RECOMMENDATION OF THE PARTIES FOR A FINAL EPA RULE ON INADVERTENT GENERATION OF PCBS

Jointly Submitted by:

ENVIRONMENTAL DEFENSE FUND
NATURAL RESOURCES DEFENSE COUNCIL
CHEMICAL MANUFACTURERS ASSOCIATION

April 13, 1983

RECOMMENDATION OF THE PARTIES FOR A FINAL EPA RULE ON INADVERTENT GENERATION OF PCBs

EXECUTIVE SUMMARY

Representatives of the Environmental Defense Fund, Natural Resources Defense Council, the Chemical Manufacturers Association and other industry groups have been meeting since last summer to develop a consensus proposal for regulation of inadvertent generation of polychlorinated biphenyls (PCBs). Following extensive discussions, some of which were attended by EPA representatives, the parties have developed proposed regulatory language and the legal and factual rationale supporting the proposed consensus regulation.

The proposal would allow manufacture of chemicals in processes that inadvertently generate PCBs only under conditions where PCBs released to product, air or water are strictly controlled and where inadvertently generated PCBs in waste streams are properly disposed. Manufacturers would be required to assure that the concentrations of inadvertently generated PCBs in products average below 25 parts per million (ppm) and are at all times below 50 ppm, concentrations released to water are below 0.1 ppm, and concentrations released to air are below 10 ppm. Certification and reporting requirements would be imposed so that EPA would be informed of certain situations where inadvertently generated

PCBs are being released. The proposal further recognizes the lesser environmental persistence of the monochloro and dichloro biphenyls as compared to the higher chlorinated biphenyls by providing discounts to be used in computing PCB concentrations for those congeners.

The parties believe this proposal is consistent with congressional intentions in Section 6(e) of the Toxic Substances Control Act, as interpreted by the U.S. Court of Appeals. The proposal would ensure that no unreasonable risks to health or the environment would be posed by inadvertent generation of PCBs. Through the strict controls imposed on all processes that inadvertently generate PCBs, the quantity of PCBs that could be released to the environment would be small. Requirement for tighter controls on such activities are anticipated to be very costly, but of minimal significance in reducing public health risks.

For further information, contact:

Jacqueline Warren, Natural Resources Defense Council, (212) 949-0049

Ellen Silbergeld, Environmental Defense Fund, (202) 387-3500

Robert J. Fensterheim, Chemical Manufacturers Association, (202) 887-1189

RECOMMENDATION OF THE PARTIES FOR A FINAL
EPA RULE ON INADVERTENT GENERATION OF PCBS

Table of Contents

RECOMMENDATION OF THE PARTIES FOR A FINAL EPA RULE ON INADVERTENT GENERATION OF PCBS

I. INTRODUCTION AND SUMMARY.

As reported to the Environmental Protection Agency (EPA) on December 21, 1982, representatives of the Environmental Defense Fund (EDF), the Natural Resources Defense Council (NRDC), and the Chemical Manufacturers Association (CMA) (hereinafter collectively called "the parties") and individual company representatives began meeting last summer to determine whether a rule on inadvertent generation of polychlorinated biphenyls (PCBs) acceptable to all parties could be drafted. The effort to achieve a consensus proposal was initiated by environmental groups and industry in light of the shared perception that their disagreements on some issues relevant to inadvertently generated PCBs should not preclude development of a reasonable rule. On December 21, the parties suggested that EPA representatives attend future meetings to monitor progress.

Since December 21, 1982, the parties have continued to work toward formulation of a joint proposal resolving all outstanding issues pertinent to inadvertent generation of PCBs. Several meetings were attended by EPA staff representatives. This document reports on the parties' progress, proposes specific regulatory language, and sets forth the scientific and legal rationales for the proposed regulation.

The parties including member companies of the PCB Program Panel (as well as other groups that have participated in the post-December meetings, including the Dry Color Manufacturers Association and Standard Chlorine Company) urge the Agency to employ this proposal as the basis for a final rule on inadvertent generation of PCBs.

The proposal has five major aspects:

(1) PCB concentrations in products are to be limited to a 25 part per million (ppm) average per year and 50 ppm at any given time. The new limit will force persons inadvertently generating PCBs who have only had to achieve 50 ppm or lower concentrations during the past four years to achieve greater control of PCBs in products.

(2) Concentrations of inadvertently generated PCBs at the point where such PCBs are vented to the ambient air are to be less than 10 ppm. Such emissions will thus be regulated for the first time, with the allowable control limit achieving concentrations at ground level lower than can be practically quantified.

(3) Concentrations of inadvertently generated PCBs discharged from manufacturing sites to water are to be less than 0.1 ppm for any resolvable gas chromatographic peak. This limitation is identical to that contained in EPA's "closed and controlled" rule, namely at the practical limit of quantitation for inadvertently generated PCBs in water.

(4) Quantitation of PCBs is to be calculated after discounting the concentration of monochloro and dichloro biphenyls by factors of 50 and 5, respectively. Such discounting reflects the data demonstrating that these lesser chlorinated biphenyls persist in the environment and bioaccumulate to a much lesser extent than the higher chlorinated biphenyls and are thus unlikely to enter the food chain.

(5) Various certification, reporting, and record maintenance requirements are included so that EPA will be aware of those processes inadvertently generating PCBs in the greatest concentrations and amounts. In addition, the proposal maintains for inadvertently generated PCBs the pre-existing requirement that process wastes above 50 ppm be disposed in accord with EPA's PCB disposal requirements.

As summarized in Sections IV and V of this document, the parties believe that there is ample legal and evidentiary support for the proposal. Taken as a whole, the proposal sets strict limits on PCB releases and assures that no unreasonable risks will be posed by inadvertently generated PCBs in products or otherwise released to the environment.

II. THE PRE-1980 BACKGROUND: CONGRESSIONAL PASSAGE OF TSCA, EPA'S 1979 RULE, AND THE COURT OF APPEALS REMAND.

The issues presented by inadvertent generation of PCBs differ significantly from the concerns that prompted Congress to include a special subsection on PCBs (Section 6(e)) when it enacted the Toxic Substances Control Act (TSCA) in 1976.[1] Congressional debates during consideration of TSCA focused on findings in the late 1960's that prior uncontrolled use had led to PCB concentrations in rivers and lakes as well as in aquatic organisms including fish. This prompted the often-repeated concern that PCBs persist in the environment, bioaccumulate in organic tissue, and thus enter the human food chain.

Congress directed its attention to intentionally manufactured PCBs, which had been produced in the United States since the 1930's for a variety of uses, especially electrical equipment dielectric fluid.[2] Throughout the congressional

---

1/ 15 U.S.C. § 2605(e).

2/ See, e.g., Toxic Substances Control Act: Hearings on H.R. 5276 and 10840 Before the House Subcomm. on Commerce and Finance, Comm. on Interstate and Foreign Commerce, 92d Cong., 2d Sess. 66 (1972) (statement of Russell E. Train); House Comm. on Interstate and Foreign Commerce, Legislative History of the Toxic Substances Control Act, 94th Cong., 2d Sess. 776 (1976) (report prepared by Council on Environmental Quality); 122 Cong. Rec. 8292 (report of Legislative Research Service), 8293 (report from Wisconsin Natural Resources), 8294 (statement of Sen. Tunney), 27186

(Footnote 2 continued on next page.)

debates, it was repeatedly noted that the sole domestic producer of PCBs had already voluntarily limited its sales exclusively to persons intending use in closed-system capacitors and transformers. Even so, Congress believed it necessary to impose an outright ban on PCB manufacture, and accordingly enacted Section 6(e) to limit strictly further intentional production and to control releases to the environment of previously manufactured PCBs.

Absent from congressional consideration of PCBs in 1976 was any explicit recognition that PCBs are also inadvertently and unintentionally generated as unwanted trace impurities during the manufacture of a wide variety of chemicals. Nowhere do the congressional debates discuss such inadvertent generation, and the statutory language of Section 6(e) thus fails to address directly control of PCBs from such sources. The underlying concern that PCBs not be released in such quantities that they accumulate in the environment and enter the food chain is, of course, common to consideration of both intentional manufacture and inadvertent generation. Not addressed during congressional passage of TSCA, however, were:

(Footnote 2 continued from previous page.)

(statement of Rep. Gude), 27187 (statement of Rep. Leggett), 27188 (statement of Rep. Downey) (1976); Toxic Substances Control Act: Hearings on S. 776 Before the Senate Subcomm. on the Environment, Comm. on Commerce, Part 2, 94th Cong., 1st Sess. 61 (1976) (statement of EPA's John L. Buckley).

