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United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 79-1580, consolidated with Nos. 79-1811 and 79-1816

ENVIRONMENTAL DEFENSE FUND, INC., PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

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

JOY MANUFACTURING COMPANY,

EDISON ELECTRIC INSTITUTE, *et al.*, AND

ALUMINUM COMPANY OF AMERICA, INTERVENORS

On Petition for Review of Regulations Promulgated by the Administrator of the United States Environmental Protection Agency

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Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

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Argued June 6, 1980

Decided October 30, 1980

Jacqueline M. Warren for petitioner. *William A. Butler* also entered an appearance for petitioner.

Angus MacBeth, Acting Assistant Attorney General, Department of Justice, with whom *John W. Lyon*, Attorney, Environmental Protection Agency, was on the brief for respondent.

Steven Rosenthal, with whom *Peter J. Nickles* was on the brief, for intervenors, The Ad Hoc Committee. *Robert A. Loeffler* also entered an appearance for intervenor, The Ad Hoc Committee. *Toni K. Allen*, with whom *Thomas H. Truitt*, *John J. Daly* and *James H. Davis* were on the brief, for intervenors, Edison Electric Institute, et al.

Lawrence A. Demase, *J. Roy Spradley* and *Blair M. Gardner* were on the brief for intervenor Joy Manufacturing Company.

Donald C. Winson and *John W. Ubinger, Jr.* were on the brief for intervenor Aluminum Company of America.

Donald L. Morgan was on the brief, for *Amicus Curiae* Color Manufacturers' Association urging that the regulations in part, be set aside.

Before: ROBINSON AND EDWARDS, *Circuit Judges*, and CORCORAN,* *United States District Judge* for the District of Columbia.

Opinion for the court filed by *Circuit Judge* EDWARDS.

EDWARDS, *Circuit Judge*: In this case the Environmental Defense Fund (EDF) petitions for review of regulations, issued by the U.S. Environmental Protection Agency (EPA), that implement section 6(e) of the Toxic Substances Control Act (TSCA).[1] That section of the Act provides broad rules governing the disposal, marking,

*Sitting by designation pursuant to 28 U.S.C. § 292(a) (1976).

[1] 15 U.S.C. §§ 2601-2629 (1976).

manufacture, processing, distribution, and use of a class of chemicals called polychlorinated biphenyls (PCBs).[2]

EDF seeks review of three aspects of the regulations.[3] First, it challenges the determination by EPA that certain commercial uses of PCBs are "totally enclosed," a designation that exempts those uses from regulation under the Act. Second, it claims that the EPA acted contrary to law when it limited the applicability of the regulations to materials containing concentrations of PCBs greater than fifty parts per million (ppm). Third, EDF challenges the decision by EPA to authorize the continued use of eleven non-totally enclosed uses of PCBs.

From our examination of the record, we find that there is no substantial evidence to support the EPA determination to classify certain PCB uses as "totally enclosed." We also find that there is no substantial evidence in the record to support the EPA decision to exclude from regulation all materials containing concentrations of PCBs below fifty ppm. Accordingly, on these first two points, we hold unlawful and set aside the challenged regulations, and remand to EPA for further proceedings consistent with this opinion.

We find, however, that there is substantial evidence in the record to support the EPA determination to allow con-

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[2] *See* 15 U.S.C. § 2605(e) (1976). For the text of § 6(e), see note 10, *infra*.

[3] EDF challenges the regulations, promulgated under § 6(e)(2) and (3) of the Act, 15 U.S.C. § 2605(e)(2) & (3) (1976), governing the manufacture, processing, distribution, and use of PCBs—the so-called Ban Regulations. *See* 44 Fed. Reg. 31,542–58 (1979) (to be codified in 40 C.F.R. pt. 761). EDF does not challenge the Disposal Regulations, issued pursuant to § 6(e)(1) of the Act. EPA issued the final Disposal Regulations over a year before the Ban Regulations. *See* 40 C.F.R. pt. 761 (1978), 43 Fed. Reg. 7,156–64 (1978). EPA later reissued the Disposal Regulations with slight modification along with the final Ban Regulations. *See* 44 Fed. Reg. 31,542–58 (1979).

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tinued use of the eleven non-totally enclosed uses. Accordingly, on this third point, we uphold the EPA regulations.

I. BACKGROUND

A. *Polychlorinated Biphenyls*

Polychlorinated biphenyls (PCBs) have been manufactured and used commercially for fifty years for their chemical stability, fire resistance, and electrical resistance properties. They are frequently used in electrical transformers and capacitors. However, PCBs are extremely toxic to humans and wildlife. The extent of their toxicity is made clear in the EPA Support Document[4] accompanying the final regulations, in which the EPA Office of Toxic Substances identified several adverse effects resulting from human and wildlife exposure to PCBs.

Epidemiological data and experiments on laboratory animals indicate that exposure to PCBs pose carcinogenic and other risks to humans. Experimental animals developed tumors after eating diets that included concentrations of PCBs as low as 100 parts per million (ppm). Experiments on monkeys indicate that diets with PCB concentrations of less than ten ppm reduce fertility and cause still births and birth defects. Other data show that PCBs may adversely affect enzyme production, thereby interfering with the treatment of diseases in humans. Support Document, *supra* note 4, at 9–18.

EPA has found that PCBs will adversely affect wildlife as well as humans. Concentrations below one ppb (part per billion) are believed to impair reproductivity of aquatic invertebrates and fish. Some birds suffered "severe reproductive failure" when fed diets containing concentrations

[4]The Support Document/Voluntary Environmental Impact Statement is located in tab F of the Joint Appendix ("J.A."). The Support Document provided the documentation for the final Ban Regulations.

of only ten ppm of PCBs. *Id.* at 19. Because PCBs collect in waterways and bioaccumulate in fish,[5] fish-eating mammals run a special risk of adverse effects. Such mammals may have "significantly higher concentrations of PCBs in their tissues than the aquatic forms they feed on." *Id.* at 36.

EPA estimates that by 1975 up to 400 million pounds of PCBs had entered the environment. Approximately twenty-five to thirty percent of this amount is considered "free," meaning that it is a direct source of contamination for wildlife and humans. The rest, "mostly in the form of industrial waste and discarded end use products, is believed to be in landfill sites and thus constitutes a potential source of new free PCBs." *Id.* at 33–34.[6] Other significant sources of PCBs include atmospheric fallout and spills associated with the use or transportation of PCBs. *Id.* at 29.

EPA concluded in the Support Document that "the additional release of PCBs" into the environment would result in widespread distribution of the PCBs and "will eventually expose large populations of wildlife and man to PCBs." *Id.* at 36–37. EPA concluded further that:

> As a practical matter, it is not possible to determine a "safe" level of exposure to these chemicals. Because PCBs are already widely distributed throughout the biosphere, they currently pose a significant risk to the health of man as well as that of numerous other living things. As a consequence, any further increase in levels of PCBs in the biosphere is deemed undesirable by EPA.

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[5] One typical study reported that fathead minnows bioconcentrated PCBs by a factor of 230,000. Support Document, *supra* note 4, at 35.

[6] However, the average non-landfill concentration of PCBs is below the level of detection. *Id.* at 34. One study indicated that only 0.1 percent of the soil samples analyzed had detectable levels of PCBs. *Id.*

Id. at 33. Because "PCBs released anywhere into the environment will eventually enter the biosphere . . . EPA has determined that any such release of PCBs must be considered 'significant.' " *Id.*

In 1972, Monsanto, the major American manufacturer of PCBs, limited its sales of PCBs to manufacturers of transformers and capacitors. It ceased all manufacture of PCBs in 1977 and shipped the last of its inventory before the end of that year. Today, PCBs are produced in this country only as incidental byproducts of industrial chemical processes. There are no known natural sources of PCBs. *Id.* at 2.

B. *Congressional Response*

Responding to the dangers associated with the use of PCBs and other toxic chemicals, Congress in 1976 enacted the Toxic Substances Control Act (TSCA), Pub. L. No. 94-469, 90 Stat. 2003 (1976). Although the Act is generally designed to cover the regulation of all chemical substances, section 6(e) refers solely to the disposal, manufacture, processing, distribution, and use of PCBs. No other section of the Act addresses the regulation of a single class of chemicals.

