonably to determine the "absence" of PCBs.

In specifying how the "absence" of PCBs is to be determined, the Agency is faced with the problem of deciding the level of sophistication that should be used in analytical techniques because the state of the art PCB analysis and quantification may be ~~as more sophistication is required for measuring PCBs in very low concentrations, the number of processes not qualifying as "closed" or "controlled" will increase and will need to be treated in the "uncontrolled release" rulemaking.~~

^{1st}
most first
First, many materials are not suitable for direct injection into a GC. Samples such as solids, tars, and corrosive materials are usually dissolved in a suitable solvent. ^{and therefore quantitative}
Frequently they are extracted into a different solvent prior to analysis. ^{Moreover,} ~~certain organic compounds may bind the PCBs and prevent their extraction in this type of procedure.~~
^{Finally,} ~~Second, there are some organic compounds whose GC retention times are the same or virtually the same as the PCBs. (Similar to)~~
Such compounds may interfere with the detection of PCBs by making their presence ^{W/N} ~~or give false quantitation of the actual amount of PCBs present.~~

In sum, EPA cannot determine its plans for the "uncontrolled ^{PCBs} ~~release~~" rulemaking until it has a reasonable estimate of the number of processes that will be subject to such rulemaking. That number cannot be determined until EPA has decided the number of processes that will be considered "closed" or "controlled." Meanwhile, EPA must resolve a number of issues in the "closed" and "controlled" process rulemaking, including the nature of the analytical techniques to be used.

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CONCLUSION

Between now and November 1, 1982, EPA will work toward resolving the aforementioned questions as expeditiously as possible. On that date EPA will report to this Court on the Agency's plans for proposing and promulgating a rule on "uncontrolled ^{PCBs} releases" of PCBs in concentrations below 50 ppm. The plans will provide an adequate period for public comment and review within the Federal Government.

EPA requests an extension until December 1, 1982, of this Court's stay of its mandate issued with respect to PCBs in concentrations below 50 ppm other than in closed manufacturing processes or in processes producing only controlled wastes.

Counsel for all parties to this proceeding have authorized us to represent that they do not oppose the report or the extension of the stay of mandate.

Respectfully submitted,

FOR RESPONDENT:

David Buente, Attorney
U.S. Department of Justice, Room 1736
Tenth and Pennsylvania Ave., N.W.
Washington, D.C. 20530
(202) 633-2807

Alan H. Carpio, Attorney
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460
(202) 426-3246

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