> The settings in which inadvertently generated PCBs are produced and used;
>
> The total quantities of such PCBs generated;
>
> The likelihood such PCBs will be released to the environment;
>
> The environmental persistence of most such inadvertently generated PCBs; or
>
> The inability of industry to eliminate totally such inadvertent PCB generation.

As detailed in Section IV below, considerable data regarding each issue has been developed by or for EPA in recent years.

Against a backdrop of silence during the congressional debates over TSCA, inadvertent generation was first identified and discussed in 1979 when EPA issued its original regulations implementing TSCA Section 6(e). EPA concluded that inadvertent generation was covered by Section 6(e), and identified "[t]wo groups of chemical[s] [that] are most affected by controls on impurities and byproducts: pigments and other chlorinated chemicals." The limited available data on processes inadvertently generating PCBs were noted by EPA, which frankly acknowledged "[t]he impact [of the final rule] on the production of other organic chemicals is not as well known."[3/] The Agency, nonetheless, hoped that most

---

3/ EPA, Final Rule on Polychlorinated Biphenyls (PCBs), Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions, 44 Fed. Reg. 31514, 31527 (May 31, 1979).

manufacturers would be able to reduce PCB concentrations below 50 ppm -- the concentration level selected as the cutoff for determining whether PCBs would be covered under Section 6(e). For persons who could not achieve such low concentrations, an exemption petition procedure was established pursuant to Section 6(e)(3)(B).[4/] As a consequence of this 50 ppm cutoff, EPA's PCB regulations did not apply to a great number of processes in which PCBs are inadvertently generated.

The 50 ppm cutoff was subsequently overturned by the Court of Appeals as unsupported by substantial evidence.[5/] Specifically with respect to inadvertent generation, the Court noted that EPA had failed to document the extent of such generation or the consequent likelihood of human or environmental exposures.[6/] Finding that EPA's 1979 record lacked substantial evidence to support the 50 ppm definition, the Court, nonetheless, noted that "some cutoff may be appropriate," and that "any determination to permit continued

---

4/ Id. at 31528.

5/ Environmental Defense Fund v. Environmental Protection Agency, 636 F.2d 1267 (D.C. Cir. 1980).

The Court stayed -- upon joint motion by all parties on February 20, 1981 -- entry of the mandate. Order in EDF v. EPA, April 13, 1981. As a result, the 1979 regulations, including the 50 ppm cutoff, have remained in effect the past two years while the Agency has been revising its PCB regulations.

6/ 636 F.2d at 1282.

use and manufacture must be made under the statutorily mandated unreasonable risk test."[7]

III. THE POST-1980 BACKGROUND: EPA'S ANPR, INTERESTED PARTY RESPONSES, AND THE CLOSED AND CONTROLLED RULE.

Following remand, EPA divided the task of considering regulation of inadvertent PCB generation into two parts. As announced on May 20, 1981,[8] EPA sought data through two Advance Notices of Proposed Rulemaking (ANPR), on inadvertent generation activities in what it termed "closed manufacturing and controlled waste" processes and on processes that would not meet those descriptions. More than 50 persons supplied information. The Dry Color Manufacturers Association (DCMA), for example, submitted extensive data describing pigment processes in which PCBs are unintentionally generated and on analytical methods for monitoring PCBs in pigments, as well as substantial monitoring results on PCB concentrations found in such activities.[9]

Data relevant to a larger universe of inadvertent generation activities were presented by CMA. Based on detailed questionnaires, CMA compiled a survey of the quantity and

---

7/ Id. at 1282, 1283 n.42.

8/ 46 Fed. Reg. 27614.

9/ DCMA, "Polychlorinated Biphenyls Unintentionally Generated in the Manufacture of Diarylide and Phthalocyanine Pigments" (June 26, 1981).

fate of inadvertently generated PCBs, determining the extent to which such PCBs are found in products, released to air or water, or disposed.[10/] Twenty-six firms reported on 135 processes. Although the survey's authors concluded there may be thousands of other processes with trace PCB impurities, they believed that the bulk of such PCBs (in terms of total quantity) were represented in the survey data base. CMA further submitted to EPA reports on the problems presented in monitoring trace impurity levels of PCBs in a wide variety of chemicals and on a round robin monitoring experiment of samples containing such PCBs.[11/]

EPA itself collected considerable data on inadvertent PCB generation. Versar, Inc., compiled for the Agency a summary of the data received in exemption petitions for processes with PCBs at concentrations above 50 ppm.[12/] Like the CMA Survey, Versar's review determined the extent to which such PCBs are found in product, released to air or water, or disposed. Under contract to EPA, Midwest Research

---

10/ Alan R. Pittaway, et al., "A Report of a Survey on the Incidental Manufacture, Processing, Distribution, and Use of Polychlorinated Biphenyl at Concentrations Below 50 PPM" (Nov. 15, 1981) (hereinafter the "CMA Survey").

11/ CMA, "The Analysis of Chlorinated Biphenyls" (Aug. 25, 1981); Heiden, Pittaway Associates, Inc., "Statistical Analysis of Data from a Round Robin Experiment on PCB Samples" (March 18, 1982).

12/ Versar, Inc., "Revised Materials Balance for Inadvertently Produced PCBs" (April 22, 1982).

Institute reviewed the technology available for, costs of, and sensitivity of PCB monitoring.[13/]

Based on this extensive new data base, which had not been available when the 1979 regulations were issued, EPA issued in October 1982 the first of two planned rules on inadvertent generation.[14/] This rule established a category of processes that inadvertently generated PCBs, denoted as "closed and controlled," to be excluded from Section 6(e) regulation, primarily on the basis that it would be administratively impossible to set limits lower than the practical limits of PCB measurement. "Closed" processes are defined as processes whose releases to product, air and water are at concentrations below the lowest practically quantifiable levels of PCBs in each of these media. "Controlled" processes

---

13/ USEPA, OPTS, EED, "Analytical Methods for By-Product PCBs -- Preliminary Validation and Interim Methods" (Oct. 11, 1982); USEPA, OPTS, EED, "Methods of Analysis for By-Product PCBs Literature Review and Preliminary Recommendations, Final Report" (Oct. 12, 1982).

EPA also obtained surveys of possible occupational and spill exposures to inadvertently generated PCBs: USEPA, OPTS, EED, "Estimation of Releases from Spills of Inadvertently Generated PCBs" (April 1982); USEPA, OPTS, EED, "Occupational Exposures to Inadvertently Produced PCBs -- Preliminary Report" (April 22, 1982).

14/ EPA, Polychlorinated Biphenyls (PCBs): Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes, 47 Fed. Reg. 46980 (Oct. 21, 1982). A petition to review this rule has been filed by CMA (D.C. Cir., Civ. No. 82-2518, filed Dec. 23, 1982). Appellate review has, however, been stayed pending final resolution of inadvertent generation regulation.

meet given standards for handling wastes containing PCBs from such processes.

In its "closed and controlled" rule, EPA recognized that there would be processes with inadvertently generated PCBs releasing PCBs above the specified lowest practically quantifiable product, air and water limits.[15/] The Agency has thus begun consideration of the need for, and design of, regulations for such processes.[16/]

Apart from EPA's own activities, two citizen petitions under TSCA Section 21 relevant to inadvertent generation issues were filed during 1982. The Dow Chemical Company and the General Electric Company each petitioned the Agency to exclude from its definition of PCBs certain chlorinated biphenyls that they maintained do not share the persistence and toxicity characteristics of higher chlorinated biphenyls.[17/] Dow petitioned to eliminate monochloro biphenyls from Section 6(e) regulation, and General Electric petitioned for exclusion of both monochloro and dichloro biphenyls. In

---

15/ Id. at 46982.

16/ EPA Report to the U.S. Court of Appeals for the D.C. Circuit in Civ. No. 79-1580 (D.C. Cir., Nov. 1, 1982).