The special attention accorded to PCBs in the Toxic Substances Control Act resulted from the recognized seriousness of the threat that PCBs pose to the environment and human health. During the debate over the Senate version of the Act, Senator Nelson, the author of the amendment adding the PCB subsection to the Senate bill, noted that PCBs were widespread in the environment and that they posed significant potential dangers to human health and to wildlife.[7] In the House of Representatives, Con-

[7] *See* 122 Cong. Rec. 8291-94 (1976), *reprinted in* House Comm. on Interstate and Foreign Commerce, Legislative History of the Toxic Substances Control Act, 94th Cong., 2d Sess., at 233-40 (1976) [hereinafter referred to as "Legislative His-

gressman Dingell introduced a similar amendment to the House version of the Toxic Substances Control Act,[8] not only because PCBs posed great dangers to the natural and human environments, but also because "the history of EPA is not one of vigorous and quick action."[9]

As enacted, section 6(e) of the Act[10] sets forth a detailed scheme to dispose of PCBs, to phase out the manufacture,

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tory"]. Section 6(e) was added to both the Senate and House bills during floor debate.

[8] *Id.* at 27184–85, Legislative History, *supra* note 7, at 580–82.

[9] *Id.* at 27185, Legislative History, *supra* note 7, at 582.

[10] Section 6(e) provides that:

> (1) Within six months after January 1, 1977, the Administrator shall promulgate rules to—
>
> (A) prescribe methods for the disposal of polychlorinated biphenyls, and
>
> (B) require polychlorinated biphenyls to be marked with clear and adequate warnings and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.
>
> Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).
>
> (2)(A) Except as provided under subparagraph (B), effective one year after January 1, 1977, no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.
>
> (B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.
>
> (C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will en-

processing, and distribution of PCBs, and to limit the use of PCBs. Specifically, section 6(e) provides that, within six months of the effective date of the Act (January 1, 1977), EPA must prescribe methods to dispose of PCBs and to

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sure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B) and (C)—

(i) no person may manufacture any polychlorinated biphenyl after two years after January 1, 1977, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after October 11, 1976.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c) of this section.

(5) This subsection does not limit the authority of the Administrator, under any other provision of this chapter or

require that PCB containers be marked with appropriate warnings. 15 U.S.C. § 2605(e)(1). One year after the effective date of the Act, PCBs can be manufactured, processed, distributed, and used only in a "totally enclosed manner." *Id.* § 2605(e)(2)(A). One year later, all manufacture of PCBs is prohibited. *Id.* § 2605(e)(3)(A)(i). Six months after that (i.e. two and one-half years after the effective date of the Act), all processing and distribution of PCBs in commerce is prohibited. *Id.* § 2605(e)(3)(A)(ii). Thus, today, except for the specified authorizations and exemptions described below, the Act permits PCBs to be used only in a totally enclosed manner, and it completely prohibits the manufacture, processing, and distribution of PCBs.

The statute sets forth only limited exceptions to these broad prohibitions. Subsection 6(e)(2)(B) allows the Administrator of EPA to authorize by rule the continued use of PCBs in a non-totally enclosed manner if he finds that the proposed activity "will not present an unreasonable risk of injury to health or the environment." *Id.* § 2605(e)(2)(B).[11] Under subsection 6(e)(3)(B), the Administrator may grant a case-by-case exemption to the prohibitions on manufacture, processing, and distribution of PCBs in subsection 6(e)(3). An exemption, which may be granted for one year subject to conditions set by the Administrator, *id.* § 2605(e)(3)(B), must be based on the Administrator's findings that "an unreasonable risk of injury to health or environment would not result, *and* . . .

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any other Federal law, to take action respecting any polychlorinated biphenyl.

[11] Although § 6(e)(2)(B) also would permit the manufacture, processing, and distribution of PCBs in a non-totally enclosed manner, that part of the Act is no longer effective. Because of the time that has elapsed between the effective date of the statute and the issuance of the regulations, the complete prohibition of those activities in § 6(e)(3) has superseded the corresponding prohibitions in § 6(e)(2).

good faith efforts have been made to develop a chemical [substitute] which does not present an unreasonable risk of injury to health or the environment." *Id.* (emphasis added).

C. *EPA's Implementation of section 6(e)*

EPA sought to implement section 6(e) through two sets of regulations. The first set of regulations—the so-called Disposal Regulations—set forth specific rules governing the disposal and marking of PCBs. The Disposal Regulations covered not only pure PCB compounds, but also materials contaminated with at least 500 ppm of PCBs. EPA chose this regulatory cutoff in order to regulate "disposal of most PCB's . . . as soon as possible." Preamble to Final Disposal Regulations, 43 Fed. Reg. 7,151 (1978). EPA warned that it was considering a new cutoff "possibly in the range of 50 ppm or below" for the proposed Ban Regulations. *Id.*

In June 1978 EPA issued proposed Ban Regulations that would implement the prohibitions mandated in subsections 6(e)(2) and (3), define "totally enclosed manner," authorize several non-totally enclosed uses, and set forth the procedures for obtaining exemptions from the prohibitions. *See* Proposed Ban Regulations, 43 Fed. Reg. 24,801 (1978). As foreshadowed in the final Disposal Regulations, the proposed and final Ban Regulations (issued May 31, 1979) set fifty ppm as the cutoff. *See* 43 Fed. Reg. 24,813 (1978), 44 Fed. Reg. 31,542 (1979) (to be codified in 40 C.F.R. § 761.1(b)). The final regulations defined all electrical capacitors, electromagnets, and non-railroad transformers as totally enclosed,[12] thus automatically exempting them

[12]The complete list of totally enclosed uses is as follows: distribution and use, except servicing, of intact, non-leaking, non-railroad PCB transformers, PCB-contaminated transformers (defined to include transformers with PCB concentrations in the dielectric [or insulating] fluid of between 50 and 500 ppm), elec-

from regulation under the Act. In the final regulations the Administrator authorized eleven non-totally enclosed uses to continue, including the servicing of totally enclosed uses,[13] based on his consideration of the health and environmental effects of PCBs, the exposure to PCBs resulting from these activities, the availability of substitutes for the PCBs, and the economic impact of restricting those uses. *See* Support Document, *supra* note 4, at v. Most authorizations continue until July 1, 1984, with some authorizations expiring sooner. Only the authorization for carbonless copy paper continues indefinitely.

II. JURISDICTION

At the outset one of the intervenors, Ad Hoc Committee on Liquid Dielectrics of the Electronic Industries Association (EIA), challenges the jurisdiction of this court to consider EDF's petition. EIA contends that under the authority of *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 598 F.2d 62 (D.C. Cir. 1978), and subsection 20(a)(2) of TSCA,[14] a federal district

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tromagnets, and capacitors; and processing, distribution in commerce, and use of PCB equipment containing intact, nonleaking capacitors. *See* Final Ban Regulations, 44 Fed. Reg. 31, 849 (1979) (to be codified in 40 C.F.R. § 761.30).

[13]The authorizations are: servicing of non-railroad transformers; use and servicing of railroad transformers; use and servicing of mining equipment; use in heat transfer systems; use in hydraulic systems; use in existing stocks of carbonless copy paper; use in pigments; servicing of electromagnets; use in natural gas pipeline compressors; use in small quantities for research and development; and use as a microscopy mounting medium. *See id.* at 31,849–61 (1979) (to be codified in 40 C.F.R. § 761.31). Detailed conditions attach to each of the authorizations.

[14]Section 20(a) in part provides that:

> any person may commence a civil action—
>
> (2) against the Administrator to compel the Adminis-

court is the proper forum in the first instance to hear EDF's claims. Upon considered review of this jurisdictional question, we find EIA's position to be without merit, and we hold that the matters at issue in this case are properly before this court for review.

In the aforecited *EDF* case, decided in 1978, EDF had challenged EPA regulations governing the discharge of PCBs into waterways.[18] Among its several claims, EDF petitioned for review of EPA's failure to regulate past manufacturers and users of PCB-contaminated equipment.

