40 CFR Part 761

[OPTS-62039A; TSH-FRL 2692-2]

Modification of Definition of Totally Enclosed Manner for PCB Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e), generally prohibits the manufacture, processing, distribution in commerce, and use of polychlorinated biphenyls (PCBs) in other than a totally enclosed manner. Section 6(e)(2)(C) of TSCA defines "totally enclosed manner" as any manner that will ensure that any exposure of humans or the environment to PCBs will be insignificant. According to this section, in determining "totally enclosed manner," the Administrator will establish by rule what constitutes significant exposure to PCBs.

In the Federal Register of May 31, 1979 (44 FR 31514), EPA issued a regulation that implemented section 6(e). In that rule, EPA defined "significant exposure" to PCBs as "any exposure of human beings or the environment to PCBs as measured or detected by any scientifically acceptable analytical method." This notice amends the May 1979 PCB Rule to: (1) Delete the definition of "significant exposure;" (2) modify the definition of "totally enclosed manner;" and (3) present the Agency's current framework for assessing PCB exposure. These modifications to the May 1979 PCB Rule are consistent with EPA's current approach to assessing exposure to PCBs.

DATES: This amendment shall be promulgated for purposes of judicial review under section 19 of the Toxic Substances Control Act (TSCA) at 1:00 p.m., Eastern Daylight Time on November 23, 1984. This amendment shall become effective on December 10, 1984.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 6(e) of TSCA generally prohibits the manufacture, processing, distribution in commerce, and use of PCBs. However, the statute provides two exceptions under which EPA may, by rule, allow a particular use of PCBs to continue. Under section 6(e)(2) of TSCA, EPA may allow PCBs to be used in a "totally enclosed manner." A "totally enclosed manner" is defined by TSCA to be "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." TSCA also allows EPA to authorize the use of PCBs in manner other than a totally enclosed manner if the Agency finds that the use "will not present an unreasonable risk of injury to health or the environment."

In the Federal Register of May 31, 1979 (44 FR 31514), EPA issued a regulation that implemented section 6(e). (This rule is hereafter referred to as the May 1979 PCB Rule and is listed in the Code of Federal Regulations under 40 CFR Part 761.) Among other things, the May 1979 PCB Rule: (1) Generally excluded from regulation materials containing PCBs in concentrations of less than 50 parts per million (ppm); (2) designated all intact, non-leaking capacitors, electromagnets, and transformers (other than railroad transformers) as "totally enclosed," and permitted their use without specific conditions; and (3) authorized 11 non-totally enclosed uses of PCBs, based on the finding that they did not present unreasonable risks. In addition, in the May 1979 PCB Rule, EPA defined the terms "significant exposure" and "totally enclosed manner" within the context of section 6(e)(2) of TSCA. "Significant exposure" was defined as any exposure of human beings or the environment to PCBs as measured or detected by any scientifically acceptable analytical method. (40 CFR 761.3(dd)). "Totally enclosed manner" was defined as any manner that will ensure that any exposure of human beings or the environment to any concentration of PCBs will be insignificant; that is, not measurable or detectable by any scientifically acceptable analytical method. (40 CFR 761.3(hh)).

The Environmental Defense Fund (EDF) successfully challenged the 50 ppm cutoff and the designation of PCB electrical equipment as "totally enclosed" in *EDF* v. *EPA*, 636 F.2d 1267 (D.C. Cir. 1980). In that decision, the U.S. Court of Appeals for the District of Columbia invalidated a portion of the rule and remanded the rule to EPA for further action. The definition of the terms "significant exposure" and "totally enclosed manner" in the May 1979 Rule were not, however, challenged and therefore not reviewed by the court in *EDF* v. *EPA*.