17/ Citizen Petition of the Dow Chemical Company to Amend 40 C.F.R. Part 761 to Eliminate Monochloro Biphenyls from Regulation as Polychlorinated Biphenyls (May 13, 1982); Citizen Petition of the General Electric Company to Amend 40 C.F.R. Part 761 to Exclude Mono- and Dichlorobiphenyls from the Definition of Polychlorinated Biphenyls (July 14, 1982).

response to each of these petitions, the Agency indicated it would consider the issues raised as part of its overall inadvertent generation rulemaking program.[18/]

IV. SUMMARY OF THE PROPOSED RULE.

The parties' proposed rule is intended to assure that no unreasonable risks will be posed by inadvertent generation of PCBs. This purpose is to be achieved by a regulation that: (i) specifies how inadvertently generated PCBs are to be measured; (ii) establishes concentration limits on release of PCBs to product, air and water; (iii) maintains process waste disposal requirements; and (iv) creates reporting mechanisms by which EPA will be informed of any significant quantities of PCBs in product or released to the environment. During the parties' deliberations, a number of possible controls and a variety of quantitated levels for such controls were discussed. The rationale supporting the various limits in the proposal is discussed in Sections V and VI of this report.

The proposal is a refinement of the EPA's closed and controlled rule. Although drafted as regulatory language that substitutes for the language in the first rule, the proposal builds upon the various sections of that rule to encompass all processes that inadvertently generate PCBs.

18/ 47 Fed. Reg. 37258 (Aug. 25, 1982); 47 Fed. Reg. 46723 (Oct. 20, 1982).

EPA's development of the closed and controlled rule was based on the collection of substantial information which, inter alia, developed a framework and rationale for excluding certain inadvertent generation activities from Section 6(e) and established limits of quantitation and detection for inadvertently generated PCBs in various media. Amendment of the closed and controlled rule as proposed here, provides the most expeditious means of resolving inadvertent generation issues, as well as avoiding confusion in the regulated community.

As in the closed and controlled rule, no limits are placed on the concentration of PCBs in process; rather, limits are only set for the PCBs of significance, namely those released to product, air or water, and thus potentially available for environmental or human exposure.

The proposed regulatory language (set forth in Attachment A and referenced by section number in the description below) establishes concentration limits on PCB releases in product, air, and water for each site where PCBs are generated. Manufacturing processes at sites meeting those limitations would be "excluded manufacturing processes" (§ 761.1 (f)(1)), not subject to further TSCA Section 6(e) regulation. To merit such exclusion:

First, PCB concentrations in products leaving a manufacturing site would have to average less than 25 ppm over each calendar year and be less than 50 ppm at any given time. § 761.3(kk)(1)(A)

Second, releases of inadvertently generated PCBs from the point where such emissions are vented to the ambient air could not exceed a concentration of 10 ppm. § 761. 3(kk)(1)(B)

Third, any release of inadvertently generated PCBs to water at the point of discharge from each plant site could not exceed 100 micrograms per liter (approximately 0.1 ppm) for any resolvable gas chromatographic peak. § 761.3(kk)(1)(C)[19/]

Fourth, inadvertent generators whose products leave manufacturing sites with PCB concentrations above 2 ppm for any resolvable gas chromatographic peak (i.e., above the practical limit of quantification) are required to notify EPA of their processes and to certify that they are complying with the proposed rule in order to achieve excluded status. § 761.185

In addition, generators of inadvertent PCBs would be required to dispose of process waste containing PCBs in accordance with the previously established PCB disposal

---

19/ The proposal also includes an "upset" provision modeled after the upset provision for NPDES permit holders in 40 C.F.R. § 122.60(h). This provision (§ 761.3(kk)(2)) allows persons who exceed the product, air and water limits due to factors beyond their reasonable control to assert such an "upset" as an affirmative defense in an enforcement proceeding provided that EPA is notified of the upset within 72 hours of its occurrence. The upset provision also does not excuse generators from complying with the requirements that product concentrations average below 25 ppm over each calendar year or that releases (including releases from upsets) to air, water, or product in any calendar year over given amounts be reported to EPA (§ 761.190).

requirements requiring special treatment of waste with PCB concentrations above 50 ppm and to maintain any monitoring results they have obtained. § 761.195, referencing §§ 761.60, 761.75 and 761.65(b)(1). These same two provisions apply to persons who process, distribute in commerce, or use products containing inadvertently generated PCBs. §§ 761.1(f)(2), 761.195, 761.200

All manufacturers would also, of course, continue to be required by OSHA, RCRA, CERCLA and other environmental regulations to meet specified control limits for the predominant chemicals in which the inadvertently generated PCBs were contained.

The rule also contains reporting provisions intended to notify EPA of any significant increases in the amount of PCBs being released. If, in any calendar year, release of PCBs to product exceeds 0.0025% of current rated capacity, or release of inadvertently generated PCBs to air or to water exceeds 10 pounds, from any manufacturing site where PCBs are generated, that fact would have to be reported to EPA. § 761.190

The proposal further recognizes that some products imported into the United States contain inadvertently generated PCBs. In order to obtain exclusion from Section 6(e), imported products must be at concentrations below the same 25 ppm average and 50 ppm peak requirements that apply to generators. §§ 761.1(f)(1), 761.3(kk)(1)(A). Importers are further required to certify to the Agency if imported products

have PCB concentrations above 2 ppm for any resolvable gas chromatographic peak (§ 761.185), and to report on the quantity of PCBs in imported products in any year that quantity exceeds 0.0025% of their annual average of imported poundage of such PCB-containing products from 1978 to 1982. § 761.190(a)

The proposal establishes a definition of PCBs that acknowledges the data indicating that monochloro and dichloro biphenyls do not persist in the environment or in mammalian tissue to the same extent as do higher chlorinated biphenyls. The various concentration limits and reporting requirements in the proposal are each based on a definition of PCBs that discounts the quantity of monochloro biphenyls by 50 and the quantity of dichloro biphenyls by 5. § 761.3(jj)

Finally, the proposal specifically defines how PCB concentrations from inadvertent generation are to be determined for all purposes. § 761.3(jj). Because analytical techniques vary in their sensitivity, the rule establishes fixed criteria for measuring trace PCBs. Any resolvable gas chromatographic peaks above the EPA-determined limits of quantitation (LOQ's of: 2 micrograms per gram in product and waste, 10 micrograms per cubic meter in air, and 100 micrograms per liter in water) are to be fully quantitated. Peaks between the limits of detection (LOD's -- determined by EPA to be one-third of the values for each LOQ)[20/] and

---

20/ 47 Fed. Reg. at 46984.

the defined LOQ's are to be quantitated as the defined LOD's. Resolvable gas chromatographic peaks below the defined LOD's would not be quantitated.

Although the proposal does not require monitoring, it reflects a recognition that many persons will monitor in order to assure compliance. Records of any such monitoring are to be maintained. § 761.200. The proposal also requires that persons required to certify compliance with the regulation because their products contain PCB concentrations with resolvable gas chromatographic peaks above 2 ppm maintain either theoretical analyses or monitoring results supporting such certification. § 761.185(c)

In sum, the proposal comprehensively sets forth for all inadvertent PCB generators limitations on PCB concentrations in product, air and water, maintains waste disposal requirements, and establishes reporting and record-keeping requirements.

V. THE FACTUAL BACKGROUND SUPPORTING THE PROPOSED RULE.

In formulating this proposal, a number of factual issues were considered, including: (i) the data available on inadvertent generation activities; (ii) sampling and monitoring consistent with the proposal; (iii) the toxicity of PCBs; and (iv) the persistence of PCBs in the environment. Each of those issues is discussed separately below.

A. The Nature of Inadvertent Generation.

Based on the data developed in the past two years, it is now apparent that, although the universe of processes that inadvertently generate PCBs is large, the total quantity of such PCBs is several orders of magnitude less than the quantities previously intentionally manufactured.

1. Chemical Processes Inadvertently Generating PCBs.

The number of chemical processes in the United States that theoretically could inadvertently generate PCBs at trace levels has been estimated perhaps to exceed 10,000.[21/] A recent report to EPA discusses 230 compounds or classes of compounds whose manufacture might generate PCBs or whose processing might have inadvertently generated PCBs present as input or chemical intermediates, and at least 41 different reactions that can directly form PCBs have been identified.[22/]

PCBs can find their way into chemical processes through two main routes: chemical reaction and contamination. PCBs can be formed at extremely low concentrations by the breakdown and reorganization of a chlorinated solvent in high

---

21/ CMA Survey, supra note 10, at 11.

22/ Memorandum to Robert A. Westin, Versar, Inc., from Stanley J. Cristol, University of Colorado, "Organic Chemical Processes Leading to Generation of Incidental Polychlorinated Biphenyls" (Feb. 10, 1983); Hutzinger, O., et al., The Chemistry of PCBs, Chapters 3, 4 (CRC Press 1974).

temperature equipment such as heat exchangers. PCBs can also be present in processes through use of feedstocks contaminated at relatively low concentrations. A manufacturing process may either destroy the PCBs or may carry them through unchanged. Because PCBs are more soluble in organic compounds, water contaminated with PCBs can easily introduce PCBs into a process involving organic chemicals.

