PART 233—INSPECTION SERVICE AUTHORITY

3. In § 233.3 of title 39, Code of Federal Regulations, add new paragraph (j) reading as follows:

§ 233.3 Mail covers

* * * * *

(j) *Military Postal System.* Section 233.3 does not apply to the military postal system overseas or to persons performing military postal duties overseas. Information about regulations prescribed by the Department of Defense for the military postal system overseas may be obtained from the Department of Defense.

Transmittal letters making changes in the pages of the International Mail Manual and the Domestic Mail Manual will be published and transmitted to subscribers automatically. Notice of issuance of the transmittal letters will be published in the **Federal Register** as provided in 39 CFR 10.3 and 111.3, respectively.

(39 U.S.C. 401(2), 401(3), 403(a), 406, 411 (1976))

W. Allen Sanders,

Associate General Counsel, Office of General Law and Administration.

[FR Doc. 82-28817 Filed 10-20-82; 8:45 am]

BILLING CODE 7710-12-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Security of Military Post Office (MPO) Mail Overseas

AGENCY: Office of the Secretary (Military Postal Service), DOD.

ACTION: Notice.

SUMMARY: On Tuesday, April 6, 1982, the Department of Defense published a notice in the **Federal Register**, (47 FR 14864), announcing a proposed agreement between the United States Postal Service (USPS) and DoD which would make DoD responsible for the security of Military Post Office (MPO) Mail overseas. This notice presents the policy of DoD concerning this subject. This policy permits DoD officials to inspect, search, and collect information concerning mail when consistent with the Fourth Amendment to the U.S. Constitution, the Uniform Code of Military Justice, and the Manual for Courts-Martial. The new policy should assist DoD in reducing the flow of drugs and other contraband in MPO mail overseas.

EFFECTIVE DATE: November 20, 1982.

FOR FURTHER INFORMATION CONTACT: Thomas C. Wright, Office of the General Counsel, Department of the Army, Room 2E729, The Pentagon, Washington, D.C. 20310, (202) 695-2253.

SUPPLEMENTARY INFORMATION: The Department of Defense received comments from the public and from other federal agencies. These comments will be addressed below.

For many years the Department of Defense has recognized the need to control contraband in MPO mail overseas. However, many regulations of the USPS, designed to apply primarily to domestic mail, were not effective to provide such control overseas where there are no postal inspectors, federal judges, or federal magistrates. A new agreement has been reached between USPS and DoD in which DoD will exercise the responsibility for policies and regulations concerning the privacy and security of MPO mail overseas.

The new policy will enable military law enforcement personnel to seek and execute search authorizations, issued pursuant to law and upon a showing of probable cause, for mail matter. At the same time, the privacy of mail shall be preserved. The new policy will also provide mechanisms for military mail covers, similar to the process currently used by USPS domestically. Provisions for random inspection of mail bags and parcels are included in order to stem the flow of drugs and other contraband through the mail. The policy does not permit opening of any piece of mail except under limited specified circumstances.

Finally, the policy recognizes the authority of United States personnel to cooperate with and assist host country authorities who may have a legitimate interest in inspecting the mail.

DOD received comments from eight sources, including other federal agencies, congressmen, unions representing federal civilian employees, and individual citizens. The comments received by DOD and the changes to the policy since the previous notice are discussed below.

The first sentence of paragraph I has been changed slightly after internal review to use terminology more accurately describing the operation of military post offices overseas.

DOD received one comment stating that the policy is too open-ended, citing paragraph I.2.a.(3) as an example. The commenter suggested that DOD leave the "other circumstances" described by that paragraph for resolution by future rulemaking. The discretion vested in the Assistant Secretary of Defense (Manpower, Reserve Affairs, and Logistics) by that paragraph is limited to a customs-type inspection of the exterior of the item of mail. This is a reasonable vesting of authority in a senior DOD official. No change has been made to this paragraph.

Paragraph I.2.b.(2) has been expanded after internal review to prescribe appropriate action when nonmailable items are detected at military post offices.

DOD received one comment questioning why mail not sealed against inspection may be opened, read, searched, or contents divulged in order to determine whether the correct postage has been paid, under paragraph I.2.b.(2).

The question misperceives the intent of this particular section. The authorized military postal clerk or postal officer may take only such actions as are necessary to determine the mailability of the contents or whether the correct postage has been paid. If the postal clerk or postal officer does not need to read the contents of the mail to make this determination, then he may not read the mail under this paragraph. To clarify this intent, the provision has been changed.

Paragraph I.3.a. has been changed as a result of internal review to add a definite time limit to the provisions regarding detention of mail.

Paragraph I.3.b. has been changed after internal review to add a cross-reference to another section of this policy.

Paragraph I.3.f. has been changed after internal review to make it clear that officials with authority to issue search authorizations also have the authority to order detention of the mail. Detention is less intrusive than search of the mail.

Paragraph I.4. has been changed after internal review to permit any person acting under the authorization of a military postal clerk or postal officer (such as, a bomb disposal expert) to act under this section regarding mail suspected of being dangerous to persons or property. It is impractical to determine now the exact status of the person who may be required to dispose of such a threat when it arises.

DOD received one comment stating that the reporting requirements under paragraph I.4. should be identical to those under paragraph I.11. DOD does not agree. The provisions of paragraph (a)(4), relating to mail reasonably suspected of being dangerous to persons or property, will be rarely used, but when they are used it will be in an emergency situation where the ordinary reporting requirements may not be practical. This commenter also complained that while the addressee was routinely informed of a seizure of his mail, the sender was notified under the regulations only if he had purchased a return receipt. While both the addressee and the sender do have an interest in the mail, DOD regards the addressee's interest as paramount. USPS has a similar provision in paragraph 115.63 of the Domestic Mail Manual.

Paragraph I.6.a.(2) was changed after internal review to include a reference to the Manual for Courts-Martial, which contains the authority for issuing search authorizations. The Manual is promulgated by Executive Order 11476 pursuant to Article 36 of the Uniform Code of Military Justice, 10 U.S.C. 836.

DOD received one comment suggesting that DOD express a preference for military judges or magistrates over commanding officers in issuing search authorizations. This comment was not adopted. The courts that have considered the constitutionality of search authorizations issued by commanding officers have unanimously upheld such searches as a general matter. Of course, when the commanding officer is not in fact "neutral and detached," just as when a magistrate or judge is not "neutral and detached," the search authorization is unlawful and the fruits of the search will be suppressed. *See*

Military Rule of Evidence 315, which is set forth in the Manual for Courts-Martial; *U.S. v. Ezell*, 6. M.J. 307 (CMA 1979). This is the same protection given in the civilian criminal system. In order to ensure respect for appropriate interests in privacy of the mail, paragraph I.6.a.(2) provides that only senior commanding officers may issue such search authorizations.

The terms "military postal official" and "senior military postal official," formerly used in paragraphs I.7, I.8, and I.11, have been changed to "senior military official" and "senior military official having responsibility for postal operations of each major overseas command within each of the respective Services." This change was made after internal review in order to describe more clearly the person who will be exercising this authority.

Paragraph I.8. was modified after internal review. Paragraph I.8.a. was added. This provision contains definition of terms used elsewhere in paragraph I.8. In paragraph I.8.b., the phrase "the request may be granted only if it demonstrates reasonable grounds for determining" has been changed to "the request may be granted only if the military official or his designee has a reasonable suspicion, based on articulable facts * * *." This change describes more clearly the appropriate standard. A provision has been added to paragraph I.8.b. that permits a mail cover to be ordered when necessary to protect the national security. This authority relates only to the ordering of mail covers, and not to ordering searches of the mail. Further, this authority may not be delegated from the senior military official described in this paragraph. Finally, paragraph I.8.f. was added to set a time limit for mail covers.

DOD received one comment that paragraph I.8.b. leaves room for the "senior military postal official" to be subjected to pressure of rank from the commanding officer of the person whose mail is to be subjected to the mail cover process. This comment was not accepted. It is DOD's view that the "senior military official having responsibility for postal operations of each major overseas command within each of the respective services" will have sufficient stature and impartiality in the exercise of this function.