As a consequence of the court's decision in *EDF* v. *EPA*, EPA Rule conducted a number of rulemaking actions. The three actions specifically relevant to the subject of today's notice of final rulemaking are the Electric Equipment Rule published in the Federal Register of August 25, 1982 (47 FR 37342); the Closed and Controlled Rule published in the Federal Register of October 21, 1982 (47 FR 46980); and the Uncontrolled PCBs Rule published in the Federal Register July 10, 1984 (49 FR 28172). In these amendments to the May 1979 PCB Rule, among other things, EPA considered the effects on human health and the environment from the manufacture, processing, distribution in commerce, and use of PCBs in certain circumstances.

In 1982, following the promulgation of the PCB Electrical Equipment Rule, the Edison Electric Institute (EEI), the National Electrical Manufacturers Association (NEMA), EDF, Natural Resources Defense Council (NRDC), and the American Paper Institute (API) filed petitions for review of the PCB Electrical Equipment Rule. These actions were consolidated in the U.S. Court of Appeals for the District of Columbia Circuit.

On March 23, 1984, EEI, NEMA, API, and EPA filed a joint motion with the Court to hold the lawsuit in abeyance pending implementation of a settlement agreement reached between these parties. The court granted this joint motion on April 25, 1984. Under the settlement, EPA agreed to a schedule for conducting a rulemaking that would address the definitions of the terms "significant exposure" and "totally enclosed manner" in § 761.3 and certain provisions of § 716.20 relating to these terms.

II. Summary of Amendments

EPA is issuing the following modifications to the May 1979 PCB Rule:

1. Deletion of the definition of "significant exposure" in § 761.3.

2. Revision of the definition of "totally enclosed manner" in § 761.3 by deleting the current definition and substituting the following: "'Totally enclosed manner' means any manner that will ensure no exposure of human beings or the environment to any concentration of PCB."

3. Revision of the introductory text of § 761.20 by deleting the sixth, seventh, and eighth sentences, which state:

> In addition, the Administrator hereby finds that any exposure of human beings or the environment to PCBs as measured or detected by any scientifically acceptable analytical method is a significant exposure

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* * Since any exposure to PCBs is found to be a significant exposure, a totally enclosed manner is a manner that results in no exposure of humans or the environment to PCBs.

The following two sentences are substituted therefor:

In addition, the Administrator hereby finds, for purposes of section 6(e)(2)(C) of TSCA, that any exposure of humans or the environment to PCBs, as measured or detected by any scientifically acceptable analytical method, may be significant, depending on such factors as the quantity of PCBs involved in the exposure, the likelihood of exposure to humans and the environment, and the effect of exposure. For purposes of determining which PCB items are totally enclosed, pursuant to section 6(e)(2)(C) of TSCA, since exposure to such items may be significant, the Administrator further finds that a totally enclosed manner is a manner which results in no exposure to humans or the environment to PCBs.

EPA is deleting the May 1979 definition of "significant exposure" because EPA believes that this definition does not accurately reflect EPA's current position on the relative risks posed by different levels of exposure to PCBs. EPA believes that on a spectrum of relative risk, there is a point at which the risk posed by exposure to a certain level of PCBs becomes insignificant, regardless of considerations such as the availability of substitute materials or the costs associated with reducing this risk to a lower level. EPA is also revising the May 1979 definition of "totally enclosed manner" to make it consistent with EPA's current policy.

In the closed and Controlled Rule, issued in October 1982, EPA first recognized that certain exposures to PCBs may not be significant. In that rule, EPA determined that exposures to PCBs at levels below the practical limits of quantitation posed *de minimis* risks.

Second, in the Uncontrolled PCBs Rule, EPA quantified the levels of exposure to PCBs which could be considered to not pose an unreasonable risk. Thus, the deletion of the definition of "significant exposure" and modification of "totally enclosed manner" are being made, in part, as a result of EPA conducting a more sophisticated quantitative exposure analysis for the Uncontrolled PCBs Rule. Through this analysis, EPA identified levels of exposure to PCBs which would not pose unreasonable risks. (For a discussion of the Agency's current approach to exposure assessment, see Unit III.A of this preamble.)