Many chemicals that result from the complex reactions where PCBs can occur are engineered for unique properties or for highly critical specialty applications. For example, PCBs are generated in the production of phenyl-containing silicone products, typically used in highly critical applications such as military and commercial aircraft, military equipment, and space vehicles.

2. Handling of Chemicals with Inadvertently Generated PCBs.

Regardless of the precise source of inadvertently generated PCBs, such PCBs are trace impurities in other chemical substances, which, because of the characteristics of the predominant chemical, are often handled in a manner that minimizes opportunities for human or environmental exposures. Many such chemicals are already regulated. For example, OSHA has established airborne occupational standards for benzyl chloride and monochlorobenzene of 5 mg/M^3 and 350 mg/M^3, respectively. Even if these chemicals contained 50 ppm PCBs, their concentrations -- when OSHA standards were being

met -- would be 0.0003 mg/M³ and 0.02 mg/M³ in benzyl chloride and monochlorobenzene, respectively. Those concentrations are far below the 1.0 and 0.5 mg/M³ OSHA standards for intentionally manufactured commercial PCB mixtures.[23] Similarly, many chemicals that may contain trace quantities of inadvertently generated PCBs, including benzyl choride and chlorobenzene, are among the substances listed as hazardous wastes whose disposal or spillage is controlled by EPA under the Resource Conservation and Recovery Act (RCRA) or Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).[24]

3. The Quantity of Inadvertently Generated PCBs.

The CMA and Versar surveys estimated that, although a large number of processes may inadvertently generate PCBs, total annual generation approximates 100,000 pounds, most of which are never released to the environment. Fewer than 11,000 pounds were estimated to enter products annually. Many such products are chemical intermediates, and the end-use products generally bind the PCBs in tight matrices.[25]

23/ OSHA regulations, 29 C.F.R. § 1910.1000, Table Z-1.

24/ EPA's RCRA regulations, 40 C.F.R. § 261.33(e),(f).

25/ CMA's Survey, supra note 10, at v-vi, covered 85 firms that produce approximately 50% of U.S. chemical industry sales. See EPA Minutes for meeting of January 27, 1982. It found 26 firms with 135 processes containing PCBs at levels

(Footnote 25 continued on next page.)

Fewer than 1,000 pounds annually are thus likely to enter the environment.[26/] Although the data on release of inadvertently generated PCBs to the environment is undoubtedly not precise, the order of magnitude of such releases is reasonably assured by the survey information.

The estimated 1,000 pounds or less annually entering the environment is but a very small percentage (0.01%) of the 10,000,000 pounds that are estimated to have entered the environment annually before PCB controls were instituted or

---

(Footnote 25 continued from previous page.)

below 50 ppm, in which a total of 13,800 pounds of PCBs are inadvertently generated each year.

Similarly, small amounts of PCBs were found unintentionally generated in processes with concentrations above 50 ppm. The approximately 40 processes for which exemption petitions were examined were estimated by EPA annually to generate about 75,000 pounds of PCBs. 47 Fed. Reg. 24976, 24978 (June 8, 1982). The Versar Study, supra note 12, determined only about 10,000 pounds of that total are in commercial chemical products.

By combining the two surveys, the total amount of PCBs inadvertently generated annually can be estimated as less than 100,000 pounds (75,000 pounds in concentrations above 50 ppm and 13,800 pounds in concentrations less than 50 ppm). Of that total generation, less than 11,000 pounds annually (about 10,000 pounds generated in concentrations above 50 ppm and 660 pounds generated at lower concentrations) enter end-use products.

Of the 660 pounds of PCBs in products in the CMA Survey, 500 pounds were encapsulated in solid matrices or degraded during further manufacturing. CMA Survey, supra note 10, at vi. See also DCMA Submission, supra note 9.

26/ A large percentage of PCBs are disposed in a controlled manner. The CMA Survey, supra note 10, at v-vi, for example, found that of 13,800 generated pounds, 9,100 pounds were incinerated. The Versar Study, supra note 12, found only 31.7 pounds annually being released to water.

the total of 180,000,000 pounds estimated to have entered the environment prior to institution of PCB controls (0.0007%).[27/]

Various monitoring studies have documented the declining load of PCBs in the environment. For example, monitoring of chub fish in Lake Michigan has found a decline in PCB concentrations since 1974 proceeding with a half-life of five years. In other words, every five years the concentration of PCBs in chubs has been reduced by 1/2 (5.5 mg/kg in 1974 to 2.2 mg/kg in 1980). A similar pattern for the Great Lakes environment has also been observed for herring gull eggs, lake trout, and actual water concentration.[28/]

The environmental load can be expected to continue to decline in the future, and the small addition of PCBs released from inadvertent generation is unlikely to affect that decline measurably. The National Academy of Sciences indicated that through 1975 a total of 180 million pounds of PCBs had entered the mobile environment. It is this load that is declining by 1/2 every five years. Hence, in 1980 the load would be 90 million pounds. If no further additions occurred, by the year 2000 (four half-lives), the initial load of 90 million in 1980 would have declined to

---

27/ 122 Cong. Rec. 8294 (daily ed. March 26, 1976) (remarks of Senator Tunney); NAS, Polychlorinated Biphenyls 6 (1979).

28/ Hartig, J. H., "Highlights of Water Quality Control in Michigan," Publication No. 4833-9804, at 13 (1981).

45 million in 1985, 27.5 million in 1990, 13.75 million in 1995, and 6.8 million by the year 2000.

Making several assumptions about inadvertently generated PCBs, their minimal effect on the declining environmental load can be seen. For example, it can be assumed that 10,000 pounds are released each year and that these inadvertently generated PCBs will degrade at the same rate as the existing PCB load, i.e., by 1/2 every five years (a likely over-estimate of both PCBs released and of their half-lives to the extent inadvertently generated PCBs are monochloro and dichloro biphenyls). In order to track this addition, a crude accounting scheme will be used. To simplify the table, a block of five years will be considered, hence every five years 50,000 pounds of PCBs will be added that will degrade by 1/2 every five years.

Mass Balance of Inadvertent PCB
Addition to Mobile Environment

		Amount Degraded			
Year	PCB Added	1980-85	1985-90	1990-95	1995-2000
1980-85	50,000	25,000	12,500	6,500	3,125
1985-90	50,000		25,000	12,500	6,250
1990-95	50,000			25,000	12,500
1995-2000	50,000				25,000
	200,000 lbs. added	25,000	37,500	43,750	46,875
		153,125 lbs. degraded			

The mass balance from this table indicates 200,000 minus 153,125, or 46,875 pounds, of PCBs would still be present in the year 2000, constituting 0.7% of the total in the mobile environment. Thus, releases from inadvertent generation addition of even 10,000 pounds of PCBs annually would have no measurable effect on the declining environmental load.

Beyond the small quantities involved, it is believed that most inadvertently generated chlorobiphenyls are monochloro and dichloro biphenyls -- lesser chlorinated biphenyls that do not persist in the environment nor bioaccumulate to the same degree as do the higher chlorinated biphenyls. Most inadvertently generated PCBs are found in liquid chemical substances that are distilled before marketing (e.g., chlorobenzene, carbon tetrachloride). During distillation, chemical substances with boiling points above those of the predominant chemical, including PCBs, will be removed (and thus left in process wastes). Most chemical products containing inadvertently generated chlorobiphenyls have boiling points lower than those of monochloro and dichloro biphenyls (with 273°C being the lowest boiling point for the monochloro biphenyls and higher boiling points for each of the 12 dichloro biphenyls). Thus, even monochloro and dichloro biphenyls will continue to exist after distillation only at trace levels. The higher chlorinated biphenyls (with boiling points above 400°C for decachloro biphenyls) will rarely, if ever, be found in chemical products that have been distilled

prior to distribution. EPA may wish to collect further data on the predominance of the lesser chlorinated biphenyls due to inadvertent generation as part of its planned rulemaking.