DOD received four comments expressing concern with the provisions of paragraph I.10.a. Formerly, that section referred to "necessary" inspections by foreign customs officials. The language in this section has been changed to clarify the operation of this section. One comment regarded the former section as inconsistent with certain Status of Forces Agreements that exempt mail from search by the host country authorities. While such an interpretation was never DOD's intent, the current section more clearly explains that Status of Forces Agreements on this matter are to be considered controlling.

One comment criticized this paragraph for its provisions permitting foreign officials to search mail in the host country. This comment also suggested that DOD exempt official mail from inspection either by foreign or military customs officials. The revisions of this paragraph make clear that DOD will do all that it can to lessen the frequency and intrusiveness of searches by foreign officials. However, DOD cannot unilaterally exempt any class of mail from inspection by foreign government officials. Further, the Department of Defense believes that all users of MPO facilities should be subject to the same procedures. This comment suggested that DOD define the word "contraband" as used in this regulation. That word is defined in DOD 4525.6–M of which this policy will become a part.

DOD received one comment expressing concern that implementation of this policy might reduce the effectiveness of the military customs inspection program. DOD is likewise concerned that this not happen, and provisions of I.10.b have been changed to delete specific reference to "military customs officials." Consequently, military customs officials will not necessarily have the additional burden of performing duties under that paragraph.

DOD received a comment that civilian employees should receive the same protection as other citizens within the United States. The policy incorporates applicable Fourth Amendment standards and other requirements as rigorously as possible. Probable cause is a requirement for the issuance of military search authorizations as well as for the issuance of civilian search warrants.

This commenter also suggested that under *Reid v. Covert*, 354 U.S. 1 (1957), military authorities are precluded from exercising criminal jurisdiction, and thus the conduct of searches, against civilians. While *Reid* does preclude the exercise of criminal jurisdiction by military authorities against civilians (with exceptions stated therein), that case does not preclude a commander from searching civilians or civilian's property. Civilian courts have uniformly upheld legitimate command-directed searches of civilians. On the same theory, mail addressed to a civilian may be searched under this policy so long as it is MPO mail overseas.

One comment suggested that DOD should not attempt to inspect the mail because Status of Forces Agreements permit foreign customs officials to open and inspect MPO mail coming into their own countries. As explained in answers to other comments, DOD seeks to conduct inspections of the mail instead of inspection by foreign customs officials. Further, such an inspection by foreign customs officials does not occur in every country, and never occurs with regard to mail going to ships on the high seas. The commenter also stated that civilian employees are opposed to being subjected to the Uniform Code of Military Justice. This policy does not subject civilians to the Uniform Code of Military Justice for criminal prosecution purposes. However, when civilians avail themselves of the benefits of the MPO system, just as when civilians avail themselves of the opportunity to enter a military installation, they subject themselves to the authority of the military to conduct searches and seizures consistent with the Fourth Amendment.

M. S. Healy,

OSD Federal Register, Liaison Officer, Department of Defense.

October 15, 1982.

[FR Doc. 82-28816 Filed 10-20-82; 8:45 am]

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federal register

Thursday
October 21, 1982

Part III

Environmental Protection Agency

Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

[OPTS-62017B; TSH-FRL 2217-6]

Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule amends portions of an existing EPA rule concerning certain chemical substances known as polychlorinated biphenyls (PCBs). The Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e), generally prohibits the manufacture, processing, distribution in commerce, and use of PCBs. This rule excludes PCBs produced in certain limited manufacturing processes from the TSCA prohibitons. Appropriate safeguards are included to ensure compliance with the conditions for exclusion provided by the rule.

DATES: These amendments shall be considered promulgated for purpose of judicial review under section 19 of TSCA at 1:00 p.m. Eastern Daylight Time on October 27, 1982. These amendments shall be effective on November 22, 1982.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-509, 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). Copies of this rule and its support documents can be obtained from the Industry Assistance Office listed above.

SUPPLEMENTARY INFORMATION: OMB Control Number: 2070-0008.

I. Recodification of 40 CFR Part 761

Notice of the recodification of 40 CFR Part 761 appears in the Federal Register of May 6, 1982 (47 FR 19527). This final rule contains the new designations:

New designation	Former designation
Subpart B	Subpart D.
§ 761.185	§ 761.45.
§ 761.3	§ 761.2.
§ 761.65	§ 761.42.
§ 761.70	§ 761.40.
§ 761.75	§ 761.41.

II. Background

Section 6(e) of the Toxic Substances Control Act (TSCA) prohibits the manufacture, processing, distribution in commerce, and use of polychlorinated biphenyls (PCBs). However, the statute enables EPA to promulgate rules to reduce the impact of the ban. EPA promulgated a rule, published in the Federal Register of May 31, 1979 (44 FR 31514), to implement section 6(e) of TSCA. This rule is listed in the Code of Federal Regulations under 40 CFR Part 761. This rule, among other things, generally excluded from the ban materials containing PCBs in concentrations under 50 parts per million (ppm).

The Environmental Defense Fund (EDF) obtained judicial review of the rule in the U.S. Court of Appeals for the District of Columbia Circuit. EDF challenged the provision described above, among others. On October 30, 1980, the court invalidated the regulatory exclusion for PCB concentrations below 50 ppm *Environmental Defense Fund* v. *EPA*, 636 F.2d 1267. The court remanded the rule to EPA for further action consistent with the opinion. The court's decision placed industries that had relied upon the PCB Ban Rule in a difficult position. Issuance of the court's mandate would have activated section 6(e)'s broad prohibitions on the manufacture, processing, distribution in commerce, and use of PCBs, resulting in the disruption of many activities in industries throughout the United States.

Accordingly, the parties to the lawsuit filed a joint motion on February 20, 1981, to seek a stay of the court's mandate. The joint motion proposed that during the period encompassed by the stay: (1) EPA would conduct new rulemaking with respect to PCBs, and (2) industry groups would initiate studies to provide information for the new rulemaking.

During discussions which led up to this joint motion, representatives of some affected industries stated that some of the processes which produce PCBs are designed and operated so that no releases of PCBs occur or that the PCBs formed in the processes are released only in wastes that are disposed of appropriately. Consequently, virtually no risk to humans or the environment is associated with such processes because the likelihood of exposure is so low. Therefore, the joint motion proposed that EPA would publish an Advance Notice of Proposed Rulemaking (ANPR) requesting comments on the possible exclusion of these PCBs from the provisions of section 6(e) of TSCA.

In addition to dealing with closed and controlled waste processes, the February 20 joint motion also proposed to publish an ANPR requesting information on all other manufacture, processing, distribution in commerce, and use of PCBs in low concentrations. PCBs generated in and released from other than closed or controlled waste processes are referred to as "uncontrolled PCBs."

On April 13, 1981, the court entered an order in *EDF* v. *EPA*, in response to the February 20 joint motion. The text of the court's order is set forth in the Federal Register of May 20, 1981 (46 FR 27615). The April 13 order stayed issuance of the court's mandate with respect to activities relating to PCBs in concentrations below 50 ppm. Thus, the 50 ppm regulatory cutoff remains in effect for the duration of the stay, and persons who manufacture, process, distribute in commerce, and use PCBs in concentrations less than 50 ppm may continue these activities during the stay. The order also adopted a plan for further actions by EPA and industry groups leading toward new EPA rulemaking on the regulation of PCBs in concentrations below 50 ppm. The April 13 order required EPA: (1) to publish two ANPRs on developing rules to cover PCBs in concentrations below 50 ppm; (2) to promulgate a final rule, within 18 months from the date of the order (i.e., October 13, 1982), with respect to exclusion of the generation of PCBs in closed and controlled waste manufacturing processes from the prohibitions of section 6(e)(3), or to explain the reasons for not proceeding with such a rule; and (3) to advise the court, within 11 months after the date of the order (i.e., March 13, 1982), of EPA's plan and schedule for further action on PCBs in concentrations below 50 ppm generated as uncontrolled PCBs.