III. Discussion of Amendments

The proposed modification of the definition of "totally enclosed manner" for PCB activities was published in the **Federal Register** of July 23, 1984 (49 FR 29625). The comment period on that proposed rule closed on August 22, 1984. Ten comments were received and were taken into consideration in issuing this final rule. In response to a request for a meeting that was received after the comment period closed, and informal informational meeting was held at EPA on September 14, 1984, for all interested parties. No new issues were raised at that time. A transcript of this meeting is part of the official rulemaking record.

A. Deletion of the Definition of "Significant Exposure"

As set out above, further rulemakings by EPA have established that there may be exposures to PCBs which are not significant. Therefore, the definition of "significant exposure" contained in the May 1979 PCB Rule does not accurately reflect the Agency's current analysis or policies concerning the risks posed by exposures to certain levels of PCBs. Moreover, the concept of "significant exposure" as used in Section 6(e) of TSCA has applicability only to the Agency's earlier determination that all intact, non-leaking capacitors, electromagnets and transformers (other than railroad transformers) could continue to be used so long as they were "totally enclosed." While the definition of "totally enclosed" was pivotal in the May 1979 PCB Rule, later rulemakings by EPA have changed the regulatory focus and basis, and at this time, the concept of a totally enclosed use has only limited applicability.

Comments were received suggesting that today's amendment may have substantial impact on other PCB regulations or enforcement actions. These comments do not accurately reflect the scope of today's action. EPA reaffirms its position that the deletion of the definition of significant exposure is relevant only to the definition of "totally enclosed manner." Further, the Agency does not intend for this action to set a precedent to require the Agency to do quantitative exposure assessments for other PCB regulatory and enforcement decisions. For example, in PCB clean up situations, case-by-case risk assessments would not be required as a result of this rule.

One commenter stated that by deleting the definition of "significant exposure," the Agency is moving from a relatively predictable standard into an area of incident-by-incident risk assessment. EPA disagrees with this comment. This action in not intended to required EPA to conduct case-by-case exposure assessments in any other PCB regulatory matter, including enforcement decisions.

Additionally, the deletion of the term "significant exposure" does not imply that the Agency has altered its views regarding the toxicity of PCBs. The Agency reaffirms its position that PCBs may cause chloracne, reproductive effects, developmental toxicity, and oncogenicity in humans exposed to PCBs. However, EPA has also determined that under certain limited circumstances, exposure to PCBs would not be significant, or therefore, present an unreasonable risk.

Since issuing the May 1979 PCB Rule and the August 1982 Electrical Equipment Rule, EPA has done considerable work in the area of exposure evaluation. Specifically, EPA considered the exposure to PCBs under the limited circumstances of the Closed and Controlled Rule and determined that these exposures would present *de minimis* risk. EPA also conducted a state-of-the-art quantitative exposure assessment which was used in support of EPA's finding in the Uncontrolled PCBs Rule that certain exposures would not present an unreasonable risk. Among the factors considered by EPA in support of these exposure evaluations were the quantity of PCBs involved in the exposure and the likelihood of exposure to humans and the environment. Based on these exposure evaluations, EPA recognizes that there may be situations in which exposure to PCBs could be insignificant.

On the basis of the exposure assessment conducted in support of the Uncontrolled PCBs Rule, EPA concluded that under certain circumstances "none of the realistic hypothetical exposures were significant, especially when compared to the 150,000,000 pounds of PCBs already existing in the environment" (49 FR 28181). This determination, in combination with the findings in the Closed and Controlled Rule that certain exposures to PCBs present *de minimis* risk, support the Agency's determination today that the definition of "significant exposure" is no longer useful or consistent with current Agency evaluations of exposure.

Two commenters on the proposed rule raised the issue that the exposure assessment methodology used in the Uncontrolled PCBs Rule is inappropriate for this rulemaking. According to these commenters, the exposure analysis conducted for the Electrical Equipment Rule is a more appropriate means of defining "significant exposure." The commenters also stated that there is no safe threshold for exposure.