Since EPA's proposals for rulemaking had covered only existing manufacturers and users, the rulemaking proceedings in the 1978 case had not covered the issues raised in EDF's petition. As a result, there was no administrative record for the court of appeals to review. Accordingly, this court dismissed that portion of the petition concerning past manufacturers and users. 598 F.2d at 90-91. Since EDF's request was for additional rulemaking, the court of appeals had no jurisdiction to consider it.

By contrast, in the present case EDF does not seek additional rulemaking on issues not covered in the proceedings below. On the contrary, the rulemaking proceedings covered precisely those issues that EDF now challenges. For example, EDF challenges the authorization of certain non-totally enclosed uses. Because the Administrator gave

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> trator to perform any act or duty under this chapter which is not discretionary
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> . . .
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> Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled.

15 U.S.C. § 2619(a)(2) (1976).

[18] EPA had issued the regulations pursuant to the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. §§ 1251-1376 (1976).

explicit notice that he was considering such use authorizations, *see* Proposed Ban Regulations, 43 Fed. Reg. 24,803 (1978), and because the ensuing rulemaking proceedings covered in detail the propriety of the use authorizations, there is a sufficient record for this court to review.

EPA also gave notice that the operational definition of "totally enclosed manner" would be an issue in the rulemaking proceedings. As the Administrator noted in his proposed regulations defining most transformers and capacitors as "totally enclosed," the rules "would apply to persons who manufacture, sell, transport, use, service, or repair electrical transformers and capacitors." *Id.* And, of course, the rulemaking proceedings resulted in a decision listing certain uses as totally enclosed.

Finally, there can be no serious contention that the administrative record on the regulatory cutoff for PCBs is insufficient for us to review. In the Preamble to the final Disposal Regulations, the Administrator noted that EPA "plans to propose a lower concentration of PCB's, possibly in the range of 30 ppm or below, to define PCB mixture in the forthcoming" Ban Regulations. 43 Fed. Reg. 7,151 (1978). In the proposed Ban Regulations, the EPA explicitly noted that it "will revise the level either upward or downward from 50 ppm, if appropriate, based on information supplied during the rulemaking on this rule." Preamble to Proposed Ban Regulations, 43 Fed. Reg. 24,801 (1978). As a result of the rulemaking proceedings, EPA set the regulatory cutoff at fifty ppm.

Thus, because the rulemaking proceedings in this case covered each of the issues here raised by EDF, the intervenors have no basis to claim that EDF is seeking additional rulemaking. As explained in the 1978 *EDF* case, a federal district court is the appropriate forum whenever a court must gather and evaluate additional evidence. 598 F.2d at 91. Here no trial is necessary for there is a complete administrative record for this court to review.

A review of the jurisdictional provisions of the Toxic Substances Control Act demonstrates that this court, and not the district court, has jurisdiction to consider EDF's petition. Section 20(a) permits suits against persons alleged to be in violation of the Act or against the Administrator for failure to perform a mandatory duty. 15 U.S.C. § 2619(a). In either of these situations, a plaintiff could not prevail unless he presented evidence or proceeded on a set of stipulated facts, both of which make the district court the appropriate forum. Section 19(a), by contrast, provides that:

> Not later than 60 days after the date of the promulgation of a rule under section . . . 2605(e) [section 6(e)] . . . of this title, any person may file a petition for judicial review of such rule with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located.

15 U.S.C. § 2618(a). Precisely because EDF is seeking review of the PCB regulations and is not prosecuting an action that would require the taking of evidence, jurisdiction lies in the court of appeals.[16]

[16] EIA's reliance on a recent Third Circuit case, *Commonwealth of Pennsylvania, DER v. EPA*, 618 F.2d 991 (3d Cir. 1980), is misplaced. In that case, the state petitioned the court of appeals for review of the Administrator's decision to defer promulgation of regulations under the Federal Water Pollution Control Act. Finding a "deferral" the same as the failure to act in *EDF v. EPA*, 598 F.2d 62 (D.C. Cir. 1978), the court held that the district court, not the court of appeals, had jurisdiction to hear the petition. Language in the Third Circuit opinion illuminates the difference between jurisdiction in the district court and the court of appeals. The court first observed that "an allegation of inadequacy of a set of regulations is quite different from an allegation that a needed regulation was nonexistent." 618 F.2d at 996. Only in the latter circumstance does jurisdiction lie in the district court. Contrary to the present case,

III. USE AUTHORIZATIONS

A. *Criteria for the "Unreasonable Risk" Determination*

The Act permits the Administrator to authorize "by rule" non-totally enclosed uses of PCBs if he finds that such uses "will not present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605 (e) (2) (B).[17] Using the criteria set forth in subsection 6(c)(1),[18]

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petitioners in *Pennsylvania v. EPA* did not "challenge the regulations which were issued, but [sought] to have us compel further promulgations." *Id.* Because petitioners sought not to suspend existing regulations, "but to order the promulgation of completely new and different regulations," only the district court had jurisdiction. *Id.* at 997. Thus, *Pennsylvania v. EPA* is in accord with our holding that this court has jurisdiction to hear EDF's petition.

[17] EDF argues that no use authorizations should be allowed since "§6(e) should be construed as a legislative finding that PCBs pose an unreasonable risk of injury to health and the environment." Petitioner's brief, p. 46. We reject this argument.

There can be no doubt, as both EDF and EPA point out in their briefs, that exposure to PCBs poses substantial risks to health and the environment. There is ample legislative history to demonstrate that Congress was aware of some of the serious risks posed by the continued manufacture and use of PCBs. This awareness, however, is a far cry from EDF's conclusion that Congress has made a specific finding that PCBs pose an *unreasonable* risk of injury to health or the environment. Moreover, were we to hold that Congress had made such a finding, § 6(e)(2)(B), permitting use authorizations, would have no meaning. Because we must construe the statute "so that no provision will be inoperative or superfluous," *Motor and Equipment Manufacturers Ass'n, Inc. v. EPA*, No. 78-1896, slip op. at 21 (D.C. Cir. Aug. 3, 1979), we reject EDF's suggested legislative finding.

[18] Subsection 6(c)(1), which governs the promulgation of rules under § 6(a) for most chemical substances, provides in part that:

> (1) In promulgating any rule under subsection (a) of this section with respect to a chemical substance or mixture,

the Administrator found that eleven non-totally enclosed uses did not present an unreasonable risk. On the basis of these findings, EPA authorized the continued use of the eleven non-totally enclosed uses here in dispute.[19]

In attacking these use authorizations, EDF claims that the Administrator employed the wrong criteria in making his determinations concerning "unreasonable risk."[20] In

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the Administrator shall consider and publish a statement with respect to—

(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

15 U.S.C. § 2605(c)(1). Subsections 6(c)(2), (3), and (4) list the procedural requirements for promulgating a rule.

Section 6(a) of the Act, which governs the regulations of non-PCB substances, permits the Administrator to issue seven types of regulations whenever he finds

that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present *an unreasonable risk of injury to health or the environment.*

15 U.S.C. § 2605(a) (emphasis added). Once he has made this finding, the Administrator is to choose the "least burdensome" regulation that will "protect adequately against such risk." *Id.*

[19] *See* note 13, *supra*.

[20] The dispute over the proper criteria arises because § 6(e) offers no definition of the expression "unreasonable risk of injury to health or the environment."

particular. EDF argues that Congress intended to preclude the Administrator from using the subsection 6(c)(1) criteria in promulgating the PCB use authorization rules.

The basis for EDF's argument is found in subsection 6(e)(4), which requires the Administrator to promulgate rules in accordance with the procedural provisions in subsections 6(c)(2), (3), and (4); no reference to subsection 6(c)(1) is found in subsection 6(e)(4).[21] EDF claims that this omission evidences a congressional intent to preclude EPA from using the 6(c)(1) criteria in making "unreasonable risk" determinations pursuant to subsection 6 (e) (2) (B). Because the Administrator used those criteria,[22] EDF argues that the unreasonable risk determinations were "fatally flawed . . . [placing] disproportionate weight . . . on the adverse economic impact of a ban, [and seriously undermining] the Congressional objective of bringing about the development and use of substitutes in existing PCB activities . . . ." Petitioner's brief, p. 57.

