**Miscellaneous notes**

TSCA was passed: PCBS are bad, ban them

EPA did rulemaking: PCBs are bad, any exposure is significant

Rulemaking: Management standards: ban the worst, mange the rest

Economic assessment: TSCA protects against “major and extensive economic disruption” for the manufacturer.

* End of pipe considerations
* Waste management costs are externalized from the manufacturing
* Likelihood of exposure considered
* Substitutes and economic significance if there are no substitutes

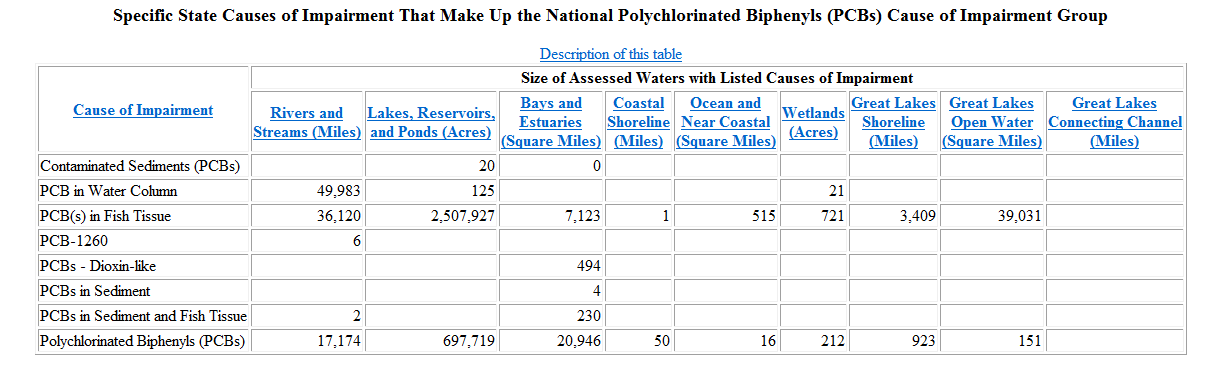
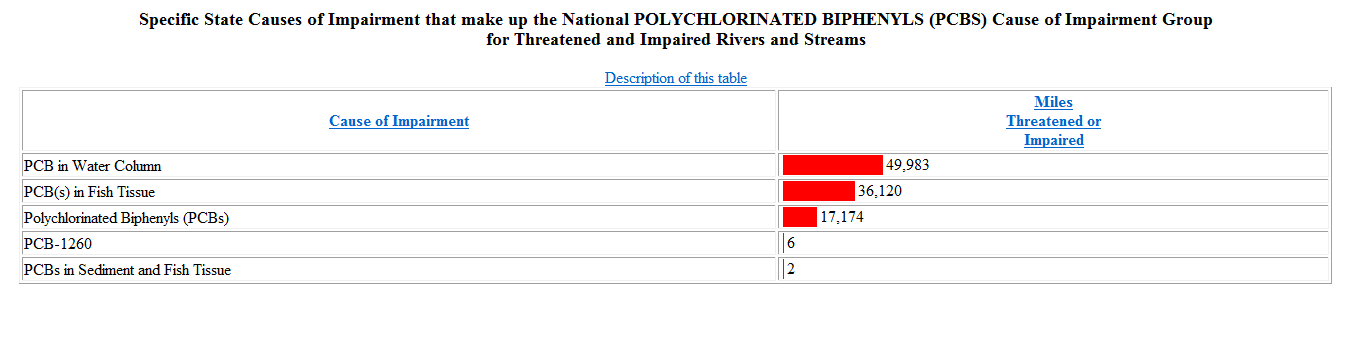
Regulatory actions have focused on “fix the problem” not “prevent the problem.”

“Exclusion” means exclusion from the rule altogether (this is currently the case for < 50 ppm PCB) vs. “reasonable use authorization” or allowable use because a ban would cause “major and extensive economic disruption.” Petitioner must prove need, normally 5 year review period. 2010 reauthorization rule the first time since the original rules were passed.