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This comment is a misinterpretation of EPA's position. The issue is whether the existing definition of significant exposure within the regulations reflects current Agency thinking concerning the risks posed by exposures to PCBs. During the Closed and Controlled rulemaking and the Uncontrolled PCBs rulemaking, EPA identified instances where exposures to PCBs could be considered insignificant. Thus, the existing definitions of significant exposure and totally enclosed manner required revision.

At the time the Electrical Equipment Rule was promulgated in 1982, the Agency had very limited information upon which to calculate estimates of exposures to PCBs. Since exposure and toxicity are the two factors that determine risk, the Agency was unable to conduct a quantitative risk assessment for PCBs based on the information then available.

Since 1982, the Agency has undertaken additional study of the exposure to PCBs in support of subsequent rulemakings. The Agency believes that these assessments are more appropriate for decision analysis than the earlier, less complete information. By removing the term "significant exposure," the Agency has not changed its position that PCBs are persistent and that exposure should be avoided. EPA also does not intend to imply that there is a safe threshold for exposure, but recognizes that in some cases exposure may not be significant as indicated by these assessments. Further in the Uncontrolled Rule, EPA also concluded that it was reasonable to regulate monochlorinated and dichlorinated biphenyls at a discounted rate since these PCBs are generally less persistent and less likely to bioaccumulate than the higher chlorinated homologs. Information submitted jointly by the CMA, EDF, and NRDC supported and encouraged the discontinuing of monochlorinated and dichlorinated biphenyls.

Two commenters stated that it is inappropriate to apply the same criteria to both Aroclor and non-Aroclor PCBs, and that the discounting of monochlorinated and dichlorinated biphenyls had been based on the existing definition of "significant exposure."

The Agency disagrees. Non-Aroclor is a generic term referring to one or more of the 209 different PCB congeners. A product containing inadvertently generated PCBs may have the same congeners in it as those present in an Aroclor PCB mixture. Thus, in general, one cannot say that the risks posed by non-Aroclor PCBs are different from the risks posed by PCBs that fall into the generic Aroclor classification.

The decision to regulate the lower chlorinated PCBs at discounted rates was based on the fact that releases of these PCBs are often uncontrolled and inadvertently generated, are generally less persistent, and are less likely to bioaccumulate. The Agency's decision to regulate PCBs on two different standards was, in part, based on the information submitted jointly by CMA, EDF, and NRDC. Based on the collective information reviewed, EPA believes that the lower chlorinated non-Aroclor PCBs present less relative risk to human health or the environment than the higher chlorinated congeners, and that relatively higher levels of exposure to the lower chlorinated PCBs would still be considered insignificant.

The Agency's action today with regard to the definitions of "significant risk" and "totally enclosed manner" has been taken to reflect the progress that the Agency has made in defining exposure, and thereby the risks, associated with PCBs. These changes to the definitions of "significant exposure" and "totally enclosed manner" are the result of the Agency's most current information.

B. Revision of the Definition of "Totally Enclosed Manner"

The current definition of "totally enclosed manner" in § 761.3 is "any manner that will ensure that any exposure of human beings or the environment to any concentration of PCBs will be insignificant; that is, not measurable or detectable by any scientifically acceptable analytical method." This final amendment would define the term as "any manner that will ensure no exposure of human beings or the environment to any concentration of PCBs."

Three of the comments received noted that the revised definition of "totally enclosed manner" was more restrictive than necessary.

The intent of the "totally enclosed" definition is not changed by the revised definition. Under either version, only PCB equipment that is intact and nonleaking qualifies as "totally enclosed." The revised definition is intended to clarify the meaning of "totally enclosed manner," and is, for the purposes of implementation, a restatement of current policy.

Two commenters raised concerns over the inclusion of the language "any scientifically acceptable analytical method," stating that use of such a method may not be reliable and that such language is too general. It should be noted that this is the same language that appeared in the original definition in the 1979 PCB Rule and has been retained in this modification of the definition to allow for the development of technology. The Agency recognizes that PCB research has continued to change and develop since it was first addressed in rulemaking. The above language was, therefore, included to allow flexibility for new developments in analytical techniques and methodologies. EPA also recognizes that designating specific methods as acceptable may not be appropriate in all situations.