In the Federal Register of May 20, 1981 (46 FR 27617 and 46 FR 27619), EPA issued two ANPRs on the 50 ppm regulatory cutoff. The ANPRs established bifurcated rulemaking proceedings with respect to PCBs in concentrations below 50 ppm. The first ANPR announced rulemaking on PCBs generated in closed and controlled waste manufacturing processes. The second ANPR announced the framework for the Agency's exploration of the scope of the problem presented by PCBs in concentrations below 50 ppm in other than closed or controlled waste processes.

On March 11, 1982, EPA submitted, in accordance with the April 13, 1981 court order, a report to the court that contained its plans for further regulatory

action on uncontrolled PCBs. EPA requested that the court allow EPA to report on its further plans for regulatory action on uncontrolled PCBs following the completion of the rulemaking on closed and controlled waste processes (but no later than November 1, 1982). EPA also requested that the court extend its stay of mandate until December 1, 1982, to allow EPA time to present its plans for regulatory action on uncontrolled PCBs to the court and for the court to respond. On April 9, 1982, the court granted EPA's requests.

In its report to the court on uncontrolled PCBs, due November 1, 1982, EPA intends to describe its plans for regulatory action on uncontrolled PCBs and at the same time, request a further extension of the court's stay of mandate, until the completion of rulemaking on uncontrolled PCBs.

After considering all comments submitted to the Agency in response to the first ANPR, EPA issued a proposed rule in the **Federal Register** of June 8, 1982 (47 FR 24976), which would exclude PCBs produced in closed and controlled waste manufacturing processes from the TSCA ban on the manufacture, processing, distribution in commerce, and use of PCBs. EPA received 48 comments on the proposed rule and, on July 26, 1982, held a public hearing in Washington, D.C. At the hearing, three participants provided testimony on various aspects of the proposed rule.

EPA has considered all the comments received on the proposed rule and has modified the proposed rule where appropriate. Further, EPA has prepared a support document for this rulemaking which addresses all major comments made on the proposed rule and includes EPA's responses to suggestions which were not incorporated in the final rule. This document, entitled "Response to Comments on the Closed and Controlled Waste Rule," is available by contacting the Industry Assistance Office (see **FOR FURTHER INFORMATION CONTACT**).

In order to avoid a "race to the courthouse" by persons seeking judicial review of this rule, EPA has decided to designate the time and date of "promulgation" of this rule as 1:00 p.m. Eastern Daylight Time on October 27, 1982. The Agency has previously taken this approach for rules promulgated under the Clean Water Act (see 40 CFR 100.01, 45 FR 26048). The Agency will be considering a general rule for TSCA similar to 40 CFR 100.01.

III. Summary of the Final Rule

The objective of this final rule is to exclude certain process situations from the prohibitions and requirements of section 6(e) of TSCA. This exclusion is voluntary; manufacturers are not required by this rule to take advantage of the exclusion.

This final rule modifies and clarifies some of the requirements presented in the proposed rule because of information obtained during the public comment period and at the public hearing on the proposed rule. Briefly, in the proposed rule: (1) EPA defined the absence of PCBs in releases from closed and controlled waste manufacturing processes by referencing an analytical technique, (2) EPA defined controlled wastes as wastes disposed of in facilities approved by EPA for the disposal of PCB wastes under 40 CFR 761.60, and (3) EPA required recordkeeping by persons taking advantage of the exclusion.

In the final rule: (1) EPA is setting numerical cutoffs for purposes of defining the absence of PCBs in releases from closed and controlled waste processes, (2) EPA is adding additional disposal mechanisms to the list of acceptable mechanisms for the disposal of controlled wastes containing PCBs in concentrations between the limit of quantitation and 50 ppm, and (3) EPA is instituting a new recordkeeping requirement and a reporting requirement in addition to the recordkeeping requirements listed in the proposed rule.

In this final rule, EPA is excluding from the requirements of section 6(e) the manufacture, processing, distribution in commerce, and use of PCBs created in closed manufacturing processes and controlled waste manufacturing processes. A closed manufacturing process is defined as a manufacturing process that produces PCBs, but releases PCBs only in concentrations below the practical limits of quantitation for PCBs in air emissions, water effluents, products, and process wastes.

Similarly, a controlled waste manufacturing process is a manufacturing process that produces PCBs, but releases PCBs only in concentrations below the practical limits of quantitation for PCBs in air emissions, water effluents, and products, and all remaining PCBs are disposed of in accordance with methods for disposal specified in this rule. Controlled wastes containing PCBs in concentrations between the practical limit of quantitation and 50 ppm, must be disposed of in a qualified incinerator (see discussion under IV.A.5.), or in an EPA-approved PCB landfill, or be stored for incineration or landfilling in accordance with § 761.65(b)(1). (Controlled wastes, containing PCBs in concentrations above 50 ppm, must be handled like all PCB waste above 50 ppm, in accordance with the existing PCB disposal and marking rule (43 FR 7150)).

For purposes of this rule, the practical limit of quantitation for PCBs in any release to air is ten micrograms per cubic meter (roughly 0.01 part per million (ppm)) per resolvable gas chromatographic peak; in any release to water, the limit is 100 micrograms per liter (roughly 0.1 ppm) per resolvable gas chromatographic peak; and in any product or waste, the limit is two micrograms per gram (2 ppm) per resolvable gas chromatographic peak. (See discussion of the practical limit of quantitation of PCBs under IV.A.3.c. for more details.) These PCB concentrations represent the lowest concentrations of PCBs which EPA believes can be practically quantified in air, water, products, and process waste streams. EPA believes that for all practical purposes, it would be impossible to determine whether regulation of PCBs below these levels had any effect on actually reducing releases of PCBs. Consequently, EPA has concluded that there would be no measurable gain in protecting the environment or public health by attempting to regulate PCB at levels that are not practically measurable.

In specifying the methods for the disposal of controlled wastes containing less than 50 ppm PCBs, EPA is confident that these wastes will be disposed of in a manner that will result in little or no environmental contamination. At the same time, EPA believes that this rule will not place unreasonable burdens on existing disposal facilities or create excessive disposal costs for manufacturers disposing of wastes containing PCBs in concentrations between the practical limit of quantitation and 50 ppm.

In addition to meeting the criteria for eligibility described above, manufacturers who want to take advantage of the exclusion must fulfill certain recordkeeping and reporting requirements. These include: (1) certifying that their processes qualify, (2) notifying EPA that they have made this certification and how they have made the determination, and (3) maintaining a record of the determination that their processes qualify for exclusion. Manufacturers are provided the option of conducting theoretical assessments to support certification or of conducting actual monitoring of PCB levels in releases. Recertification and renotification of EPA are required upon significant process changes.

In providing for theoretical assessments in lieu of actual monitoring

of PCB levels, EPA has concluded that such determinations may be possible in certain process situations; therefore, it would be unreasonable to require actual monitoring of PCB levels in all situations. Manufacturers have the burden of making the decision about when a theoretical assessment in lieu of actual monitoring of PCB levels is appropriate. Because of the difficulty of estimating actual PCB levels, EPA recommends that a theoretical assessment be used to qualify for the exclusion only when the results of the theoretical assessment indicate that PCB concentrations in releases will be substantially below the practical limits of quantitation.

EPA is issuing some general guidelines for conducting a theoretical assessment to aid manufacturers in completing this assessment. Nonetheless, EPA expects that each individual manufacturer will exercise judgment in choosing the methodology to be used in conducting a theoretical assessment, and in deciding when to undertake chemical analysis of process streams to determine if a process qualifies for exclusion.

EPA will not be performing theoretical assessments in enforcement inspections to determine whether a process qualifies for exclusion, but rather, will be conducting chemical analysis of process streams. In monitoring compliance with this rule, if EPA identifies a process that is supported by a complete theoretical assessment but is determined to be operating in violation of TSCA section 6(e) (through chemical analysis of process releases), then the process will be ineligible for exclusion, regardless of the results of the manufacturer's theoretical assessment.