Without more, however, we find that the omission of a reference to subsection 6(c)(1) in 6(e)(4) does not imply that Congress meant to *prevent* EPA from considering the challenged criteria in making unreasonable risk determinations under 6(e)(2)(B). There is nothing in the wording of the statute or the legislative history that affirmatively supports the position of EDF.

The structure of section 6(e) also indicates that EDF's position is incorrect. Because section 6(e) uniquely applies to a single class of chemicals, some provision was needed to establish *procedural* guidelines for the issuance of rules

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[21] Subsection 6(e)(4) provides: "Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c) of this section."

[22] "Although not subject to section 6(c)(1) of TSCA, EPA used the criteria in section 6(e)(1) to determine whether or not the risk from a non-totally enclosed activity is 'unreasonable.'" Preamble to Final Ban Regulations, 44 Fed. Reg. 31,529 (1979).

regulating the use of PCBs. Reference to subsections 6(e)(2), (3), and (4) fulfilled that need, whereas reference to subsection 6(e)(1), a *substantive* provision, was simply unnecessary. Because there is no compelling evidence to support the position advanced by EDF, and because of the deference that we must accord an agency's reasonable interpretation of its statute, *see Power Reactor Dev. Co. v. Int'l Union of Elec., Radio and Machine Workers*, 367 U.S. 396, 408 (1961), we conclude that the statute does not preclude the EPA from using the subsection 6(e)(1) criteria in making the unreasonable risk determinations under 6(e)(2)(B).

Moreover, because the expression "unreasonable risk of injury to health or the environment" is left undefined in section 6(e), the Administrator was required to give some meaning to it. Since the 6(e)(1) criteria obviously pertain to factors of "unreasonable risk," it was entirely appropriate for EPA to consider such criteria in ascribing a meaning to the use authorization provision in 6(e)(2)(B). EDF has shown nothing to indicate otherwise. In fact, EDF does not really contest use of the first three criteria in 6(e)(1)—i.e. the effects on health and on the environment, and the availability of substitutes. Rather, EDF's primary focus is on the fourth criterion in 6(e)(1), relating to the economic consequences of the authorization. Yet, EDF's objections to the "economic consequences" criterion cannot stand in the face of section 2(c) of the Act, which expressly requires the Administrator to consider such factors.[23]

Furthermore, the particular economic factors that EPA took into account were plainly reasonable.[24] The Adminis-

[23] Section 2(c) of the Act requires the Administrator to "consider the environmental, economic, and social impact of *any action* the Administrator takes or proposes to take under this chapter." 15 U.S.C. § 2601(c) (1976) (emphasis added).

[24] Because the Act does not define the factors that go into the Administrator's determination of unreasonable risk, we may

trator did not simply propose to consider the effect of the ban on industry, but also the effects on "the national economy, small business, technological innovation, the environment, and public health." *See* note 18, *supra*. This formulation, which considers a broad range of benefits and costs of the ban and use authorization, is entirely consistent with the section 2(c) requirement that the Administrator consider the economic and social impact on his actions.

Because the 6(c)(1) criteria fulfill an express mandate of the statute and reflect a reasonable interpretation of an ambiguous phrase, we conclude that the Administrator did not err in choosing those criteria to make the unreasonable risk determinations under 6(e)(2)(B).[25]

B. *Application of the Criteria*

EDF's final attack on the use authorizations is that the Administrator did not properly apply his own criteria in

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reasonably look to the interpretation of similar provisions in other statutes. In *Forester v. Consumer Product Safety Comm'n*, 559 F.2d 774 (D.C. Cir. 1977), this court considered challenges to regulations issued under the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261–1274 (1976). Under that Act the Commission could issue regulations whenever it found "an unreasonable risk of personal injury or illness." *Id.* § 1261(s). The court held that this determination involved a balancing between "the severity of the injury that may result from the product, factored by the likelihood of the injury [and] the harm the regulation itself imposes upon manufacturers and consumers." 559 F.2d at 789. The court derived this balancing from tort law. The criteria that the EPA Administrator has chosen in the present case reflect a similar balancing.

[25] Because we find that the Administrator's decision to use the § 6(c)(1) criteria for the unreasonable risk determination in § 6(e)(2)(B) was reasonable, those are the criteria against which we review the findings of unreasonable risk.

making the unreasonable risk determinations. Here, too, we reject EDF's position.[26]

The standard of judicial review for rules promulgated under section 6(e) is expressly set forth in subsection 19(c)(1)(B)(i): "the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record." 15 U.S.C. § 2618(c)(1)(B)(i). Evidence includes "any matter in the rulemaking record." *Id.*

The substantial evidence standard[27] mandated by the Act is generally considered to be more rigorous than the

[26] In its reply brief, EDF notes that it does not challenge the authorizations for carbonless copy paper, mining equipment, hydraulic and heat transfer systems, and natural gas pipeline compressors, because the "time periods [for the authorizations are] relatively short, [and because] the quantity of PCBs involved in these uses is miniscule in comparison to the amount permitted to continue in transformers and large capacitors." Petitioner's reply brief, p. 33 n.1. Because use in microscopy mounting medium, research and development, and pigments also involves small amounts of PCBs or short authorization periods, *see* Preamble to Final Ban Regulations, 44 Fed. Reg. 31,535–37 (1979), we assume that EDF does not challenge these authorizations. We note, however, that our review of the record finds substantial evidence supporting the Administrator's decision to authorize those uses. As a result, we restrict our discussion in the text to the servicing of transformers and electromagnets, and the use and servicing of railroad transformers.

EPA's use authorizations for servicing non-railroad transformers and electromagnets are predicated in part on its determination that non-railroad transformers and electromagnets are totally enclosed. *See id.* at 31,530, 31,536. Because of our disposition of EDF's challenge to the Administrator's decision finding that these classes of uses are totally enclosed, *see* section V, *infra*, the present discussion applies only to transformers and electromagnets that are actually totally enclosed.

[27] The Supreme Court has said that "[s]ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a

arbitrary and capricious standard normally applied to informal rulemaking.[28] Under the substantial evidence standard, a reviewing court must give careful scrutiny to agency findings and, at the same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise. Because administrative decisions often involve judgments based on incomplete or even conflicting scientific data, the agency "may have to fill gaps in knowledge with policy considerations." *AFL-CIO v. Marshall*, 617 F.2d 636, 651 (D.C. Cir. 1979). Consequently, reviewing courts "must examine both factual evidence and the agency's policy considerations set forth in the record." *Id.* The court's role in reviewing regulations is to ensure public accountability "by requiring the agency to identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument." *United Steelworkers of America v. Marshall*, No. 79-1048, slip op. at 15 (D.C. Cir. Aug. 15, 1980). With these general guidelines in mind, we review EPA's PCB use authorizations.

In an attempt to reduce the costs of compliance and the risks associated with exposure to PCBs, the Administrator created two categories for transformers—PCB-contaminated transformers (containing PCB concentrations between fifty and 500 ppm) and PCB transformers (containing PCB concentrations greater than 500 ppm).

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reasonable mind might accept as adequate to support a conclusion." *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

[28] *But see Pacific Legal Foundation v. Dep't of Transportation*, 593 F.2d 1338, 1343 n.35 (D.C. Cir. 1979) (court agrees with "emerging consensus of the Courts of Appeals that the distinction between the arbitrary and capricious standard and substantial evidence review is largely semantic").

Because the Administrator found that proper protective clothing and good management practices should reduce PCB exposure to "very low levels," the regulations permit routine servicing of PCB transformers and electromagnets. Preamble to Final Ban Regulations, 44 Fed. Reg. 31,531 (1979).[29] Additionally, the Administrator heard uncontradicted evidence that a prohibition of routine servicing would significantly increase the chances of catastrophic transformer failure, presenting "far greater risks to health and the environment than that associated with the minimal PCB exposure during routine servicing." *Id.* However, the Administrator found that the rebuilding of PCB transformers and electromagnets (i.e. non-routine servicing) risks greater exposure to PCBs due to leaks, spillage, or volatilization of the dielectric. The Administrator also found that a prohibition against "any servicing (including rebuilding) of PCB Transformers that involves removing the coils from the casing . . . will cost about $12 million the first year and steadily less each year thereafter." *Id.* Applying these findings to the 6(e)(1) criteria, the Administrator ruled that continued routine servicing, without rebuilding, and not involving the removal of coils, would present no unreasonable risk of injury.[30] The uncon-

[29] While the evidence on the effectiveness of protective clothing and good management practices is scanty, it is uncontradicted in the record. This evidence is enough to meet the substantial evidence standard. Of course, should EDF discover that the protective clothing and management practices do not protect workers to the degree mandated by the statute, it can initiate a proceeding for new rulemaking. *See* 15 U.S.C. § 2620 (1976).