**Notes from References**:

* [Federal Register Notice (Pre-Publication):Revision of Certain Federal Water Quality Criteria Applicable to Washington (PDF)](https://www.epa.gov/sites/production/files/2016-11/documents/washington_rule_wqs_part_131_2040_af56_final_rule_frn_20161024_webpostingversion.pdf)[[1]](#footnote-1)

Establishes a federal Water Quality Standard for PCB in Washington State of 7 ppq.

* Magnitude of the Problem: from EPA ATTAINS database[[2]](#footnote-2) Number of PCB TMDLs: 504 Number of Impaired waters achieving water quality standards for PCBs: 0

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [**Cause of Impairment Group**](javascript:void(0)) |  | **Size of Assessed Waters with Listed Causes of Impairment** | | | | | | | | | | | | | | | | | | | | |
|  | [**Rivers and Streams (Miles)**](javascript:void(0)) | | | [**Lakes, Reservoirs, and Ponds (Acres)**](javascript:void(0)) | [**Bays and Estuaries (Square Miles)**](javascript:void(0)) | [**Coastal Shoreline (Miles)**](javascript:void(0)) | [**Ocean and Near Coastal (Square Miles)**](javascript:void(0)) | | [**Wetlands (Acres)**](javascript:void(0)) | [**Great Lakes Shoreline (Miles)**](javascript:void(0)) | | [**Great Lakes Open Water (Square Miles)**](javascript:void(0)) | |  |  |  |  |  |  |  |
| [Polychlorinated Biphenyls (PCBs)](javascript:%20newWindow%20=%20openWin(%20'https://ofmpub.epa.gov/waters10/attains_nation_cy.cause_detail?p_cause_group_name=POLYCHLORINATED%20BIPHENYLS%20(PCBS)',%20'Definition',%20'width=640,height=400,toolbar=1,location=1,directories=0,status=1,menuBar=1,scrollBars=1,resizable=1'%20);%20newWindow.focus()) | | | 81,626 | 3,204,557 | | 28,287 | 50 | | 531 | 933 | 4,332 | 39,183 | |
|  | | |  |  | |  |  | |  |  |  |  | |
|  | | |  |  | |  |  | |  |  |  |  | |

* About the 50 ppm nominal limits[[3]](#footnote-3)

From EDF vs EPA 1980 636 F2d.1267

IV. THE FIFTY PPM REGULATORY CUTOFF

52

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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn33) materials with lower concentrations remain unregulated under the TSCA regulations.[34](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn34) 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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn35) there is no substantial evidence in the record to support the Administrator's decision to establish a regulatory cutoff at fifty ppm.

53

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.

54

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 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.

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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.

56

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 increase 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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn36)

57

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.

58

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), U.S.Code Cong. & Admin.News 1976, p. 4491 (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 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).

59

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 co-authored 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.[37](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn37)

60

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.[38](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn38) 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 have adverse effects,[39](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn39) the Administrator's flat exclusion of some industrial sources of contamination must undergo careful scrutiny.[40](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn40) 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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn41) Thus, a desire to exclude ambient sources of contamination, without more, cannot support the regulatory cutoff.

61

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 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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn42) 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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn43)

62

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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn44) See Alabama Power Co. v. Costle, 636 F.2d 323, 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 357-360 (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 358-360, 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 358-359. However, "(t)he agency's burden of justification in such a case is especially heavy." Id. at 359.

63

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.

64

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 360. That power "is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design." Id. at 360. 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.

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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](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn45) Consequently, we conclude that the de minimis exception to the Act is not available to justify the fifty ppm cutoff.[46](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn46)

66

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.[47](https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html#fn47) Thus, we remand this part of the record to EPA for further proceedings.

* Economic Analysis for the Final Rule Sep 82 [This document examines the economic impact on the industry generating the inadvertent PCBs vs EPA regulatory options. It does not include the life cycle cost of managing the product once it has entered the consumer market.]