C. Miscellaneous Issues

One commenter noted that the introductory text of § 761.20 did not provide for "use" of equipment containing PCBs. The language cited by the commenter is not changed by this rule. As stated in the Electrical Equipment Rule of 1982, the use of specified types of equipment containing PCBs is allowed under certain conditions. This use authorization and the conditions applicable to it are not affected by today's action.

Two comments were received concerning the term "any concentration" relative to the use, maintenance and servicing of nonleaking electrical equipment containing PCBs. One commenter felt that a 50 ppm or greater limitation should be added for clarification. Another commenter questioned whether routine maintenance and servicing of PCB transformers would now be considered as an "exposure of human beings or the environment to any concentration of PCBs." EPA feels that by deleting the term "significant exposure" it is not necessary to specify a concentration limitation. The revised definition of "totally enclosed manner" includes language ensuring that no exposure of human beings or the environment will occur.

The amended definition also does not change the conditions regarding maintenance and servicing of PCB transformers, as specified in the Electrical Equipment Rule of 1982. This rule describes conditions which allow for the continued use of PCB transformers and other PCB-containing equipment. These conditions include categories of PCB equipment subject to regulation, time restrictions, and conditions associated with use. Routine maintenance and servicing activities such as dielectric strength testing, the filtering of dielectric fluids and "topping off" with dielectric fluid is permissible as described in § 761.30(a)(2) of the Electrical Equipment Rule of 1982. The

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servicing of sweat residues that do not require repair to prevent further leaking, requires proper cleanup within 48 hours, and the PCB-contaminated materials disposed of in a timely fashion.

One comment related concern over EPA's draft PCB policy on the possibility of changing "background levels" to "specific levels of detection." This comment is not related to this amendment of the definition of "totally enclosed," but is instead related to a PCB cleanup policy. Since this rule does not deal with the PCB cleanup policy, it is inappropriate for EPA to respond to this issue in the context of this rule.

IV. Agency's Position on Health and Environmental Effects of PCBs

A. Human Health Effects From Exposure to PCBs

The effects of PCBs have been previously described in various documents that are part of the administrative record for the various PCB rulemakings. Copies of these documents are available through EPA's TSCA Assistance Office (see address above listed under "**FOR FURTHER INFORMATION CONTACT**").

EPA has determined that PCBs are toxic and persistent. PCBs can enter the body through the lungs, gastrointestinal tract, and skin; circulate thrughout the body; and be stored in the fatty tissue.

In some cases, chloracne may occur in humans exposed to PCBs. Chloracne is painful, disfiguring, and may require a long time before the symptoms disappear. Although the effects of choloracne are reversible, EPA considers these effects to be significant.

In addition, EPA finds that PCBs may cause reproductive effects, developmental toxicity, and oncogenicity in humans exposed to PCBs. Available data show that some PCBs have the ability to alter reproductive processes in mammalian species, sometimes even at doses that do not cause other signs of toxicity. Animal data and limited available human data indicate that prenatal exposure to PCBs can result in various degrees of developmentally toxic effects. Postnatal effects have been demonstrated in immature animals after exposure to PCBs prenatally and via breast milk.

Since the administration of PCBs to experimental animals results in tumor formation, reproductive effects, and developmental toxicity, EPA finds that there is the potential to produce these effects in humans exposed to PCBs. EPA finds no evidence to suggest that the animal data would not be predictive of the potential for oncogenic effects in humans.

Available data indicate little or no mutagenic activity from PCBs. EPA believes, however, that more information is needed to draw a conclusion on the possibility of mutagenic effects from PCBs.

B. Environmental Effects of PCBs

In previous PCB rules, EPA concluded that PCBs can be concentrated in freshwater and marine organisms. The transfer of PCBs up the food chain from phytoplankton to invertebrates, fish, and mammals can result ultimately in human exposure through consumption of PCB-containing food sources. Available data show that PCBs affect the productivity of phytoplankton communities, cause deleterious effects on environmentally important freshwater invertebrates, and impair reproductive success in birds and mammals.