[30] EDF's repeated attempts to equate risk of exposure to PCBs and unreasonable risk is misguided. Although the EPA has determined that no level of exposure can be considered safe, and that therefore, any exposure should be considered "significant," that determination does not imply that the exposure is unreasonable. EPA expressly noted that its definition of insignificant "is not a determination that any exposure to PCB's

tradicted evidence and the explication of policy considerations in the present record is sufficient to uphold the use authorization for routine servicing of PCB transformers and electromagnets.

Because they contain lower concentrations of PCBs, PCB-contaminated transformers present correspondingly smaller risks associated with exposure. Accordingly, the Administrator found that routine servicing of PCB-contaminated transformers presents no unreasonable risk of injury. Furthermore, because ninety-nine percent of all large transformers are PCB-contaminated transformers, a prohibition on rebuilding could cause "extremely high" costs. *Id.* Balancing these factors, the Administrator concluded that there was no unreasonable risk associated with the rebuilding or other extensive servicing of PCB-contaminated transformers.

Through these two classifications the Administrator has sought to encourage users to convert to PCB-contaminated transformers by draining their PCB transformers and refilling them with some other dielectric fluid. Only after converting the transformers can users rebuild their transformers, thereby reducing operating costs. Thus, the Administrator has created an incentive to dispose of PCBs without imposing extraordinary costs on industry. These policy considerations and findings reflect the criteria outlined in subsection 6(c)(1). Because the Administrator has carefully articulated his policy judgments, and because there is substantial evidence in the record to support his findings, we uphold the use authorization for PCB-contaminated transformers.

The Administrator's authorization of the use and servicing of railroad transformers also reflects a proper

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presents an unreasonable risk." Preamble to Proposed Ban Regulations, 43 Fed. Reg. 24,906 (1978). Rather, "the finding that any exposure to PCB's is significant serves simply to define any activity that emits or discharges PCB's as not 'totally enclosed.' " *Id. Cf.* note 17, *supra*.

balancing of the subsection 6(c)(1) criteria. Because of the strenuous conditions under which they operate, railroad transformers often leak PCBs onto railroad beds,[31] risking exposure to the environment and to workers and other persons near rail lines. On the other hand, nearly 1,000 of these transformers are currently used in railroad engines. A flat prohibition of their use would produce "an unacceptably severe curtailment of railroad service." *Id.* at 31,532.

In order to balance the social and economic impact of a prohibition against the risks to health and the environment, the Administrator sought a solution that would permit continued use while promoting conversion to non-PCB dielectric fluid. In reaching his solution, the Administrator considered the ninety million dollars in costs associated with immediate conversion to non-PCB dielectrics and the undetermined safety risks associated with fire and explosion in using non-PCB dielectrics. Consequently, EPA issued regulations requiring railroads to reduce the concentration of PCBs in railroad transformers to six percent (60,000 ppm) by 1982, and to 1,000 ppm by 1984. This timetable, EPA believes, will give it sufficient time to evaluate the risks associated with use of non-PCB fluids, and will also substantially reduce the costs of compliance. *Id.* at 31,533.

It is clear that the Administrator has properly applied the 6(c)(1) criteria in making the unreasonable risk determinations. Where scientific knowledge is incomplete, EPA has set forth specific policy considerations explaining the final regulations. Finding substantial evidence in the rec-

[31] This situation is the principal reason for the Administrator's conclusion that railroad transformers cannot be considered totally enclosed. *See* Preamble to Final Ban Regulations, 44 Fed. Reg. 31,532 (1979).

ord to support the Administrator's findings, we uphold the authorizations for railroad transformers.[32]

IV. The Fifty PPM Regulatory Cutoff

As a part of the regulatory scheme for PCBs under section 6(e), EPA limited application of the Disposal and Ban Regulations to materials containing concentrations of at least fifty ppm of PCBs. With one exception,[33] materials with lower concentrations remain unregulated under the

[32] EDF also claims that the length of the use authorization (five and one-half years) is an abuse of discretion in light of Congress' intent to eliminate usage of PCBs. We reject this claim. First, the statute provides no time limit on use authorizations, in contrast to the one-year limit on exemptions. *See* 15 U.S.C. § 2605(e)(3)(B). This difference between use authorizations and exemptions indicates that the Administrator has broad discretion in setting time limits on use authorizations. So long as the uses do not present an unreasonable risk, the Administrator may authorize their continued use.

Second, EPA has not, as EDF claims, silently authorized indefinite servicing of transformers. The authorization is specifically limited to five and one-half years, after which EPA intends to review the authorizations. Even though the statute allows totally enclosed uses (i.e. most transformers) to continue indefinitely, EPA limited the use authorizations (i.e. servicing transformers) so that it could reassess the risks involved and determine whether "improved technology or development of new PCB substitutes could reduce the need for the authorization." Preamble to Final Ban Regulations, 44 Fed. Reg. 31,530 (1979). Particularly in light of EPA's plans to reevaluate the risks associated with non-totally enclosed uses, we cannot find that the Administrator abused his discretion with respect to the time limits set on use authorizations.

[33] EPA prohibited the use of waste oil containing any detectable amount of PCBs, as a sealant, coating, or dust control agent. *See* 44 Fed. Reg. 31,549 (1979) (to be codified in 40 C.F.R. § 761.30(d)).

TSCA regulations.[34] EDF contends that this limitation contravenes the statutory command in subsections 6(e)(2)(A) and 6(e)(3)(A) to regulate "any polychlorinated biphenyl." While we do not adopt all of EDF's reasoning, we find that, under the applicable standard for judicial review,[35] there is no substantial evidence in the record to support the Administrator's decision to establish a regulatory cutoff at fifty ppm.

Throughout the rulemaking proceedings for both the Disposal and Ban regulations, EPA assumed that it would adopt some sort of regulatory cutoff. In the Disposal Regulations, EPA set the cutoff at 500 ppm, not because of health and environmental considerations, but in order to choose "a level at which regulated disposal of most PCB's can be implemented as soon as possible." Preamble to Final Disposal Regulations, 43 Fed. Reg. 7,151 (1978). EPA was reluctant to impose a lower cutoff since, from available information, the agency could not determine the "regulatory impact on commercial products" for lower levels. Subsequent to those proceedings, however, the agency acquired evidence that led it to believe that the "impact on commercial products of defining lower levels of contamination as 'PCB Mixtures' appears less than first believed . . . . [As a result], the Agency plans to propose a lower concentration of PCB's, possibly in the range of 50 ppm or below, to define PCB mixture in the forthcoming" Ban Regulations. *Id.*

In the proposed Ban Regulations, EPA listed four reasons for setting the regulatory cutoff at fifty ppm. First, EPA believed that a fifty ppm limit would "exclude from

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[34] Section 6(e) "does not limit the authority of the Administrator, under any other provision of this chapter or any other Federal law, to take action respecting any polychlorinated biphenyl." 15 U.S.C. § 2605(e)(5).

[35] See the discussion of the substantial evidence standard in section III, *supra*.

the rule municipal sludges and other mixtures containing low (less than 50 ppm) levels of PCB's whose presence is due to ambient levels of PCB present in the air or water." Preamble to Proposed Ban Regulations, 43 Fed. Reg. 24,804 (1978). As EPA develops in its brief, Congress did not design section 6(e) to regulate ambient sources of PCBs. Second, EPA believed that some industrial chemical processes inevitably produce traces of PCBs, and that careful controls could reduce the concentrations of PCBs only to fifty ppm. Third, EPA felt that it was impractical to regulate the "diffuse and extremely numerous PCB sources" with concentrations below fifty ppm. *Id.* EPA believed that the proposed cutoff would ensure maximum effectiveness of the regulation by focusing "Agency attention under TSCA upon the most significant and controllable sources of PCB exposure." *Id.* Fourth, the agency believed that other statutes were available to regulate low concentrations of PCBs, particularly municipal sludges and dredge soils.