“In May 1979 EPA promulgated the original PCB ban rule, which permitted the manufacture, processing, distribution, and use of PCBs in concentrations less than 50 ppm. The Court remanded the rule to EPA because EPA did not present sufficient evidence to justify the 50 ppm cut-off decision. The Court ordered that a rule dealing with the incidental generation of PCBs in closed and controlled manufacturing processes be promulgated by October 13, 1982. EPA is promulgating a final rule which excludes closed and controlled processes from the PCB ban. This report estimates the costs and benefits of the final rule as well as other regulatory alternatives considered by EPA”

* 4 regulatory options for regulation PCBs incidentally generated in closed or controlled processes
  + Exemption petition process: used as a baseline to measure costs and benefits of the other three options
  + Theoretical assessment of the level of PCB release
  + Theoretical assessment or testing for self-certification (chosen alternative)
  + Only testing for self-certification
* The final rule excludes certain closed systems and controlled waste processes where only minute quantities of PCBs are released.
* Magnitude of the inadvertent generation problem: 26 chemical firms generated 13,800 pounds of PCBs in 135 manufacturing processes (abt 1982) CMA estimated that “up to thousands of processes” may generate PCBs and VERSAR identified 130-500 processes. [These estimates assume a closed process where “no PCBs” are released to air, water and waste and a controlled process “no PCBs” are released to air, water streams; < 50 ppm released to products and all wastes go to EPA-approved disposal facilities.
* The report looked at incremental costs and benefits against a baseline case of manufacture, processing, and distribution of PCBs. Incremental costs included 1) additional health risks resulting from any exposure to PCBs from processes which would have been subject to the ban had they not been excluded, and 2) additional costs incurred by manufacturers due to self-certification.
* Practical Quantification Limit, i.e., “no release” = 100 micrograms/liter water, 2 micrograms/gram organic waste stream.

5/31/1979 44 FR 31514 Polychlorniated Biphenyls: Criteria Modification; hearings

Key points:

* P 31551 Required an exemption for diarylide and phthalocyanine pigments after 7/1/79
* P 31515 Regulation removes 5700 lbs PCB/year from pigments
* P 31516 Reguatory limit established based on cost/benefit to manufacture. Low concentration no established to protect enforcement resources – other places (i.e., Clean Water Act) in place to protect the environment. “0” PCB in road oiling because of “substantial and direct entry of PCB into road and waterways and into food chain.

“After reviewing the public comments, informal hearing testimony, and other information in the rulemaking record and then evaluating the available options, EPA concludes that retaining the PCB cut-off limit at 50 ppm provides adequate protection for human health and the environment while defining a program that EPA can effectively implement.

* P 31526 Equal treatment of importers and manufacturers
* P 31527 It is expected that the manufacturing process will be controlled so that PCBs are less than 50 ppm at any point in the process.
* P 31529 To authorize activity, it must not pose and unreasonable risk of injury to human health or the environment –good faith efforts for substitutes are needed.
* P 31530 pigments can be diluted
* P 31535 pigments in paint, similar to waste oil
* P 31537, P 31539 Intent of TSCA is to stop production of PCBs
* P 31538 Analytical methods have improved

**Other references key facts**

Lisa Rodenburg reference regarding testing of printed materials and leachability of PCBs

City of Spokane Product testing report

Hydroseed testing report

Ecology product testing results

1. https://www.epa.gov/sites/production/files/2016-11/documents/washington\_rule\_wqs\_part\_131\_2040\_af56\_final\_rule\_frn\_20161024\_webpostingversion.pdf [↑](#footnote-ref-1)
2. https://ofmpub.epa.gov/waters10/attains\_nation\_cy.control#total\_assessed\_waters [↑](#footnote-ref-2)
3. https://law.resource.org/pub/us/case/reporter/F2/636/636.F2d.1267.79-1816.79-1811.79-1580.html [↑](#footnote-ref-3)