PCBs also are toxic to fish at very low exposure levels. The survival rate and the reproductive success of fish can be adversely affected in the presence of PCBs. Various sublethal physiological effects attributed to PCBs have been recorded in the literature. Abnormalities in bone development and reproductive organs also have been demonstrated.

EPA conducted an environmental risk assessment of PCBs including a review of available environmental data. This assessment can be found in the support document entitled "Environmental Risk and Hazard Assessments of Polychlorinated Biphenyls" (September 1983). EPA concluded that ambient concentrations and food chain transport of PCBs may impair the reproductive potential of commercially valuable fish and certain wild mammals. PCB residues also are strongly correlated with reductions in natural populations of marine mammals and may be correlated with declines in river otter populations. High PCB residues have been found in various birds, especially gulls and carnivorous birds, but no resulting effects have been demonstrated.

In addition, EPA estimated the toxicity for the monochlorinated through hexachlorinated biphenyls and for decachlorinated biphenyls. These estimates show that as the number of chlorine atoms on the biphenyl molecule increases, the no observable effect concentration (NOEC) for fish decreases.

V. Judicial Review

Judicial review of this final rule may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested parties an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA will promulgate this rule for purposes of judicial review 2 weeks after publication of the final rule in the **Federal Register**. The effective date will be calculated from the promulgation date.

VI. Official Record of Rulemaking

In accordance with the requirements of section 19(a)(3) of TSCA, EPA is issuing the following list of documents which constitute the record of this rulemaking. However, public comments and the transcript of the informal meeting are not listed, because these documents are exempt from **Federal Register** listing under section 19(a)(3). The public record is available for review and copying in Rm. E-107, 401 M Street, SW., Washington, D.C. from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

A. Previous Rulemaking Records

(1) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Disposal and Marking Final Regulation" published in the **Federal Register** of February 17, 1978 (43 FR 7150).

(2) Official rulemaking record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibition Rule" published in the **Federal Register** of May 31, 1979 (44 FR 31514).

(3) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce and Use Prohibitions: Use in Electrical Equipment" Published in the **Federal Register** of August 25, 1982 (47 FR 37342).

(4) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution, and Use in Closed and Controlled Waste Manufacturing Processes" published in the **Federal Register** of October 21, 1982 (47 FR 46980).

(5) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations" published in the **Federal Register** of July 10, 1984 (49 FR 28172).

B. "Federal Register" Notices

(6) USEPA, "Polychlorinated Biphenyls (PCBs) Disposal and Marking Final Regulation." 43 FR 7150; February 17, 1978.

(7) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions." 44 FR 31514; May 31, 1979.

(8) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use

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Prohibitions; Use in Electrical Equipment." 47 FR 37342; August 25, 1982.

(9) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes." 47 FR 46980; October 21, 1982.

(10) USEPA, "Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions, and Use Authorizations." 49 FR 28154; July 10, 1984.

VII. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must judge whether a rule is a "major rule" and, therefore, subject to the requirement that a Regulatory Impact Analysis be prepared. EPA has determined that this amendment to the PCB rule is not a major rule as the term is defined in section 1(b) of the Executive Order, because the annual effect of the rule on the economy will be substantially less than $100 million; it will not cause a major increase in costs or prices for any sector of the economy or for any geographic region; and it will not result in any adverse effects on competition, employment, investment, productivity, or innovative or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. This final rule merely modifies the definition of "totally enclosed manner" under section 6(e)(2)(C) of TSCA (without changing the regulatory effect of the definition) and is consistent with the Agency's current policy on assessing of PCB exposure.

This amendment was submitted to the Office of Management and Budget (OMB) prior to publication as required by the Executive Order.