EPA believes that recordkeeping and reporting are necessary to ensure that only processes which meet the definitions of closed and controlled waste processes are permitted to operate under this exclusion. A reporting requirement also enables EPA to develop an effective compliance monitoring program. Thus, EPA has determined that the benefits of instituting a reporting requirement far outweigh the costs to manufacturers of submitting this information to EPA.

TSCA explicitly provides only for case-by-case exceptions to the ban on the manufacture, processing, distribution in commerce, and use of PCBs. However, Federal courts have recognized the "de minimis" exception to legislative mandates. Although the court in *EDF* v. *EPA* overturned portions of the Agency's PCB regulations, it nevertheless noted that administrative agencies have the power "inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered de minimis." 636 F. 2d 1283. Courts and agencies should be reluctant to apply a statute literally in pointless expenditure of effort, where regulation would yield a gain of trivial or no value. EPA has evaluated closed and controlled waste manufacturing processes in this context and finds that circumstances surrounding these processes may fairly be considered de minimis situations.

A substantial number of industry comments have criticized EPA for failure, in this rule, to deal with the entire universe of PCBs generated in low concentrations. Some would have the Agency use this rule as a vehicle to create exclusions from the regulatory ambit of section 6(e) for all low concentration PCBs on the basis that they present de minimis risks to health or the environment. EPA emphasizes that this rule has a more limited purpose. It is intended only to exclude a specific class of chemical processes from further regulation. This rule does not establish a single PCB concentration below which all PCBs are excluded from regulation and above which all PCBs will always be regulated.

EPA is not prepared at this time to make any decisions on processes releasing PCBs in concentrations above the practical limits of quantitation. For those instances in which PCBs are generated and released in concentrations below 50 ppm, but are not excluded by this rule, EPA intends to request a further stay of the D.C. Circuit Court's mandate until an additional rule can be promulgated. Under the terms of such a stay, PCBs produced in processes not qualifying as closed or controlled waste processes under this regulation could continue to be generated in the interim period. In any case, until that further stay is granted, a manufacturing process not qualifying as a closed or controlled waste process under this regulation, but producing and/or releasing PCBs in concentrations below 50 ppm, may continue, at least for the period of the current stay of the Court's mandate. The current stay extends to December 1, 1982.

EPA intends to submit a plan for addressing other than closed and controlled waste processes to the court by November 1, 1982. In the next PCB rulemaking, EPA intends to determine whether other PCBs may present de minimis risks, whether some other forms of administrative exclusion might be appropriate, or whether any exclusion at all is appropriate.

Since the closed and controlled waste process exclusion is voluntary, manufacturers who believe they qualify for the exclusion set out in this final rule have the option of delaying their decision on whether to take advantage of the exclusion until the next PCB rulemaking is completed.

IV. Major Elements of the Final Rule

A. Definitions of Closed and Controlled Waste Manufacturing Processes

1. *Historical perspective.* During the course of discussions among EPA, EDF, and industry immediately after the court's decision, industry suggested that manufacturing processes that produce PCBs but do not release PCBs be excluded from the TSCA section 6(e) ban on the manufacture, processing, distribution in commerce, and use of PCBs. EPA and EDF agreed. From the literal definitions of these process types, it logically follows that if no PCBs are released from a process or if PCBs are released only to wastes that are destroyed or otherwise properly disposed of, then the exposure and risk to humans and the environment from these processes must be extremely small. There would be little or no benefit from regulating the processes under section 6(e) since there could be no reasonable means of determining whether any regulatory actions could actually reduce human or environmental exposure.

The practical application of this concept requires an understanding of the way chemical processes work. Chemical manufacturing processes are generally made up of a series of unit operations. Each unit operation causes chemical and/or physical changes in the material passing through the process. These changes are brought about by the chemical reactions or various types of physical manipulations that are never one hundred percent effective or complete.

In some processes which manufacture PCBs in low concentrations, virtually all the PCBs are destroyed in the process or are drawn off in a waste stream. However, there inevitably will be at least a few molecules of PCBs in every product or effluent that exits the process.

EPA recognized at the time of proposal the need to define, in a practical sense, the absence of PCBs in releases to the environment from these processes. Specifically, EPA recognized that it had to establish how the absence of PCBs is defined in air emissions, water effluents, products, and wastes from closed processes; and how the

absence of PCBs is defined in air emissions, water effluents, and products from controlled waste processes. Further, EPA recognized the need to specify appropriate methods for disposal of process wastes from controlled waste processes to insure that PCBs and the toxic decomposition products which can result from incomplete combustion would not be released to the environment from disposal operations.

2. *Defining the absence of PCBs in products, wastes, emissions and effluents.* In the June 8, 1982, proposed rule, EPA specified in analytical method and procedures to be used to determine the absence of PCBs. If PCBs were absent from all releases to air, water, and products (and wastes from closed processes), using EPA's method and procedures, the process would be eligible for exclusion. Under this approach, EPA gave some general guidance concerning the PCB concentrations it expected its procedures to be capable of quantifying (see 47 FR 24980).

EPA proposed this approach for several reasons. The Agency believed that the choice of analytical method was one of the major sources of variability when attempting to measure PCBs. During the fall of 1981, the Chemical Manufacturers Association (CMA) conducted a round robin experiment in which five different samples of material from processes which manufacture PCBs as a byproduct were analyzed by eight different laboratories using a total of ten different analytical methods. The round robin experiment shows considerable variability in the results obtained by the ten different methods. Specifying the analytical method would eliminate one of the sources of this variability.

EPA also believed that specifying a method was preferable to specifying a cutoff because the difficulty of analyzing products and wastes varies considerably among processes. EPA believed that with a numerical cutoff specified, some companies would be able easily to measure PCBs in their process streams below the cutoff, and other companies might have extreme difficulty measuring PCBs at the cutoff due to chemical matrix effects. In this regard, a numerical cutoff might put greater burdens on some manufacturers. EPA believed that specifying an analytical procedure would mitigate this problem.

The majority of comments submitted in response to the proposed rule criticized the proposed approach, and suggested alternate means for defining the absence of PCBs in releases from closed and controlled waste manufacturing processes. These comments maintain that the approach proposed by EPA provides no target for the analytical chemist because, with enough resources, a chemist would ultimately be able to measure any level of PCBs. These comments indicate that with improving analytical techniques, it would be virtually impossible to state that any substance is absent from a particular matrix. In the case of PCBs, they believe that by investing greater and greater resources in the extraction, cleanup, and analysis of given samples, lower and lower amounts of PCB congeners will become quantifiable, almost without limit. In light of this, the comments state that it is not possible for a chemist simply to stop analyzing his samples at a particular point and honestly certify that the PCBs are not quantifiable. A chemist can only certify that PCBs are not present above a specific preestablished concentration.

EPA agrees with these comments and has concluded that "nonquantifiable" PCBs could be defined differently by different parties, even if the analytical hardware to be used for the analysis is specified by regulation. Further, EPA also agrees with other comments that maintain that the limits of PCB quantitation will vary depending on the particular CGC/EIMS instrument used for analysis. These comments have pointed out that several instrument manufacturers currently market a variety of CGC/EIMS instruments, each of which has its own characteristics and inherent sensitivity.

Several comments have suggested that EPA specify the sample size, the extraction protocol, the cleanup procedures, and other details of the analytical method by regulation, to eliminate some of these sources of variability in measuring PCBs. Other comments have supported EPA's efforts to keep these parameters open and flexible, to accommodate various situations. Still other comments have suggested that it may be ultimately impossible to specify these parameters given the wide range of sample types which require analysis.

EPA agrees that given the wide variety of matrices in which PCBs are found, it is not practical or feasible to establish detailed procedures for the analysis of PCBs, especially in the areas of extraction and cleanup of samples for analysis. This is because different types of samples require different types and degrees of extraction and cleanup prior to anlaysis. EPA further agrees with testimony provided at the public hearing which suggested that the proposed approach was not practical and that a preferred approach would be for EPA to set a numerical cutoff, and thereby allow each individual laboratory to develop the appropriate procedures specific to the analysis of particular process samples.