In the final Ban Regulations, EPA adopted the proposed fifty ppm regulatory cutoff. Although industry favored a cutoff of 500 ppm in order to reduce the costs of complying with the regulations, EPA found that industry could comply with the more stringent standard. *See* Preamble to Final Ban Regulations, 44 Fed Reg. 31,516 (1979). Furthermore, lowering the cutoff from 500 to fifty ppm would "result in substantially increased health and environmental protection." *Id.*

A cutoff below fifty ppm, on the other hand, would "provide an additional degree of environmental protection but would have a grossly disproportionate effect on the economic impact and would have a serious technological impact on the organic chemicals industry." *Id.* While it did not have firm data, EPA believed that for some chemical processes, it was technically impossible to eliminate the inadvertent production of PCBs. EPA also feared that because of limited disposal facilities, a lower cutoff would in-

crease disposal requirements and interfere with the disposal of high concentration wastes. In short, EPA believed that the fifty ppm cutoff "provides adequate protection for human health and the environment while defining a program that EPA can effectively implement." *Id.*[36]

Both EPA and EDF claim that the statutory language and legislative history support their positions on the regulatory cutoff. The statutory language is simple: "no person may . . . use any polychlorinated biphenyl in any manner other than in a totally enclosed manner." 15 U.S.C. § 2605(e)(2)(A). Similarly, the prohibitions on manufacture; processing, and distribution refer to "any polychlorinated biphenyl." *See id.* § 2605(e)(3)(A). Taken literally, this language might require EPA to regulate every molecule of PCB. We are reluctant, however, to impose such an extreme interpretation absent support in the legislative history.

The legislative history reveals that Congress was aware of existing environmental contamination by PCBs—the so-called ambient sources of contamination. For example, during the Senate debate of the amendment adding section 6(e) to the TSCA bill, Senator Nelson, who introduced the amendment, read into the record reports showing the widespread environmental contamination by PCBs. *See* 122 Cong. Rec. 8292-94 (1976), *reprinted in* Legislative History, *supra* note 7, at 235–40. Congressman Dingell noted their "widespread use and dispersal." H. R. Rep. No. 1341, 94th Cong., 2d Sess. 133 (1976) (supplemental views of Congressman Dingell), *reprinted in* Legislative History, *supra* note 7, at 508, and cited examples of contaminated waterways throughout the United States. *Id.* at 134, *reprinted in* Legislative History, *supra* note 7, at

[36] EPA also retained the waste oil exception to the 50 ppm cutoff. EPA found this exception necessary because this use resulted in "direct and widespread environmental contamination." *Id.*

509. *See* 122 Cong. Rec. 27187 (1976), *reprinted in* Legislative History, *supra* note 7, at 587-89 (Congressman Leggett, discussing the widespread contamination of birds and fresh water fish).

EPA concluded, we believe correctly, that despite Congress' recognition that existing contamination of PCBs in the environment posed continuing risks to humans and wildlife, Congress did not design section 6(e) to regulate ambient sources of PCBs. Congressman Gude, who coauthored section 6(e), argued that it "will speedily eliminate the *introduction of additional PCB's* into the environment." *Id.* at 27186, *reprinted in* Legislative History, *supra* note 7, at 585 (emphasis added). Congressman Leggett noted that "PCB's cannot be removed from the environment" and that even if "PCB's were eliminated now," waterways will remain contaminated for years. *Id.* at 27187, *reprinted in* Legislative History, *supra* note 7, at 588. From these statements we conclude that section 6(e) was intended to regulate point sources of contamination.[67]

[67] From the sparse legislative history of § 6(e), it also appears that Congress focused its attention on the deliberate use, manufacture, and distribution of PCBs. Throughout the congressional debate, members of Congress referred to Monsanto Company as the sole producer of PCBs. *See* 122 Cong. Rec. 8294 (1976), *reprinted in* Legislative History, *supra* note 7, at 240 (Senator Tunney, speaking in support of the section, referred to Monsanto as the "sole domestic manufacturer of PCB's"); *id.* at 27187, *reprinted in* Legislative History, *supra* note 7, at 588 (Congressman Leggett, speaking in support of the corresponding section in the House bill, referred to Monsanto as "the only American manufacturer of PCB's"). Because Congress may not have been aware that other manufacturers produce PCBs as an incidental by-product of their manufacturing processes, it is possible that Congress did not intend to regulate the incidental manufacture of PCBs.

However, given Congress' deep concern with the dangers associated with PCBs, prompting it to include a special section

Partly in order to incorporate congressional intent, the Administrator chose a regulatory cutoff at a level that he felt would exclude the ambient sources from regulation.[35] We are troubled by this regulation, however, since the purpose of section 6(e) is to prevent the "introduction of additional PCB's into the environment." The selection of a cutoff undermines the congressional intent to regulate non-ambient sources of PCBs if non-ambient sources of contamination remain unregulated. It is equally troubling that the Administrator apparently is not aware of the amount of PCBs excluded from regulation by the fifty ppm or other possible cutoffs. Particularly because the Administrator has found that any exposure to PCBs may

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governing PCBs in an otherwise general act, we cannot find that Congress intended to exclude incidentally manufactured PCBs from the Act. Congress' express concern with widespread contamination and worker exposure, the chemical's toxicity at extremely low levels, and the statutory language of "any polychlorinated biphenyl in any manner" lead us to conclude that Congress intended to include all commercial sources within the EPA regulations. As EPA noted in the Preamble to the final Ban Regulations:

> the prohibition applies to the manufacture of any substance or mixture that contains PCB at 50 ppm or greater, including PCB that is an intermediate or "impurity" or "by-product" . . . . While the production of PCBs under such circumstances may not be intentional and may have no independent commercial value, section 6(e) of TSCA applies to *any* production of PCBs.

Preamble to Final Ban Regulations, 44 Fed. Reg. 31,527 (1979) (emphasis in original). Because it is reasonable, we defer to this construction of the statute by EPA. *See Power Reactor Dev. Co. v. Int'l Union of Elec., Radio and Machine Workers*, 367 U.S. 396, 408 (1961).

[35] EDF does not dispute that the Administrator must design the regulations so as to exclude ambient sources. In its brief, EDF emphasizes that § 6(e) was intended to regulate "*commercial* activities involving PCBs." Petitioner's brief, p. 32 (emphasis in orginial).

have adverse effects.[39] the Administrator's flat exclusion of some industrial sources of contamination must undergo careful scrutiny.[40] While some cutoff may be appropriate, we note that the Administrator did not explain why the regulation could not be designed expressly to exclude ambient sources, thus directly fulfilling congressional intent, rather than achieve that goal indirectly with a cutoff, thereby partly contravening congressional intent.[41] Thus, a desire to exclude ambient sources of contamination, without more, cannot support the regulatory cutoff.

EPA also seeks to justify the regulatory cutoff on the basis of the serious impact a lower cutoff would have on industries that inadvertently produce PCBs during the manufacturing process. *See* Preamble to Final Ban Regulations, 44 Fed. Reg. 31,516 (1979). As EPA readily concedes, however, the inadvertent commercial production of

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[39] The Administrator found "that any release of PCBs into the environment will eventually result in widespread exposure of wildlife, including some of man's major food sources, and humans and that any such exposure may have adverse effects." Support Document, *supra* note 4, at 8.

[40] In *EDF v. EPA*, 598 F.2d 62, 88 (D.C. Cir. 1978), this court noted that an Administrator has a "heavy burden" to explain the basis for a decision to permit the continued use of chemicals that cause cancer in experimental animals. Of course, the standard of review in the present case, as well as the earlier *EDF* case, is the "substantial evidence" standard. *See* section III, *supra*.

[41] Moreover, the evidence in the record indicates that the vast majority of ambient sources of contamination contain considerably less than one ppm of PCBs. *See* PCB Sampling Program for Florida Power & Light Co., at 9–16, *reprinted in* J.A. tab TT; Spagnoli & Skinner, *PCB's in Fish from Selected Waters of New York State*, 11 Pesticides Monitoring J. 69, 73–83 (1977), *reprinted in* J.A. tab UU. Because some ambient sources have concentrations greater than 50 ppm, EPA must be regulating them under the current regulations. Not only has EPA been seeking to avoid this activity, it is contrary to congressional intent.