4. Reduction of Inadvertent Generation.

Eliminating PCBs totally from any chemical process would require a significant research undertaking. Besides the analytical problems associated with finding PCBs at extremely low levels, it is difficult to determine which reactions are responsible because the reaction kinetics of trace contaminants is a relatively unexplored field. Interferences, competing reactions, and other factors make it extremely difficult to determine the precise mechanism of PCB production. There are many interacting variables: reactant concentrations, order of reactant addition, process temperature, pressure, hold-up time, catalytic effects, and mixing. For example, lowering the process temperature 10°C may reduce the reaction rate and thus PCB generation. However, this would also reduce the primary reaction rate thereby requiring much greater recycling to get the same amount of production. The ratio of PCBs per pound of primary product may remain the same or may increase due to a larger recycle stream.

To date, there has been little success in reducing the formation of PCBs in extremely low concentrations. Each different process requires an entirely different research project in order to reduce or eliminate PCB generation.

Often there may be negligible effect, if any, on the amount of PCBs generated.29/

29/ Most of the success in reducing PCB concentrations has been made through engineering process modifications that reduce, not the total poundage of PCBs formed, but only concentrations at various stages in the process. When this has been accomplished, it has been only at substantial capital investment and great energy costs. The standard separation processes -- (1) distillation; (2) extraction; (3) adsorption; (4) absorbtion; and (5) precipitation -- provide only limited opportunities for PCB reduction:

(1) The separation of trace contaminants by distillation generally requires one or more of the following: (a) widely differing boiling points between desired output and trace contaminants; (b) very high reflux ratio (recycle with attendant high energy cost penalty); or (c) reduction in yield of desired output with a corresponding increase in waste for disposal. In addition to the operating cost penalties inherent in (b) and (c), capacity reduction caused by high recycle and/or reduced yield require substantially greater investment to achieve the same output results;

(2) Extraction processes depend on partition coefficients or measures of lack of affinity of solvent for product but with significant affinity of solvent for solute. In the case of PCBs, the most successful extractions proceed in the wrong direction, i.e., from contaminated water or raw material inputs to process streams. Thus, there are no known successful extraction processes for removing trace levels of PCB from each chemical process;

(3) Adsorption processes rely on the surface characteristics of solids to retain preferentially the contaminant while allowing product to pass unaffected. Complicated procedures are usually needed to limit yield loss. Adsorbants are usually regenerated in place by removal of concentrated contaminants for subsequent disposal. Substantial capital investment is usually required, and such processes are only sometimes successful in reducing trace contaminants to lower levels;

(4) Absorption processes are most often applied to the preferential removal of certain gases or vapors. Absorption has no known applications to the reduction of trace PCB contamination from inadvertent generation;

(Footnote 29 continued on next page.)

As EPA concluded in its closed and controlled rule preamble, a ban on inadvertent generation of PCBs could cause a "major disruption of the chemical industry and several other industries in the United States," could "cost billions of dollars," and could "disrupt the manufacture of a wide variety of products, including paints, varnishes, enamels, agricultural chemicals, adhesives and sealants, printing ink, plastic materials, drugs, and soaps and cosmetics."30/

* * *

In sum, many processes may inadvertently generate PCBs, but severe technical limitations preclude the possibility of reducing PCB concentrations below the trace levels typically found due to such generation. Nonetheless, the total quantity of such PCBs is very small in comparison to quantities of PCBs previously intentionally manufactured or found in the ambient environment. Continued generation of PCBs at such trace levels will not measurably affect the already declining environmental load.

(Footnote 29 continued from previous page.)

(5) Precipitation of PCBs into solids is possible depending on the degree of separation between solubility in the mother liquid and absorbability in the solid -- a ratio not often favorable for PCB precipitation.

30/ 47 Fed. Reg. at 46989.

B. Monitoring Trace, Inadvertently Generated PCBs.

As reflected in the closed and controlled rule,[31] various practical problems exist in monitoring inadvertent PCBs at the parts-per-million and lower levels. These difficulties are addressed in our proposal as explained below.

First, variability in the monitoring method requires that any measurements be considered within the context of standard deviations consistent with validated methods for measuring PCBs. Recognition of such variability is essential for determining compliance with and enforcing the rule proposed here.

Variability is generally expressed as the standard deviation of the total analytical method. A control chart approach to recording and reporting analytical results is one acceptable means of recognizing and accounting for such variability.[32] The control chart would reflect the variability of the method for product concentrations, for example, by establishing 2 standard deviation warning limits and 3 standard deviation control limits at the proposed 25 ppm average and 50 ppm maximum excursion regulatory levels. These limits would be empirically determined for each method

---

31/ 47 Fed. Reg. 46980.

32/ See ASTM Manual on Presentation of Data and Control Chart Analysis, STP 15D, ASTM, Philadelphia, PA (1976).

during method validation and would be monitored by quality control samples during use of the method. Data points exceeding the nominal regulatory limits, but not exceeding the 3 standard deviation control limits, would not be considered violations of the rule.[33/]

Second, the analytical work necessary for a reasonable regulation with respect to such quantification issues was done by EPA as part of the closed and controlled rulemaking. As discussed in the preamble to that rule,[34/] consideration of available monitoring technology, instrument sensitivity, reasonable sample sizes, extract and injection volumes, and interferences and matrix effects, led EPA to conclude that the practical limits of quantitation for inadvertently generated PCBs are 2 micrograms per gram in product and waste, 10 micrograms per cubic meter in air, and 100 micrograms per liter in water, for each resolvable gas chromatographic peak. EPA further determined that the practical

---

33/ Analytical results should be corrected for recovery, and some guidance on acceptable standard deviations (on a relative basis) are necessary to preclude excessively lenient control limits. Any such guidelines should be based on acceptable analytical practices. See, e.g., Crummet, W. B., et al., "Guidelines for Data Acquistion and Data Quality Evaluation in Environmental Chemistry," 52 Anal. Chem. 2242-2249 (1980); Rogers, L. B., et al., "Improving Analytical Chemical Data Used for Public Purposes," 60 Chem. Eng. News 44-48 (1982); Olynyk, P., et al., "Simultaneous Qualitative and Quantitative Analyses. I. Precision Study of Compounds Amenable to the Inert Gas-Purge-and Trap Method," 19 J. Chromatog. Sci. 377-382 (1981); Glaser, J. A., et al., "Trace Analyses for Wastewaters," 15 Environ. Sci. Technol. 1426-35 (1981).

34/ 47 Fed. Reg. at 46984-86.

limits of detection in each medium are one-third as much. The parties' proposal builds on that assessment by using these same parameters.

Some of the limits in the proposed rule are, like the closed and controlled rule, set in terms of concentration numbers for any resolvable gas chromatographic peak. Other limits relevant to determining whether a manufacturing process is excluded, such as those for product and air, however, are in terms of total PCB concentrations (which will often be represented by more than one resolvable peak). In order to specify how measurements shall be made for determination of total PCBs, the proposal requires that any peaks above the prescribed LOQ be counted fully and that peaks between the prescribed LOD and LOQ be counted as the LOD.

Third, various protocols for monitoring PCBs with a variety of sampling frequencies have been considered by the parties. The proposal does not require monitoring. Many processes are likely to have PCB levels that can be determined through theoretical analyses to be well below the limits set by the rule, thus making monitoring unnecessary. In recognition of the fact that many manufacturers will monitor, the rule does require, however, that if any monitoring occurs, records of such monitoring must be maintained. In addition, it is recognized that monitoring data will be crucial to companies if enforcement inspections

indicate that a generator is not in compliance with the rule. Data necessary to demonstrate statistical variations in monitoring or annual averages in product concentrations that may be necessary to rebut enforcement monitoring results are unlikely to be available without a sampling and monitoring program.

C. The Toxicology of PCBs.

The toxic potency of PCBs has been reviewed many times. As part of the closed and controlled rulemaking, extensive reviews of PCB toxicology were presented by both CMA and the Edison Electric Institute.[35/] EPA reviewed both of these reviews and compiled its own conclusions on the toxic potential of PCBs.[36/] Needless to say, differences exist among the reviews of the PCB toxicology, and those differences are represented among the parties making this proposal. Basic agreement, though, does exist on several aspects of the toxicology of PCBs -- agreement sufficient to allow parties with differing ultimate views to find that this proposal would assure an absence of unreasonable risk.

35/ Ecology and Environment, Inc., "Summary of the Health Effects of PCBs" (Nov. 25, 1981), submitted by CMA with "Reference Material for the Summary of the Health Effects of PCBs;" USWAG, Edison Electric Institute, Comments and Studies on the Use of Polychlorinated Biphenyls, Vol. II, "Potential Health Effects in the Human from the Exposure to Polychlorinated Biphenyls and Related Impurities" (Feb. 12, 1982).