Even if EPA could establish standards for the rigor of extraction and cleanup, an alternative suggested by some comments, many comments on the proposed rule have criticized EPA's proposed approach on separate grounds. Specifically, many persons have maintained that with advances in analytical procedures for the extraction and cleanup of samples, and technological improvements in the actual analytical hardware, in time, lower and lower levels of PCBs will be subject to regulation under section 6(e) of TSCA. Thus, specifying an analytical technique in the absence of a numerical cutoff would result in a moving regulatory target. These comments argue, then, that a numerical cutoff is not only preferable, but necessary to avoid the problems which would be encountered by adopting an approach that would result in a moving regulatory target.

In response to the comments received on the proposed rule, EPA has concluded that using an analytical method to define the absence of a chemical may result in substantially different limits of quantitation for different process samples, and therefore, substantially different levels of release. Depending upon the analyst, the analytical hardware, and the specific techniques used, especially in the areas of extraction and cleanup of samples prior to analysis, limits of quantitation could vary by several orders of magnitude. Further, EPA agrees with comments that suggest that nonquantifiable levels could vary over time, as new developments in cleanup and extraction protocols and improvements in analytical hardware occur. Therefore, EPA has decided to establish numerical cutoffs for purposes of defining the absence of PCBs in air emissions, water effluents, products, and process wastes from closed and controlled waste manufacturing processes.

Although EPA believes that with a numerical cutoff specified some companies will be able easily to measure PCBs in their process streams at the cutoff, others may have extreme difficulty quantifying PCBs at the cutoff due to chemical matrix effects. However, comments on the proposed rule acknowledged the advantages and disadvantages of the available alternatives and expressed clear preference for the approach set out in

this final rule. Thus, EPA has concluded that there are substantial merits in setting numerical cutoffs. First, numerical cutoffs are fixed and will not move in time independent of EPA intervention. Second, numerical cutoffs are not open to widely differing interpretations. Finally, numerical cutoffs provide targets for the analytical chemist. In addition to specifying numerical cutoffs, EPA is also recommending an analytical technique and methods for the analysis of air samples, water samples, and product and process waste samples for byproduct PCBs (see discussion under IV.A.3.b.).

3. *Establishing the numerical cutoffs*—a. *Limit of Detection (LOD) v. Limit of Quantitation (LOQ).* The analytical system most often used to monitor PCB's includes a gas chromatograph with a suitable detector. The detector response is converted to an electrical signal which is recorded on a strip chart, and the quantity of material present can be determined by measuring the intensity of the respose. When only the matrix is passing the detector, the detector generates an electrical signal, referred to as "background" or "noise." Detecting and confirming the presence the PCBs depends on the analyst's ability to measure an increase in the recorded electrical signal above this noise.

The lowest concentration of a substance than an analytical process can detect is referred to as the limit of detection (LOD). A commonly used standard is that an LOD should be based on a ratio of at least three between the average magnitude of the electrical signal from the sample and the standard deviation of the electrical signal from the background. This ratio is called the signal-to-noise ratio.

The lowest concentration of a substance that an analytical process can reproducibly quantify with a known level of precision is referred to as the limit of quantification (LOQ). A commonly used standard is that an LOQ should be based on a signal-to-noise ratio of at least ten.

One comment expressed preference for the use of "nondetectable" PCBs versus "nonquantifiable" PCBs as the definition of the absence PCBs for purposes of defining closed and controlled waste manufacturing process. The comment suggested that EPA require that releases be tested at the limit of detection (LOD) for the presence of PCBs, primarily because the statutory ban speaks in terms of "any" PCBs. EPA has concluded, as explained in IV.B. below, that PCBs present in concentrations below the LOQ present a de minimis risk to public health and the environment. Furthermore, it is not practical to test releases of PCBs at the LOT because it may be impossible to confirm the identity of the PCBs at that level. This is particularly important in the analysis of PCBs present as byproducts and impurities because in many instances chemically similar compounds are also present in the sample undergoing analysis. For compliance monitoring purposes, a PCB concentration at or near the LOQ is needed to confirm the identity of the chlorinated biphenyl. For this reason, EPA has selected LOQ instead of LOD for purposes of defining the absence of PCBs in releases from closed and controlled waste manufacturing processes.

b. *Selecting the analytical technique.* LOQs, in general, vary with: (1) the analytical technique, (2) the analytical method, and (3) the type of chemical matrix in which the PCBs are found. For purposes of this rule, an analytical technique is defined as the type of analysis. Thin-layer chromatography, gas chromatography coupled to mass spectrometry, and high performance liquid chromatography are all examples of analytical techniques. In order to determine what the practical LOQ is for PCBs, EPA first evaluated several different types of analytical techniques (with varying degrees of sophistication), and considered the complexities of the chemical matrices in which the PCBs are found, the availability and cost of analytical hardware, and the cost of conducting analyses. As a general rule, more sophisticated analytical techniques are more costly and less readily available, but are capable of measuring PCBs at lower concentrations (i.e., these techniques have very low LOQs) than less sophisticated techniques. (See "Methods of Analysis for Incidentally Generated PCBs Literature Review and Preliminary Recommendations" for a further discussion of available analytical techniques for PCB analysis.)

In selecting the most appropriate analytical technique, EPA first identified analytical techniques that were specific for PCB byproduct analysis. EPA then considered the sensitivity of the identified techniques, the availability of the instrumentation, and the cost of obtaining the instruments and conducting the analyses.

In the proposed rule, EPA selected capillary gas chromatography (CGC) coupled to electron impact mass spectrometry (EIMS) as the analytical technique to be used in determining whether PCBs were quantifiable in releases from a manufacturing process. For purposes of this rule, EPA selected CGC/EIMS because: (1) it is cost effective for the analysis of air, water, products, and process waste samples, (2) it is reproducible, and (3) it provides confirmatory evidence for PCBs. EPA expected this technique to supply reliable data of known quality if users implemented an appropriate and documented quality assurance plan. The vast majority of comments on the proposed rule that addressed this point agreed with EPA that CGC/EIMS is the preferred technique for the analysis of PCB byproducts.

During the public comment period for the proposed rule, and during the development of the final rule, EPA sponsored preliminary analytical method validation studies to test the efficacy of CGC/EIMS for the analysis of PCBs. The method validation exercise was undertaken to check the validity of the proposed protocol for the analysis of PCBs in commercial products and process waste streams in particular. Data are presented in the analytical method validation study from the evaluation of the efficiency of cleanup and extraction protocols as well as from the actual (CGC/EIMS) analyses of process samples (See MRI reports: "Analytical Methods for Incidentally Generated PCBs—Preliminary Validation and Interim Methods"). The data generated from the analysis of PCBs in the matrices studied indicate that the method is applicable and useful for the analysis of PCBs. Although additional validation work is continuing and additional data will be gathered, this technique is the most reasonable analytical procedure currently available for the analysis of PCBs generated as byproducts and is thus appropriate for use in implementing this regulation. Testimony provided at the public hearing on the proposed rule supported the method validation trials conducted by the Midwest Research Institute (MRI) as technically competent.

Since the majority of comments that addressed this point supported the proposed selection of CGC/EIMS as the preferred technique, EPA has selected CGC/EIMS as the analytical technique from which it would estimate the practical LOQs of PCBs in air emissions, water effluents, products, and process waste streams for purposes of defining closed and controlled waste manufacturing processes in this final rule.

c. *Establishing the practical LOQs of PCBs.* For purposes of this rule, an analytical method is defined as a series of procedures used when chemically analyzing a sample. Analytical methods

include procedures for sample collection, protocols for the extraction and cleanup of samples, and procedures for the analysis of the specimen by the analytical technique. The limit of quantitation of a particular analytical method is a function of six major factors: (1) the inherent sensitivity of the analytical instrument, (2) the size of the sample taken for analysis, (3) the volume extracted, (4) the volume injected into the instrument, (5) the amount of interferences, and (6) the degree of the chemical matrix effects.