VIII. Regulatory Flexibility Act

Under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 605, the Administrator may certify that a rule will not, if promulgated, have a significant impact on a substantial number of small entities and, therefore, does not require a regulatory flexibility analysis.

This rule modifies the definition of "totally enclosed manner" in the 1979 PCB Rule. Since EPA expects this rule to have no negative economic effect to any business entity, I certify that this rule would not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required and will not be completed for this rulemaking.

IX. Paperwork Reduction Act

This final rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 761

Hazardous substances, Labeling, Polychlorinated biphenyls, Recordkeeping and reporting requirements, Environmental protection.

(Sec. 6, 90 Stat. 2020, Pub. L. 94-469 (15 U.S.C. 2605))

Dated: November 1, 1984.

William D. Ruckelshaus,

Administrator.

PART 761—[AMENDED]

Therefore, 40 CFR Part 761 is amended as follows:

1. In § 761.3, the definition of "significant exposure" is removed, and the definition of "totally enclosed manner" is revised to read as follows:

§ 761.3 Definitions.

* * * * * *

"Totally enclosed manner" means any manner that will ensure no exposure of human beings or the environment to any concentration of PCBs.

* * * * *

2. In § 761.20, the introductory text is revised to read as follows:

§ 761.20 Prohibitions.

Except as authorized in § 761.30, the activities listed in paragraphs (a) and (d) of this section are prohibited pursuant to section 6(e)(2) of TSCA. The requirements set forth in paragraphs (b) and (c) of this section concerning export and import of PCBs for purposes of disposal and PCB Items for purposes of disposal are established pursuant to section 6(e)(1) of TSCA. Subject to any exemptions granted pursuant to section 6(e)(3)(B) of TSCA, the activities listed in paragraphs (b) and (c) of this section are prohibited pursuant to section (6)(e)(3)(A) of TSCA. In addition, the Administrator hereby finds, under the authority of section 12(a)(2) of TSCA, that the manufacture, processing, and distribution in commerce of PCBs at concentrations of 50 ppm or greater and PCB Items with PCB concentrations of 50 ppm or greater present an unreasonable risk of injury to health within the United States. This finding is based upon the well-documented human health and environmental hazard of PCB exposure, the high probability of human and environmental exposure to PCBs and PCB Items from manufacturing, processing, or distribution activities; the potential hazard of PCB exposure posed by the transportation of PCBs or PCB Items within the United States; and the evidence that contamination of the environment by PCBs is spread far beyond the areas where they are used. In addition, the Administrator hereby finds, for purposes of section 6(e)(2)(C) of TSCA, that any exposure of human beings or the environment to PCBs, as measured or detected by any scientifically acceptable analytical method, may be significant, depending on such factors as the quantity of PCBs involved in the exposure, the likelihood of exposure to humans and the environment, and the effect of exposure. For purposes of determining which PCB Items are totally enclosed, pursuant to section 6(e)(2)(C) of TSCA, since exposure to such Items may be significant, the Administrator further finds that a totally enclosed manner is a manner which results in no exposure to humans or the environment to PCBs. The following activities are considered totally enclosed: distribution in commerce of intact, nonleaking electrical equipment such as transformers (including transformers used in railway locomotives and self-propelled cars), capacitors, electromagnets, voltage regulators, switches (including sectionalizers and motor starters), circuit breakers, reclosers, and cable that contain PCBs at any concentration and processing and distribution in commerce of PCB Equipment containing an intact, nonleaking PCB Capacitor. See paragraph (c)(1) of this section for provisions allowing the distribution in commerce of PCBs and PCB Items.

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[FR Doc. 84-29274 Filed 11-7-84; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 663

[Docket No. 40453-4053]

Pacific Coast Groundfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of continuation of fishing restriction and request for comments.

SUMMARY: NMFS issues this notice announcing continuation of current fishing restrictions for the *Sebastes* complex of rockfish north of Cape Blanco, Oregon. This notice rescinds that part of the Federal Register notice (49 FR 30948, August 2, 1984) which announced intent to close the target fishery when landings reached a certain

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