36/ USEPA, OPTS, HERD, "Response to Comments on Health Effects of PCBs" (Aug. 18, 1982).

D. The Various Persistences of Chlorobiphenyls in the Environment.

Despite the opportunities for monochloro and dichloro biphenyls to enter the environment, monochloro biphenyls have not been detected and dichloro biphenyls have been detected only in some studies, and then at very low levels, in environmental and human monitoring. Approximately 10 million pounds of monochloro and more than 100 million pounds of dichloro biphenyls were produced in the U.S. from 1930 to 1978 as components of commercial chlorinated biphenyl mixtures.37/ During the latter part of this period, production was shifted toward lower chlorinated products as the persistence of higher chlorinated biphenyls became recognized. Nonetheless, both environmental and human monitoring have not detected monochloro biphenyls and have detected few, if any, dichloro biphenyls.38/

The failure to find monochloro biphenyls, and the near absence of dichloro biphenyls, in either environmental or

---

37/ See NAS, Polychlorinated Biphenyls Table D.3 at 148 (1979); Monsanto, "PCB's: A Report on Uses, Environmental and Health Effects and Disposal" (undated); USWAG, supra note 35, at 16.

38/ See, e.g., Hesselberg, R.J. and J.G. Seelye, "Identification of Organic Compounds in Great Lakes Fishes by Gas Chromatography/Mass Spectrometry: 1977," Administrative Report No. 82-1 (Great Lakes Fishery Laboratory, Ann Arbor, MI, January 1982); Wolff, M.S., et al., "Disposition of Polychlorinated Biphenyl Congeners in Occupationally Exposed Persons," 62 Toxicol. Appl. Pharmacol. 294-306 (1982);

(Footnote 38 continued on next page.)

tissue sampling is not unexpected. Monochloro and dichloro biphenyls are less likely to adsorb to solids, more likely to dissolve in water, more likely to move from natural water bodies to air, and more likely to photodegrade than more highly chlorinated biphenyls. Each of these physical properties leads to less environmental persistence. In addition, monochloro and dichloro biphenyls are also more likely to be biodegraded than the higher chlorinated biphenyls.39/ Each of these factors contributes to the conclusion reached by Nisbet that the chlorinated biphenyls with three or fewer chlorine atoms are largely removed from the environment.40/ Beyond the lesser persistence of monochloro and dichloro biphenyls in the environment, they are also more likely to

---

(Footnote 38 continued from previous page.)

Mes, J., D.J. Davies and P.Y. Lau, "The Effect of Extraction Technique on the Fat Content, Polychlorinated Biphenyl Level and Tri- to Octabiphenyl Distribution in Human Milk," 9 Chemosphere 763-69 (1980); Jensen, S. and G. Sundstrom, "Structures and Levels of Most Chlorobiphenyls in Two Technical PCB Products and in Human Adipose Tissue," 3 Ambio 70-76 (1974).

39/ Furukawa, K., K. Tonomura and A. Kamibayashi, "Effect of Chlorine Substitution on the Biodegradability of Polychlorinated Biphenyls," 35 Appl. Environ. Microbiol. 223-27 (1978).

40/ Nisbet, I.C.T. and A.F. Sarofim, "Rates and Routes of Transport of PCBs in the Environment," 1 Environ. Hlth. Perspec. 21-38 (1972).

be metabolized and eliminated and thus less likely to bioaccumulate than the more highly chlorinated biphenyls.41/

The chart on the following page portrays the variations found in various studies between persistence of the monochloro and dichloro biphenyls and trichloro biphenyls. Even greater persistence distinctions have been found in these studies to exist between monochloro and dichloro biphenyls and the higher chlorinated biphenyls.

41/ Sugira, K., et al., "Accumulation of Organochlorine Compounds in Fishes: Difference of Accumulation Factors by Fishes," 6 Chemosphere 359-64 (1979); Nebeker, A.V., F.A. Puglisi and D.L. DeFoe, "Effect of Polychlorinated Biphenyl Compounds on Survival and Reproduction of the Fathead Minnow and Flagfish," 103 Trans. Am. Fish. Soc. 562-68 (1974); Branson, D.R., et al., "Bioconcentration of 2,2',4,4'-Tetrachlorobiphenyl in Rainbow Trout as Measured by an Accelerated Test," 104 Trans. Am. Fish. Soc. 785-92 (1975); Chiou, C.T., et al., "Partition Coefficient and Bioaccumulation of Selected Organic Chemicals," 11 Environ. Sci. & Technol. 475-78 (1977).

DATA COMPARING PERSISTENCE OF MONOCHLORO, DICHLORO AND TRICHLORO BIPHENYLS

		Predicted Homolog Distribution in Lake Michigan	R*	Environmental Persistence 1/2-Life, Days	R*	Human Milk Samples % Total PCBs	R*
	TRI	49%	1	579	1	6	1
(1)	DI	16%	3	158	4	0	-
	M	1%	49	3.2	180	0	-

		CAPACITOR WORKERS Plasma (ppb)	R*	CAPACITOR WORKERS Adipose (ppm)	R*	FISH Bioconcentration Factor		R*
	TRI	27	1	9	1	(2,5,2')	12,000	1
(1)	DI	0.7	39	0.1	90	(2,2')	3,300	4
	M	0	--	0	--	(2)	2,000	6

			Trout Bioconcentration Factor	R*	Residence Time, Days, in Water	R*	Lake Water 1/2-Life, Days	R*
	TRI	(2,5,2')	2617	1	273	54	1,197	1
(2)	DI	(2,2')	1119	2	93	18	385	3
	M	(4)	1005	3	5	1	33	36

(1) Moolenaar, R. J., Recent Advances in Exposure, Health and Environmental Effects Studies of PCB, Bethesda, Maryland (May 12 & 13, 1982).

(2) Citizen Petition of The Dow Chemical Company to amend 40 C.F.R. 761 (May 13, 1982).

* R = Ratio of the given raw data.

As the data on the chart on the previous page demonstrate, large distinctions exist between persistence of monochloro and dichloro biphenyls and of trichloro biphenyls. Although no figures emerge from the various studies to express the variation with exact consistency, the parties agree that a system of discounting monochloro and dichloro biphenyls is appropriate. We propose a factor of 50 for monochloro biphenyls and a factor of 5 for dichloro biphenyls, which are protective of the public health. Although the data are not available today, other PCB isomers may have lesser persistence characteristics comparable to the monochloro and dichloro biphenyls. The parties thus encourage EPA to consider discounting factors for other isomers if and when such data are developed.

* * *

In sum, substantial data on inadvertent generation activities, on monitoring PCBs from such generation, on the toxicity of PCBs, and on the variations in persistence of the chlorinated biphenyls support development of a reasonable rule on the inadvertent generation. As explained below, when these data are assessed in terms of risk and benefit, it can reasonably be concluded that unreasonable risks will not be posed by inadvertently generated PCBs under the proposed regulation.

VI. THE LEGAL/EVIDENTIARY JUSTIFICATION FOR THE PROPOSED RULE.

The parties have assessed both the legal framework for PCB regulation and the factual background to support regulation in formulating this proposal. The proposal is premised on the conclusions that no unreasonable risks would be posed by inadvertent generation of PCBs controlled as proposed here and that such a finding legally supports the proposal under TSCA Section 6(e).

A. The Legal Unreasonable Risk Criterion.

Because Congress did not explicitly recognize that PCBs were inadvertently generated as an impurity in a variety of chemical processes, TSCA Section 6(e) does not speak of regulation of such PCBs. However, EPA's 1979 PCB rule interpreted the statute to apply to inadvertently generated PCBs. This interpretation was challenged in two petitions for judicial review,[42/] each of which has been stayed pending completion of this rulemaking. The D.C. Circuit has expressed an inclination to defer to EPA on its interpretation of TSCA Section 6(e).[43/] At the same time, the court

---

42/ Aluminum Company of America v. EPA, D.C. Cir. No. 79-1811; General Electric Company v. EPA, D.C. Cir. No. 79-1816.

43/ EDF v. EPA, 636 F.2d at 1281 n.37.

suggested that Section 6(e) allows for reasonable regulation, short of a total ban of PCBs, consistent with the unreasonable risk criterion found several times in Section 6.[44/]

Regulating inadvertently generated PCBs presents difficult problems for both the regulated community and EPA because of Congress' failure to deal with the issue specifically in Section 6(e). Applying an outright ban to the thousands of manufacturing processes in which PCBs may be generated unavoidably as impurities or byproducts would mean prohibiting manufacture of a host of important -- in some cases critical -- products, an outcome Congress clearly did not consider. The only express escape valve specified in Section 6(e) for manufacturers subject to a prohibition is the annual exemption process, Section 6(e)(3)(B). This demanding exemption process, however, was not designed for large numbers of applicants.[45/]

As an alternative to such a regulation, EPA can define a manner in which products of manufacturing processes that inadvertently generate PCBs may continue to exist consistent

---

44/ 636 F.2d at 1282 n.42.