The LOQ of an analytical method depends upon the values selected for the factors listed above. For each variable, values could be selected that would ultimately minimize (or maximize) the overall LOQ of an analytical method. However, there is a limit to the degree to which the LOQ can be minimized without significantly increasing the cost and difficulty of analysis. To select reasonable values to assign to each of these variables (for purposes of calculating the practical LOQ of PCBs), EPA balanced the benefits of increased sensitivity versus the resultant increased costs and practical considerations associated with minimizing the LOQ.

The class of PCBs is made up of 209 individual chemical compounds, individually referred to as chlorinated biphenyl congeners. Using CGC, each separate resolvable peak on a gas chromatograph may represent a single chlorinated biphenyl congener, or it may represent more than one chlorinated biphenyl congener. Comments on the proposed rule have pointed out that all 209 PCB congeners cannot, for all practical purposes, be individually resolved by CGC/EIMS, or by any other single analytical instrument currently in existence. Thus, although it may be most desirable to define the absence of PCBs on a per congener basis, this is not possible because this separation cannot be accomplished for every sample. To accommodate this situation, EPA is defining the absence of PCBs by setting numerical cutoffs according to PCB levels represented by resolvable gas chromatographic peaks. To qualify for exclusion, no single peak on a gas chromatogram can register PCBs at or in excess of the numerical cutoffs set by EPA for PCBs in air, water, or products (or wastes from closed processes).

1. *Instrument sensitivity.* Depending upon the particular CGC/EIMS instrument used to analyze for PCBs, the instrument's sensitivity (or limit of quantitation) may be one picogram per resolvable gas chromatographic peak, one microgram per resolvable peak, or an intermediate level. Although this wide range of sensitivities exists for CGC/EIMS equipment, highly sensitive equipment is very costly and not generally available in most analytical laboratories. To calculate the practical LOQ of PCBs, EPA selected a value for the sensitivity of CGC/EIMS that is representative of the average minimum sensitivity of this type of analytical technique. This required a balancing of sensitivity versus costs and availability.

EPA selected ten nanograms (ng) per resolvable gas chromatographic peak as a reasonable estimate of the average sensitivity of CGC/EIMS. This number represents the smallest amount of a substance that a typical EIMS system can measure and is EPA's estimate of the average minimum amount of PCBs expected to be measured.

The determination that ten ng per resolvable gas chromatographic peak represents the average minimum amount expected to be measured was based upon contacts with a manufacturer of GC/MS equipment about the sensitivities and costs of available CGC/EIMS instruments; more costly instruments are capable of measuring PCBs at lower levels. Available data indicate that the cost of CGC/EIMS equipment ranges from $87,000 for the least sensitive equipment, through $380,000 for the most sensitive equipment (see records of telephone communications between Redford and Moll of EPA and Finnigan MAT). EPA selected this level of sensitivity as representative of an average sensitivity of CGC/EIMS because it is intermediate in sensitivity, and CGC/EIMS instruments capable of measuring this level are readily available, are of moderate cost, and are expected to be currently available in most analytical laboratories.

This estimate of the average system sensitivity is also supported by research results reported by Dr. E. Pellizari of Research Triangle Institute in his 1981 report entitled: "State-of-the-Art Instrumental Analysis in Environmental Chemistry," which appeared in Chapter 10 of "Environmental Health Chemistry." Dr. Pellizari reports a minimum detection range for EIMS from one nanogram through .1 milligram. EPA's estimate of ten ng/peak as an average sensitivity falls within the range of Dr. Pellizari's reported detection limits for any peak on an EIMS (since limits of quantitation are often at least three times as high as limits of detection).

Further, the Dry Color Manufacturers Association's (DCMA's) research on the analysis of PCBs in organic pigments reports the sensitivity of CGC/EIMS as ten ng per resolvable gas chromatographic peak (see page 5 of "An Analytical Procedure for the Determination of Polychlorinated Biphenyls in Dry Phthalocyanine Blue, Phthalocyanine Green and Diarylide Yellow Pigments; Proposed by the Dry Color Manufacturers Association").

2. *Sample size.* The actual minimum quantitatable level for an analytical method depends on not only the inherent sensitivity of the analytical instrument, but also the amount of original sample that had its PCB contents extracted and condensed for analysis by CGC/EIMS. For instance, a sample that is ten times larger than another from the same source would contain the same concentration (ug/volume) of PCBs but would actually contain ten times the mass of PCBs (nanograms). When both are concentrated to one milliliter, the extract resulting from the larger sample would be ten times more concentrated than the other, and when injected into the detector, it would yield a response ten times greater. This would translate to a quantitation limit in the larger sample that was ten times lower than in the smaller sample.

However, there is a limit to the extent to which one can maximize the sample size (in an attempt to minimize the LOQ) without encountering substantial additional costs in collection and extraction, and experiencing handling difficulties. Larger sample sizes require longer collection times (especially pertinent in air sampling), more effort (resources) in extraction and cleanup, and in some cases, may require specialized equipment.

With this relationship in mind, EPA has estimated reasonable sample sizes, ones that would provide enough material for a reasonable determination as to whether PCBs are present without presenting sampling and handling problems. These estimated sample sizes are: Ten cubic meters for air, one liter for water, and fifty grams for products or process waste streams. Then cubic meters of air, and one liter of water are commonly accepted sample sizes for these media, considering the type of chemical undergoing analysis (i.e. halogenated aromatics).

In selecting 50 grams as a reasonable sample size for products and process wastes, EPA analyzed available data and developed a list of expected products containing PCBs as impurities or byproducts. For each product on the list, EPA considered various sample sizes, ranging from one gram to 100 grams, and selected the most

appropriate sample size for each individual product. EPA considered the capacity of typical laboratory equipment, the physical and chemical properties of the product/sample, handling problems, measurement problems, the inherent cost of the material to be analyzed, and other related factors in determining the most appropriate sample sizes for each individual product. After considering appropriate sample sizes for individual products, EPA selected 50 grams as representative of a reasonable sample size for products and process wastes (see "Rationale for Levels of Quantitation for CGC/EIMS," "Rationale for Choosing a Reasonable Sample Size and Matrix Interference Allowance for the PCB Analytical Method," "PCB Quantitation List Parameters," and "Transmittal of MRI's PCB Quantitation List Parameters Memorandum with Additional Comments").

3. *Extract and injection volumes.* For air, water, products, and process waste samples, typical extract and injection volumes would be one milliliter and one microliter, respectively. The Midwest Research Institute (MRI), in conducting CGC/EIMS method validation trials (see "Analytical Methods for Incidentally Generated PCBs—Preliminary Validation and Interim Methods"), considered several extraction volumes and injection volumes. The volumes selected as reasonable by EPA were determined to be most appropriate during these trials. Larger injection volumes either might damage the mass spectrometer or the chromatographic column. Smaller injection volumes, below one microliter, would increase the likelihood of measurement errors, decreasing the accuracy of any measured PCB level. Increases in the extract volume or greater concentration of the extract either lowers recovery efficiency, overly concentrates the injection, or requires excessive efforts to extract and condense the extract. With extraction volumes below one milliliter, the potential for measurement errors and losses from evaporation increases, decreasing the accuracy of the PCB levels measured (see "PCB Quantitation List Parameters," and "Transmittal of MRI's PCB Quantitation List Parameters Memorandum with Additional Comments").

4. *Interferences and matrix effects.* In the absence of interferences and matrix effects, the estimated lower limits of quantitation of PCBs in air, water, products, and process wastes, using CGC/EIMS, reasonable sample sizes, and reasonable extract and injection volumes, would be one microgram per cubic meter (roughly 0.001 ppm) in air, ten micrograms per liter (roughly 0.01 ppm) in water, and .2 microgram per gram (0.2 ppm) in products and process waste streams, per resolvable gas chromatographic peak. These lower limits of quantitation assume an instrument sensitivity of ten ng per resolvable gas chromatographic peak, reasonable sample sizes, and reasonable extract and injection volumes.