PCBs is to be regulated under the Act. *See* note 37, *supra*. By providing a blanket exemption for concentrations below fifty ppm, the Administrator has circumvented the authorizations and exemptions requirements provided in the statute. EPA made no finding that the cutoff would involve no unreasonable risk to health or the environment.[42] As the EPA noted in its Support Document for the final Ban Regulations, justifying a fifty rather than a 500 ppm cutoff, "the authorization and exemption processes are the most effective way to deal with any difficulties. The authorization and exemption processes allow the Agency to tailor the compliance requirements and to be informed as to which companies are having problems and how they are disposing of their waste streams." Support Document, *supra* note 4, at 93–94. We agree with EPA. Consequently, the burdens faced by industries cannot be the basis for the fifty ppm cutoff.[43]

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[42] In fact, the Administrator did not significantly discuss the benefits to human health that would result from a lower cutoff. In light of the Administrator's statement that "[t]he manufacture of PCBs as intermediates, impurities and byproducts almost always involves some human and environmental exposure," Preamble to Final Ban Regulations, 44 Fed. Reg. 35,127 (1979), we are convinced that any determination to permit continued use and manufacture must be made under the statutorily mandated unreasonable risk test.

[43] While our holding does not depend on it, our conclusion is reinforced by EPA's concession that it does not have "firm data" on the technological difficulties faced by industry because of the lower cutoff. Preamble to Final Ban Regulations, 44 Fed. Reg. 31,516 (1979). Particularly because only a few industries may inadvertently produce small amounts of PCBs, a cutoff applying to all sources of contamination is hardly justified. The appropriate mechanisms that address industry burdens are the statutory authorization and exemption procedures.

An additional distinction between exemptions and a regulatory cutoff confirms our holding. The cutoff is a flat exception allowing the indefinite manufacture of PCBs. It circumvents

One of the intervenors, Edison Electric Institute (EEI), and EPA have attempted to justify the fifty ppm cutoff as an administratively created exemption to the Act.[44] *See Alabama Power Co. v. Costle*, No. 78-1006 (D.C. Cir. Dec. 14, 1979). Under the heading of "administrative necessity," this court has recognized that an agency may depart from the requirements of a regulatory statute. *See id.* at 36–41 (opinion for the court by Leventhal, J.). While the court in *Alabama Power* emphasized that "[c]ategorical exemptions from the clear commands of a regulatory statute, though sometimes permitted, are not favored," *id.* at 36–37, it also noted that there is "substantive authority [for an agency] to take appropriate action to cope with the administrative impossibility of applying the commands of the substantive statute." *Id.* at 38–39. However, "[t]he agency's burden of justification in such a case is especially heavy." *Id.* at 40.

Considerations such as the availability of enforcement resources are relevant to the administrative necessity exemption. It appears, however, that EPA is not even aware of the amount of PCBs left unregulated by the cutoff. Having made no showing that it cannot carry out the statutory commands for concentrations of PCBs below fifty ppm, EPA fails to meet its heavy burden. Thus, administrative need, on this record, provides no basis for the fifty ppm cutoff.

EEI also seeks to justify the regulatory cutoff under a second principle, the "*de minimis*" exception to statutory commands. In *Alabama Power*, this court found that an agency has the power, "inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered *de minimis*." *Id.* at 41. That power

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Congress' intent, as expressed in the exemption provisions, to allow *yearly* review of PCB manufacturing, processing, and distribution. *See* 15 U.S.C. § 2605(e)(3)(B).

[44] EPA's discussion of this issue is cursory at best. *See* Respondent's brief, p. 35 n.20.

"is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design." *Id.* at 42. As the *Alabama Power* court emphasized, *de minimis* authority may be available "when the burdens of regulation yield a gain of trivial or no value." *Id.* It is not sufficient that the agency may believe that the costs outweigh the benefits, for Congress has already made the judgment that the benefits of regulation are sufficient.

The record in the present case is replete with findings and data that PCBs are toxic to wildlife in concentrations well below fifty ppm. Furthermore, the record shows that PCBs bioaccumulate in animals, concentrating as they move up the foodchain. Most importantly, EPA expressly found that any exposure of PCBs to the environment or humans could cause adverse effects. These findings leave us unable to say that the Administrator could rationally conclude that the benefits of regulating concentrations below fifty ppm are of no value.[45] Consequently, we conclude that the *de minimis* exception to the Act is not available to justify the fifty ppm cutoff.[46]

[45] In fact, EPA expressly recognizes that a lower cutoff would "provide an additional degree of environmental protection." Preamble to Final Ban Regulations, 44 Fed. Reg. 31,516 (1979).

[46] Of course, EPA may find after further consideration that some level of unregulated exposure is trivial. We are not mandating that EPA promulgate regulations that cover all detectable concentrations of PCBs in non-ambient sources. However, in order to justify a regulatory cutoff under the *de minimis* principle, EPA must find the concentration at which there are only trivial benefits to be derived from regulation.

EPA's and ELA's reliance on *Monsanto Co. v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979), is misplaced. In that case this court held that the *de minimis* principle allowed the FDA to determine "that the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns." *Id.* at 955. In making such a determination, which leaves unregulated certain chemicals (or, in the present case, certain concentrations of chemicals), the Administrator "must state the reasons for exercising this limited exemption author-

We reemphasize that the Administrator has other, more appropriate means providing him with flexibility to avoid disproportionate impacts on industries or on health and the environment. Those tools are the authorization and exemption provisions in subsections 6(e)(2)(B) and 6(e)(3)(B). The standards enunciated therein, requiring findings of no "unreasonable risk of injury to health and the environment" and, in the case of exemptions, good faith efforts to find substitutes, reflect a plain congressional intention that cannot be ignored. For if there is an unreasonable risk of injury, as there may be given EPA's findings, surely Congress did not intend to permit the continued use, manufacture, processing or distribution of PCBs in concentrations below fifty ppm. EPA's *ad hoc* consideration of economic impact and disposal requirements, leading to a conclusion that the fifty ppm cutoff "provides adequate protection for human health and the environment," Preamble to Final Ban Regulations, 44 Fed. Reg. 31,516 (1979), is neither as rigorous nor as strict as the statutorily required unreasonable risk determination based on the subsection 6(c)(1) criteria.[*] Thus, we remand this part of the record to EPA for further proceedings.

V. Totally Enclosed Uses

EDF also petitions for review of the Administrator's decision to list several uses, including non-railroad trans-

ity." *Id.* at 966. There is nothing in the record to indicate that the Administrator relied on the *de minimis* principle.

[*] So that there is no misunderstanding, we are not striking down the 50 ppm cutoff because EPA has failed to justify that particular level instead of a slightly lower level. "In reviewing a numerical standard, we must ask whether the agency's numbers are within a 'zone of reasonableness,' not whether its numbers are precisely right." *Hercules, Inc. v. EPA*, 598 F.2d 91, 106–07 (D.C. Cir. 1978). EPA has failed to adduce substantial evidence that 50 ppm is within the zone of reasonableness.

formers, capacitors, and electromagnets.[48] as totally enclosed uses and therefore exempt from the regulations promulgated under section 6(e). Because we find no substantial evidence in the record to support the Administrator's classifications, we remand this part of the record for further proceedings.

There can be no serious doubt that Congress intended to permit the continued use of PCBs in a "totally enclosed manner."[49] The statute defines that expression to mean "any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule." 15 U.S.C. § 2605(e)(2)(C).

In both the proposed and final Ban Regulations, EPA defines " 'insignificant exposure' as no exposure." *See*

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[48] *See* note 12, *supra*. The discussion in this section applies to all PCB uses classified as totally enclosed.

[49] The statutory language plainly indicates that § 6(e)(2)(A) does not cover totally enclosed uses. That section prohibits use of "any polycholorinated biphenyl in any manner *other than in a totally enclosed manner*" (emphasis added). The clear meaning of this provision is that totally enclosed uses are permitted to continue.