45/ The Section 6(e)(3)(B) exemption petition process has further legal and practical problems if it alone is used as a basis for resolving the inadvertent generation issue, as exemption petitions must detail good faith efforts to develop substitutes -- a requirement that has no relevance to inadvertently generated PCBs that are, by definition, unwanted impurities.

with Congress' mandate. The unreasonable risk analysis Congress has prescribed in Section 6(e) and in other parts of TSCA Section 6, which the Court acknowledged in EDF v. EPA, provides the proper criterion for such regulation. Unreasonable risk assessment is called for under both Section 6(e)(2)(B) (authorizing use of PCBs in other than a totally enclosed manner if such use will not present an unreasonable risk) and Section 6(e)(3)(B) (authorizing exemption of manufacturing, processing and distribution in commerce if an unreasonable risk will not result). Inadvertent generation activities involve both generation and use of PCBs. PCBs are generated at low levels in many chemical processes. In many more processes, previously-generated PCBs are present and could thus be considered "used" within the context of Section 6(e)(2).

Although none of the subsections of Section 6(e) provides the specific framework for reasonable regulation of inadvertent generation, read together the various subsections demonstrate congressional intent, as found by the Court of Appeals, that practical regulatory alternatives to a total ban are proper if no unreasonable risks are presented. By adopting an unreasonable risk test to justify the proposal here, EPA would be honoring congressional intentions and assuring the public that it has reasonably regulated PCB inadvertent generation.

B. Assessing Risks Under the Proposed Regulation.

The proposed regulation would strictly limit the possibility of environmental or human exposures to PCBs from inadvertent generation. In the past four years, the potential for such exposures has been limited solely by the 1979 definition of PCBs as chemical substances containing more than 50 ppm PCBs. For substances below that definition, no PCB-specific regulations have been imposed. With the proposal here, not only will pre-existing OSHA, RCRA and other environmental regulations for the predominant chemicals in which inadvertently generated PCBs are found continue to control PCB releases, but also, strict limits will be set for PCB releases to product, air and water.

First, the regulation imposes a 25 ppm annual average on products. The new limit will force persons inadvertently generating PCBs who have only had to achieve 50 ppm concetrations during the last four years to achieve greater control of PCBs in product.

Second, water concentration limits for persons inadvertently generating PCBs are being imposed that are as tight as those imposed in the closed and controlled rule. Inadvertent generators are not excluded from Section 6(e) coverage unless water discharges from each manufacturing site are at levels lower than 100 micrograms per liter (roughly 0.1 ppm) for any resolvable gas chromatographic peak. As in

the closed and contolled rule, this limitation is as low as the practical limits of quantitation allow.

Third, inadvertent PCB generators are limited to releases to air of less than 10 ppm, measured at the stack where such emissions are vented to the ambient environment. Based on a standard dispersion model, this limit will result in ground level concentrations significantly lower than the practical limit of quantitation -- 10 micrograms per cubic meter -- set for air releases in the closed and controlled rule.

Finally, process wastes above 50 ppm must continue to be disposed under PCB-specific disposal requirements.

The potential for environmental or human risk from inadvertent generation activities is further subject to control by the proposed reporting requirements. First, any persons who monitor for PCBs are required to maintain records of that monitoring, which can be reviewed by EPA in enforcing the rule. Second, any generator or importer of inadvertent PCBs whose products contain PCBs in concentrations greater than 2 ppm for any resolvable gas chromatographic peak is required to certify compliance with the requirements of this rule to be eligible for exclusion. Finally, each year inadvertent generators are required to report to EPA if their releases of PCB to product, air or water exceed certain given total quantitites. For example, any person releasing more than 10 pounds of inadvertently generated PCBs either to air or to water in any year must report that fact to EPA.

Through these reporting requirements, EPA will be aware of any processes that are releasing even these small amounts of PCBs to the environment.

As detailed above in Section V, the surveys of inadvertent generation activities have estimated approximately 11,000 pounds of PCBs entering products. Most such PCBs are in products from which human and environmental exposures would be unlikely, and only approximately 1000 pounds actually are released to the ambient environment. In its closed and controlled rule, EPA declared that the less than 1,000 pounds annually of PCBs it estimated are likely to enter the environment from closed and controlled processes would lead to exposures that are "negligible."[46/]

In sum, quantities of inadvertently generated PCBs released to the environment under existing regulations are but a small percentage of PCBs already in the environment, and such releases will not measurably affect continuation of the decline in the environmental load of PCBs. As the proposed regulation sets strict limits on future releases, especially to air and water, inadvertent generation will in the future not contribute in any meaningful sense to environmental or human risks.

46/ 47 Fed. Reg. at 46989.

C. Assessing Benefits of PCB-Containing Chemicals.

Balanced against the risks posed by PCBs released to the environment due to inadvertent generation are the benefits of the chemicals containing such impurities. (No benefits exist in the PCBs themselves as they are unwanted impurities.) As detailed above, PCBs may be inadvertently generated in a large number of important chemicals, many of which have unique importance for particular uses. As EPA has already recognized, banning manufacture of such chemicals because of trace levels of PCBs would have major impacts on the economy.

Because it is not feasible to ban manufacture of all chemicals that contain inadvertently generated PCBs, the only alternative regulatory rule would be a tighter limitation on PCB concentrations than proposed here. However, each process where inadvertent generation occurs requires separate attention to determine whether it is even possible to prevent PCB generation, or reduce PCB concentrations once generated. As detailed above, the chemistry of inadvertent generation is not well understood. Thus, attempts to affect that generation would require major research and development efforts with no guarantee of success. Methods available for reduction of once-generated PCBs are also largely unexplored.

Although costs for reduction of PCBs in most processes have not been quantitated, several examples demonstrate that

such costs are quite high. One company, for example, was forced to expend $884,000 in development costs and $5,650,000 in investment costs to reduce inadvertently generated PCB levels in the product from one process below 100 ppm concentrations.[47/] Similar substantial costs might be imposed on all inadvertent generators were they required to lower PCB levels below those set forth in this rule. EPA may wish to seek additional cost data as part of its rulemaking to supplement examples such as that described above.

D. Balancing Risks and Benefits.

Although not quantified, anticipated costs of reducing PCB concentrations below the already low part per million levels proposed here are likely to be substantial. These costs could be particularly large given the sizeable number of, as yet, unidentified processes with trace PCBs. On the other hand, having identified the processes most likely to release any measurable quantities of inadvertently generated PCBs, having placed strict controls on such releases, and having determined from several surveys that the sum total of all PCBs released from such activities will be very small, the risks posed by controlled inadvertent generation should be minimal.

47/ See CMA, "Comments in Response to Two Advanced Notices of Proposed Rulemaking," 59-60 (Nov. 25, 1981).

In sum, great assurance exists that PCBs released by inadvertent generation activities will not measurably influence existing environmental PCB loads, nor retard the already-in-progress declining load due to restrictions on intentional manufacture. Balancing such major costs against the minimal benefits of any tighter control, it can reasonably be concluded that the proposed regulation will assure an absence of unreasonable risk from inadvertent PCB generation.

ATTACHMENT A

THE PROPOSED REGULATORY LANGUAGE

Attachment A

THE PROPOSED REGULATORY LANGUAGE

PART 761

POLYCHLORINATED BIPHENYLS (PCBs)
MANUFACTURING, PROCESSNG, DISTRIBUTION
IN COMMERCE, AND USE PROHIBITIONS

40 C.F.R. Part 761 is amended as follows:

1. Paragraph (f) of § 761.1 is deleted and new paragraph (f) is added to read as follows:

§ 761.1 Applicability.

* * * * * *

(f) Unless and until superseded by any new medium-specific regulations:

(1) Persons who inadvertently manufacture or import PCBs generated as unintentional impurities in excluded manufacturing processes (as defined in § 761.3(kk)) are exempt from the requirements of Subparts B and D, provided that such persons further comply with §§ 761.185, 761.190, 761.195, and 761.200; and

(2) Persons who process, distribute in commerce, or use chemicals containing PCBs as a result of inadvertent generation are exempt from the requirements of Subparts B and D, provided that such persons comply with §§ 761.195 and 761.200.