However, interferences and matrix effects are commonly experienced in the analysis of PCB byproducts because of the similarity in chemical structure between the PCBs produced in the process and the matrix of chemical substances in which the PCBs are found. In byproduct PCB analysis, these factors influence an analytical instrument's ability to measure accurately low level PCBs. Therefore, an allowance for these considerations must be made in calculating the practical LOQ for PCBs in air, water, products and process waste streams.

To accommodate this situation, EPA assumed an upper quantitation limit of 100 ng per resolvable peak as a reasonable allowance for interferences and matrix effects. This allowance is supported by experimental data produced by MRI through method validation trials (see "Analytical Methods for Incidentally Generated PCBs—Preliminary Validation and Interim Methods," "PCB Quantitation List Parameters," "Rationale for Choosing a Reasonable Sample Size and Matrix Interference Allowance for the PCB Analytical Method," and "Transmittal of MRI's PCB Quantitation List Parameters, Memorandum with Additional Comments"). MRI found that in the analysis of some samples, interferences and matrix effects were negligible, thus, the LOQ approximated the lower quantitation limit of the analytical instrument. However, in the analysis of other samples, interferences and matrix effects were significant, and resulted in a LOQ that was two orders of magnitude higher than the lower quantitation limit of the analytical instrument. EPA's estimate of a reasonable allowance for interferences and matrix effects is one order of magnitude higher than the average lower quantitation limit of CGC/EIMS as estimated by EPA.

5. *Conclusion.* Per peak then, the practical LOQ of PCBs in air corresponds to ten micrograms per cubic meter (roughly 0.01 ppm); in water, 100 micrograms per liter (roughly 0.1 ppm); and, in products and process waste streams, two micrograms per gram (2 ppm). This means that for a process to be eligible for exclusion under the closed and controlled waste process exclusion, no single peak on a gas chromatogram registers PCBs in excess of: ten micrograms per cubic meter in air emissions, 100 micrograms per liter in water effluents, and two micrograms per gram in products and uncontrolled waste streams, regardless of the number of PCB congeners known to be or expected to be represented by the peak. (See Unit IV.B. for a discussion of the extremely low exposure which will result from setting cutoffs at these levels.)

EPA considered setting numerical cutoffs based on total PCBs, instead of setting numerical cutoffs according to levels represented by resolvable gas chromatographic peaks. Under that approach, EPA would attempt to estimate an average number of gas chromatographic peaks that would be resolved upon analysis of process samples, and then multiply that average number by the practical limits of quantitation per resolvable peak. This approach would result in separate numerical cutoffs for total PCB levels in air emissions, water effluents, products, and wastes from closed processes.

After evaluating this approach, EPA concluded that there is insufficient information upon which to base an estimate of the average number of PCB congeners created in manufacturing processes. Although some information on PCB concentrations in products and processes is available, little comprehensive factual data are available on the type and number of different congeners created in these processes. Without this type of information, EPA could not support any estimate of the average number of congeners created in manufacturing processes.

d. *Aroclor v. non-Aroclor PCB analysis.* The limits of quantitation of PCBs in air, water, products, and wastes, discussed in the preceding unit, are EPA's estimates of the practical limits of quantitation of PCBs produced as byproducts and impurities (non-Aroclor PCBs). These PCBs are not easily measured in air emissions, water effluents, products, or process waste streams, because up to 209 different chemical compounds can be produced and be present in different concentrations in a sample undergoing analysis. Before these PCBs can be measured in a sample, they must first be identified as PCBs.

In contrast, PCBs produced for use as dielectric fluids (Aroclors) are much

more easily measured. These PCBs display characteristic patterns upon analysis that are easily recognizable as representing PCBs. Unlike these PCBs, PCBs produced as byproducts and impurities do not display characteristic or easily recognizable patterns upon analysis. (See "Methods of Analysis for Incidentally Generated PCBs Literature Review and Preliminary Recommendations" for a comparison of the methods for Aroclor vs. non-Aroclor PCB analysis.)

Because of this fact, and the need to identify byproduct PCBs as truly PCBs, the limits of quantitation of byproduct PCBs in different media may be several orders of magnitude higher than the limits of quantitation of Aroclor PCBs in these same media. Thus, other environmental regulations pertaining to the release of Aroclor PCBs (such as under the Clean Water Act, 33 U.S.C. 466 *et seq.*) may place limits on the release of PCBs that are orders of magnitude below the practical limit of quantitation for byproduct PCBs as established in this final rule.

4. *Determining what constitutes a process.* In the proposed rule, EPA applied the exclusion to any person who produces PCBs in a chemical manufacturing "process" which qualifies as a closed manufacturing process or a controlled waste manufacturing process. Comments received in response to the proposed rule requested clarification of the term "process" in the definitions of closed and controlled waste manufacturing processes. The comment said that the term "process" could be open to differing interpretations; it could, at one extreme, mean a single unit of a multi-unit operation operating at a site, or, at the other extreme, it could mean the entire series of operations (possibly operating at different geographic localities) leading to the production of a final commercial product.

EPA defines the term "process" in this final rule to mean all the unit operations operating at a site. Therefore, PCB-containing isolated intermediates manufactured at one location on a plant site can be processed further at some different on-site location. Analytical or theoretical analyses of PCB levels in the product would take place only prior to its removal from the site. Similarly, PCB concentrations in water effluents and process wastes would be analytically determined or theoretically estimated only prior to the release from a site.

Because it is difficult to define the boundaries of the atmosphere surrounding a facility, for air emissions, PCB concentrations would be determined at the most convenient sampling point prior to release to the atmosphere.

For water effluents, PCB levels would be determined prior to release from the site. For example, if deep well injection is used to dispose of water effluents from a process, PCB levels would need to be determined at some point prior to injection. The objective is to allow companies to determine PCB levels in the water effluent as close to the final point of release to the environment as possible. If on-site water treatment occurs, PCB levels would need to be analytically or theoretically determined only prior to release to the receiving body of water (i.e., at the point of outflow from the on-site water treatment facility).

EPA uses the term site to mean a contiguous property unit. Property divided only by a public right-of-way is considered one site. There may be more than one manufacturing plant on a single site (See 40 CFR 710.1(a)).

5. *Determining appropriate methods for disposal.* EPA already has in effect a Disposal and Marking Rule (40 CFR 761.60) which requires PCBs in concentrations over 50 ppm to be stored and disposed of in accordance with the criteria prescribed under §§ 716.65, 761.70, and 761.75. These are the same disposal criteria that EPA proposed for the disposal of wastes (containing any concentration of PCBs) from controlled waste processes in the proposed rule.

EPA proposed these mechanisms for disposal of controlled wastes on the premise that EPA must be reasonably confident that the wastes from controlled waste processes are disposed of in a manner which results in negligible environmental contamination. Although this basic premise remains valid, EPA has concluded that certain less costly, alternate disposal mechanisms would result in negligible environmental contamination as well.

Several comments criticized the proposed requirement that wastes from controlled waste manufacturing processes be incinerated in EPA-approved PCB incinerators. They maintain that in selecting this regulatory option, EPA did not consider the enormous potential costs of disposing of wastes containing PCBs in concentrations between the LOQ and 50 ppm in EPA-approved PCB incinerators. Data were provided by the CMA which indicate that the costs of destroying liquid wastes containing PCBs in EPA-approved PCB incinerators is $0.23 per pound of waste. Thus, as the concentration of PCBs in the wastes decreases, the cost of disposal per pound of PCB increases substantially. At PCB concentrations near the practical limit of quantitation in wastes, the cost of disposal in EPA-approved PCB incinerators per pound of PCB could be very high.