Nothing in the legislative history contradicts our conclusion that Congress intended totally enclosed uses to continue unregulated. In introducing the amendment adding § 6(e) to the TSCA bill, Senator Nelson was careful to distinguish between "closed" and "non-enclosed" uses. *See* 122 Cong. Rec. 8292 (1976), *reprinted in* Legislative History, *supra* note 7, at 234. His statement that § 6(e) would provide "over a period of time the elimination of the use in open or closed systems of PCB's," *id.*, reflects not a ban on totally enclosed uses of PCBs, but recognition that elimination of manufacturing, processing, and distribution of PCBs will, as machinery wears out, eliminate all uses of PCBs.

Preamble to Proposed Ban Regulations, 43 Fed. Reg. 24, 805 (1978).[50] Because "any release of PCBs into the environment will eventually result in widespread exposure of wildlife, including some of man's major food sources, and humans and that any such exposure may have adverse effects," Support Document, *supra* note 4, at 8, EPA concluded that there was "no rational basis for selecting any particular exposure level above zero for the purposes of this regulation." Preamble to Proposed Ban Regulations, 43 Fed. Reg. 24,805 (1978).

Despite these strict standards, EPA contends that its classifications fulfill the statutory and regulatory mandates. Its designation of totally enclosed uses does not include all transformers, capacitors, and electromagnets, but only the "intact, non-leaking" variety.[51] By definition, if a transformer is leaking, it is not totally enclosed and therefore is not exempt from the Act or the regulations.

This scheme, however, begs the question. Under the current regulations, EPA has no idea which PCB uses are "intact, non-leaking." The current regulatory structure provides no procedures for inspection or even self-reporting of leaks or other forms of contamination. Absent such procedures, EPA's regulations are a blanket exception for transformers, capacitors, and electromagnets, which use the vast majority of all PCBs in commercial use. Without a better justification, the regulation cannot stand.

EPA seeks support for its position in the legislative history. During the Senate debate, Senator Nelson identified "carbonless paper, paints, coatings, soaps, and copying ink toners" as "nonenclosed uses." 122 Cong. Rec. 8292 (1976), *reprinted* in Legislative History, *supra* note 7, at 234. At

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[50] The preamble to the final regulations does not discuss the definition, but refers to the preamble to the proposed regulations. *See* 44 Fed. Reg. 31,518 (1979).

[51] *See* note 12, *supra*.

the same time he referred to "electrical capacitors and transformers" as "closed uses." *Id.*, *reprinted in* Legislative History, *supra* note 7, at 234.

These and similar statements do not support EPA's de facto classification of capacitors, transformers, and electromagnets as totally enclosed. First, Congress left to the Administrator the task of deciding which uses were to be deemed totally enclosed. The statute delegates to the Administrator the duty of ensuring that human and environmental exposure is "insignificant," a word that he must define. Second, given Congress' enactment of a special section for regulating PCBs, we cannot believe that Congress meant to leave unregulated leaking transformers, capacitors, and electromagnets. Congress could not have intended to designate, whether explicitly or implicitly, *all* transformers, capacitors, and electromagnets as totally enclosed. Third, references in the congressional debates to "closed uses," do not necessarily refer to "totally enclosed" uses. Put simply, closed systems develop leaks.[52]

EPA argues briefly that the record contains substantial evidence supporting the agency's classification of transformers, capacitors, and electromagnets as totally enclosed. In fact, there is no substantial evidence. To begin with, we have found no evidence in the record discussing the probabilities or magnitudes of leaks from capacitors. This plainly does not amount to substantial evidence. As such, capacitors cannot be classified as totally enclosed uses.

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[52] No doubt transformers, capacitors, and electromagnets are "closed uses." Otherwise, the liquid PCBs would spill out. The problem is identifying those that leak, whether due to design defect, accident, or some other cause. Senator Nelson emphasized this point when, after discussing "closed" and "non-enclosed" uses, he separately defined "totally enclosed manner" as ensuring that " 'any leakage of a PCB from its enclosure will be insignificant.' " 122 Cong. Rec. 8292 (1976), *reprinted in* Legislative History, *supra* note 7, at 234.

Furthermore, EPA points to no evidence describing electromagnets as totally enclosed. The only evidence in the record that we have found is one statement by Commonwealth Edison Co. that they had one electromagnet, and that during normal operation there is no exposure to humans or the environment. *See* J.A. tab Y. From this statement, it is not clear what constitutes "normal operation." Perhaps leakage occurs during abnormal operation or through human error. Perhaps abnormal operations occur frequently. We cannot know the answers to these and other questions, for EPA failed to collect evidence on them. Furthermore, this sort of evidence, regarding a single electromagnet—especially in light of the severe consequences associated with even small leaks—cannot constitute substantial evidence that electromagnets are totally enclosed.

Finally, the EPA's evidence that transformers do not leak comprises three general statements by industry representatives to the effect that totally enclosed containers do not leak. One commentator from the Nebraska Power Industry Committee stated that use of transformers "generally involves no release of PCBs." J.A. tab O. This statement does not amount to substantial evidence that the regulations "ensure" that there is no exposure. Furthermore, there is evidence in the record directly contradicting the industry's statements. One commentator stated that transformers "occasionally blow up and occasionally are mishandled." J.A. tab S. Another commentator, from the Michigan Department of Natural Resources, testified that "we recognized that environmental losses can occur through accidental rupture or leakage." J.A. tab L. He concluded that "we still believe that a high risk of exposure and environmental losses likely exist in such facilities." *Id.*

In light of the record in this case, we find that there is no substantial evidence that the regulations concerning totally enclosed uses "will *ensure* that any exposure of

human beings or the environment to a polychlorinated biphenyl will be insignificant." 15 U.S.C. § 2605(e)(2)(C) (emphasis added). This lack of substantial evidence calls into question EPA's implicit finding that it can designate entire classes of uses, rather than individual containers, as totally enclosed. Of course, we are not directing EPA to apply the "totally enclosed" proviso on a more individualized basis. On the present record, however, EPA's findings as to which PCB uses may be classified as totally enclosed cannot stand. Accordingly, we remand the record to the EPA for further proceedings consistent with this opinion.

VI. Conclusion

On the basis of the foregoing, we find that there is substantial evidence in the record to support the use authorizations; therefore, we uphold those regulations. However, because we find no substantial evidence in the record to support either the fifty ppm cutoff or the EPA classification of certain PCB uses as totally enclosed, these latter two regulations cannot be upheld. Consequently, we set aside the regulations dealing with the fifty ppm cutoff and the classification of certain PCB uses as totally enclosed, and remand those portions of the record for further proceedings consistent with this opinion.

We feel constrained to add one final note to emphasize our concern in this case. Human beings have finally come to recognize that they must eliminate or control life threatening chemicals, such as PCBs, if the miracle of life is to continue and if earth is to remain a living planet. This is precisely what Congress sought to do when it enacted section 6(e) of the Toxic Substances Control Act. Yet, we find that forty-six months after the effective date of an act designed to either totally ban or closely control the use of PCBs, 99% of the PCBs that were in use when the Act

was passed are still in use in the United States.[42] With information such as this in hand, timid souls have good reason to question the prospects for our continued survival, and cynics have just cause to sneer at the effectiveness of governmental regulation.

The EPA regulations can hardly be viewed as a bold step forward in the battle against life threatening chemicals. There is no substantial evidence in the record to support certain of the EPA regulatory enactments, and portions of the regulations are plainly contrary to law. Thus, the effort by EPA has, in certain respects, fallen far short of the mark set by the congressional mandate found in section 6(e) of the Toxic Substances Control Act.

On remand, we trust that EPA will act with a sense of urgency to find effective solutions to enforce the Act. We are not so naive as to assume or suggest that hasty responses will ensure effective regulations. However, we are well able to see, from the plain text of the Act, that the deadlines for the enactment of regulations to enforce section 6(e) have passed. We therefore believe that EPA should act with expedition to complete the important task assigned to it by Congress.

So ordered.

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[42] A recent House committee report on the proposed Toxic Substances Control Act Amendment of 1980, H.R. 7126, lamented that the "EPA definition [of totally enclosed uses] exempted from the [§6(e)] ban approximately 99 percent of all PCB's found in the United States." H.R. Rep. No. 968, 96th Cong., 2d Sess. 6 (1980).