II. Paragraphs (jj) and (kk) of § 761.3 are deleted and new paragraphs (jj) and (kk) are added to read as follows:

§ 761.3 Definitions.

* * * * * *

(jj) For purposes of §§ 761.1(f), 761.3(kk), 761.185, 761.190, 761.195, and 761.200, PCBs means the quantity of PCBs to be calculated following division of the quantity of monochlorinated biphenyls by 50 and the quantity of dichlorinated biphenyls by 5. In determining the quantity of PCBs, the analytical methods used shall not quantitate the value of resolvable chromatographic peaks below the practical limits of detection for each medium (3.33 micrograms per cubic meter in air, 33.3 micrograms per liter in water, and 0.66 micrograms per gram in product and waste), but shall quantitate the value of all resolvable chromatographic peaks above the practical limits of quantitation for each medium (10 micrograms per cubic meter in air, 100 micrograms per liter in water, and 2 micrograms per gram in product or process waste) and shall use, as the quantitated value for all resolvable gas chromatographic peaks below the limits of quantitation but above the practical limits of detection, the specified practical limit of detection for that medium.

(kk) (1) "Excluded manufacturing process" means a manufacturing process in which PCBs, as defined in § 761.3(jj), are generated and from which releases to products, air and

water meet the requirements of §§ 761.3(kk)(1)(A), (B) and (C); or, the importation of products containing PCBs as unintentional impurities, which products meet the requirements of § 761.3(kk)(1)(A).

(A) The concentration of PCBs in products leaving any manufacturing site or imported into the United States averages less than 25 micrograms per gram over the calendar year and at any given time is less than 50 micrograms per gram.

(B) The release of inadvertently generated PCBs, at the point at which emissions are vented to ambient air, is at concentrations less than 10 parts per million.

(C) The amount of inadvertently generated PCBs added to water discharged from a manufacturing site is less than 100 micrograms per resolvable gas chromatographic peak per liter of water discharged.

(2) Persons who inadvertently generate PCBs may assert as an affirmative defense in actions brought for non-compliance with the requirements of subsections (1)(A), (B) or (C), that any such non-compliance was caused by an "upset," provided that:

(A) "Upset" means an exceptional incident in which there is unintentional and temporary non-compliance with the requirements of subsections (1)(A), (B) or (C) because of factors beyond the control of the generator. An upset does not include non-compliance to the extent caused

by operational error, improperly designed or inadequate equipment, lack of preventative maintenance, or careless or improper operation; and

(B) Any person wishing to establish the affirmative defense of upset shall demonstrate through properly signed contemporaneous operating logs, or other relevant evidence, that:

(i) An upset occurred and that the specific cause(s) of the upset can be identified;

(ii) The process was at the time being properly operated; and

(iii) The generator submitted notice of the upset to EPA within 72 hours of knowledge of the upset.

(C) Occurrence of an upset or upsets shall not excuse persons who inadvertently generate PCBs from complying with the annual requirements imposed by §§ 761.3(kk)(1)(A), or 761.190.

III. Section 761.185 is deleted and new section 761.185 is added to read as follows:

§ 761.185 Certification program and retention of records by importers and persons generating PCBs in excluded manufacturing processes.

(a) In addition to meeting the basic requirements of § 761.3(kk), manufacturers with processes inadvertently generating PCBs and importers of products containing inadvertently generated PCBs shall report to EPA, through filing of

a document as described in subsection (b), any excluded manufacturing process or imports for which the concentration of PCBs in product leaving the manufacturing site or imported is greater than 2 micrograms per gram for any resolvable gas chromatographic peak. Such reports shall be filed within 90 days after promulgation of this regulation; or, if no processes or imports require reports at that time, within 90 days of having processes or imports for which such reports are required.

(b) Persons required to report by subsection (a) shall transmit a letter notifying EPA of the number, the type, and the location of excluded manufacturing processes in which PCBs are generated, or of imports, in which the concentration of PCBs in product leaving any manufacturing site or being imported is greater than 2 micrograms per gram for any resolvable gas chromatographic peak. Such persons shall also certify:

(1) Their compliance with all requirements of § 761.1(f), including applicable requirements for air and water releases and process waste disposal;

(2) Whether determinations of compliance are based on actual monitoring of PCB levels or on theoretical assessments; and

(3) That such determinations of compliance are being maintained.

(c) Any person who reports pursuant to subsection (a):

(1) Shall have performed either a theoretical analysis or actual sampling of PCB levels; and

(2) Shall maintain (for a period of 3 years after a process ceases operations or importing ceases, or for 7 years, whichever is shorter) records containing the following information:

(i) Theoretical analysis. (A) The reaction or reactions believed to be producing the PCBs, the levels of PCBs generated, and the levels of PCBs released;

(B) The basis for all estimations of PCB concentrations; and

(C) The name and qualifications of the person or persons performing the theoretical analysis; and

(ii) Actual monitoring. (A) The method of analysis;

(B) The results of the analysis, including data from the Quality Assurance Plan;

(C) The name of the analyst or analysts; and

(D) The date and time of the analysis.

(d) The certification required by subsection (b) must be signed by a responsible corporate officer. This certification must be maintained by each facility or importer for a period of three years after a process or importing ceases operation, or for seven years, whichever is shorter, and must be made available to EPA upon request. For the purpose of this section, a responsible corporate officer means:

(1) A president, secretary, treasurer, or vice president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation; or

(2) The manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding $25,000,000 (in second quarter 1980 dollars), if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

(e) Any person signing a document under subsection (d) shall also make the following certification:

> I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate information. Based on my inquiry of the person or persons directly responsible for gathering information, the information is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for falsifying information, including the possibility of fines and imprisonment for knowing violations.
>
> Dated:_____
>
> Signature:_____

(f) For purposes of § 761.185, the term PCBs is defined by § 761.3(jj).

IV. Paragraph 761.190 is added to read as follows:

§ 761.190 Reporting by persons generating PCBs in excluded manufacturing processes.

In addition to meeting the basic requirements of § 761.3 (kk), PCB-generating manufacturing processes or importers of PCB-containing products shall be considered "excluded manufacturing processes" only if the owner/operator or importer reports the following data to EPA:

(a) The total quantity of PCBs in product from excluded manufacturing processes leaving any manufacturing site in any calendar year when such quantity exceeds 0.0025% of that site's rated capacity for such manufacturing processes as of [the date this regulation is promulgated]; or the total quantity of PCBs imported in any calendar year when such quantity exceeds 0.0025% of the average total quantity of such product containing PCBs imported by such importer during the years 1978, 1979, 1980, 1981 and 1982;

(b) The total quantity of inadvertently generated PCBs released to the air from excluded manufacturing processes at any manufacturing site in any calendar year when such quantity exceeds 10 pounds; or

(c) The total quantity of inadvertently generated PCBs released to water from excluded manufacturing processes from any manufacturing site in any calendar year when such quantity exceeds 10 pounds.

(d) For purposes of subsections (a), (b) and (c), the term PCBs is defined by § 761.3(jj).

V. New § 761.195 is added to read as follows:

§ 761.195 Process waste disposal by generators and processors of chemical substances containing inadvertently generated PCB impurities.

(a) Persons who manufacture, process, distribute in commerce, or use chemicals containing inadvertently generated PCBs shall, for any process waste containing PCBs at concentrations greater than 50 micrograms per gram, incinerate such waste in accordance with § 761.60, landfill such waste in a landfill approved under the provisions of § 761.75, or store such waste for such incineration or landfilling in accordance with the requirements of § 761.65(b)(1).

(b) For purposes of subsection (a), the term PCBs is defined by § 761.3(jj).

VI. New § 761.200 is added to read as follows:

§ 761.200 Maintenance of monitoring records by persons who import, manufacture process, distribute in commerce, or use chemicals containing inadvertently generated PCBs.

(a) Any persons who import, manufacture, process, distribute in commerce, or use chemicals containing inadvertently generated PCBs who perform any actual monitoring of PCB levels shall maintain records of any such monitoring for a period of three years after a process or importing ceases operation, or for 7 years, whichever is shorter.

(b) Monitoring records maintained pursuant to subsection (a) shall at a minimum contain:

(1) The method of analysis;

(2) The results of the analysis, including data from the Quality Assurance Plan;

(3) The name of the analyst or analysts; and

(4) The date and time of the analysis.