Further, comments indicate that unlike mineral oil contaminated with low level PCBs, chemical manufacturing process waste streams with similarly low levels of PCBs cannot, in general, be used as fuel in high efficiency, energy generating boilers because of their high chlorine content. Finally, certain comments indicate that since there are so few EPA-approved PCB incinerators in existence, priority should be given to the destruction of higher concentration wastes in these facilities. Restricting the incineration of controlled wastes containing less than 50 ppm PCBs to EPA-approved PCB incinerators would place demands on these facilities, which could result in a shortage of PCB disposal capacity.

One comment, however, strongly supported EPA's proposal to require the incineration of controlled wastes in EPA-approved PCB incinerators. Specifically, the comment stated that incinerators used for the destruction of PCBs should be required to meet certain standards to prevent the formation and release of dibenzofurans and other potentially toxic products of incomplete combustion.

As a result of the comments received in response to the proposed rule, EPA has decided to modify the requirement that wastes from controlled waste manufacturing processes be disposed of in EPA-approved PCB incinerators. Certain less costly disposal mechanisms should result in negligible environmental contamination as well, and further, should preclude the formation of toxic incomplete combustion products.

Thus, in this final rule, EPA is allowing PCB wastes (containing PCBs in concentrations below 50 ppm) to be destroyed in incinerators which have been approved under section 3005(c) of the Resource Conservation and Recovery Act (RCRA) 42 U.S.C. 6925(c). The incinerator must be capable of destroying compounds which are less readily burned than the PCB homologs in the waste. The manufacturer of PCBs who wishes to qualify for exclusion under the controlled waste exclusion by disposing of PCB wastes in a RCRA-approved incinerator is responsible for determining that the incinerator is capable of destroying the PCBs, and for certifying that this is the case (see IV.D.). The manufacturer is also responsible for obtaining reasonable assurances that the incinerator, when burning PCB waste, will be operated under conditions that have been shown

to enable the incinerator to destroy less readily burned compounds. Manufacturers may use heat of combustion or other indicators of ease of incinerability addressed in the "RCRA Guidance for Hazardous Waste Incineration," to support this certification. This approach should ultimately increase the number of incinerators qualified for the destruction of PCBs and should also prevent the formation of toxic products of incomplete combustion during incineration.

One of the factors used to determine how efficiently a substance may be destroyed is the heat of combustion. Heat of combustion is the heat evolved when a definite quantity of a substance is completely burned. According to classical thermodynamics, compounds with lower heats of combustion should be less readily burned and should require higher temperatures for destruction than compounds with higher heats of combustion. Heat of combustion values are measured under controlled laboratory conditions or derived from theoretical calculations.

Under RCRA, EPA has developed a ranking of hazardous constituents based on heat of combustion values. This hierarchy allows the applicant for a permit to incinerate hazardous wastes to demonstrate the required level of performance for a large number of constituents of a waste stream by successfully burning one or several of those which are most difficult to destroy. In the permitting of facilities, EPA does not intend to use the incinerability ranking alone, but rather, to use it in conjunction with the permit writer's engineering judgment. The list provides the permit writer and the applicant for the permit with a useful means of identifying the constituents of a waste which are likely to be most difficult to destroy, and may be used in conjunction with other information relating to the incinerability of an organic constituent, when available (see "RCRA Guidance for Hazardous Waste Incineration").

The "RCRA Guidance for Hazardous Waste Incineration" contains this list of compounds, including the PCB homologs, ranked according to heats of combustion. While EPA has little experimental data that indicate that heat of combustion is the best criteria (or the only criteria) to be used in judging the relative ease of destruction of chemical compounds, it can be used as an indicator (see "A Method for Designation of the Principal Organic Hazardous Constituents for Hazardous Waste Incineration," "Heats of Formation and Combustion from the Method of Handrick," "Comparison of Ranking Factors," and "RCRA Guidance for Hazardous Waste Incineration"). Thus, manufacturers may use heat of combustion values to support their determination that a particular RCRA-approved facility is capable of destroying their PCB wastes.

Although RCRA requires a minimum destruction and removal efficiency of 99.99 percent for the incineration of chemical wastes, and the TSCA requirements will result in a minimum destruction efficiency of 99.9999 percent (for the incineration of PCBs in concentrations over 50 ppm) EPA believes that for PCBs in concentrations below 50 ppm, a destruction and removal efficiency of 99.99 percent is adequate to insure only negligible environmental release. If one assumes that all the PCBs created in closed and controlled waste manufacturing processes (approximately 56,000 pound) will be incinerated annually in these RCRA-approved incinerators, then the difference in destruction efficiencies between the proposed requirement and the final rule will result in a maximum of an additional 5.54 pounds of PCBs released annually throughout the entire United States as a result of the modification to the proposed requirement.

In addition to allowing the destruction of controlled wastes in certain RCRA-approved incinerators, EPA is also adding to the list of acceptable disposal mechanisms, the destruction of controlled wastes (containing PCBs in concentrations between the limit of quantitation and 500 ppm) in any high efficiency boiler that has been specifically approved to burn PCBs present in fluid other than mineral oil, in accordance with the requirements of § 761.60(a)(3). This will create an additional mechanism for the disposal of controlled wastes, while providing continued protection against the formation of toxic incomplete combustion products during incineration. Wastes containing PCBs in concentrations between the practical limit of quantitation and 50 ppm may also be destroyed in EPA-approved PCB incinerators as well, and would qualify as controlled wastes. This rule does not change the requirements of the PCB Marking and Disposal Rule (40 CFR 761.60) for the disposal of PCBs in concentrations over 50 ppm.

Thus, these modifications will: (1) Increase the number of incinerators ultimately available for the destruction of PCB wastes; (2) reduce the potential for accidents during the transport of wastes; (3) ultimately provide for less costly disposal alternatives to manufacturers disposing of controlled wastes; and (4) should continue to provide protection against the formation of toxic incomplete combustion products during incineration.

B. The De Minimis Determination

1. *Exposure Analysis.* EPA's rough estimate of the amount of PCBs produced in closed and controlled waste manufacturing processes is less 56,000 pounds per year. Of these roughly 56,000 pounds of PCBs, extremely small quantities of PCBs in concentrations below the practical limits of quantitation will be released to the environment in wastes from closed processes and in air emissions, water effluents, and products. Actual environmental releases from products are expected to be in concentrations even less than the limits of quantitation, since the PCBs in many products are bound in solid matrices (e.g., paints and polymers). Although wastes from controlled waste processes will contain higher concentrations of PCBs, the requirements for handling these wastes will prevent significant releases to the environment.

Based on available information (supplied by CMA), EPA estimates that less than one thousand pounds of byproduct PCBs are likely to actually enter the environment each year from closed and controlled waste manufacturing processes. The estimated actual releases to the environment from closed and controlled waste processes is only 0.0006 percent of the estimated 150,000,000 pounds of PCBs that currently exist in the environment as free PCBs. Further, this amount is only 0.0001 percent of the estimated 750,000,000 pounds of PCBs currently in use in electrical equipment in the United States.

EPA is imposing both recordkeeping and reporting requirements (see IV.D.) to reduce the likelihood of processes being mislabeled as closed or controlled waste manufacturing processes when releases are actually above the practical limits of quantitation. These requirements help to ensure that PCBs released to the environment as a result of this exclusion remain below the practical limits of quantitation.

2. *De Minimis Finding.* TSCA section 6(e) specifically bans the manufacture, processing, distribution in commerce, and use of PCBs in other than a totally enclosed manner. To be eligible for exclusion from the provisions of section 6(e), processes must meet EPA's definitions of closed or controlled waste manufacturing processes. This means

that releases of PCBs in products, air emissions, and water effluents are below practical limits of quantitation. For closed manufacturing processes, releases of PCBs in wastes are also below the practical limit of quantitation. Wastes from controlled waste processes are disposed of in qualified incinerators (see discussion under IV.A.5.) or in landfills approved under § 761.75 or are stored for incineration or landfilling in compliance with the standards and requirements prescribed in § 761.65(b)(1). Recordkeeping and reporting by manufacturers helps to ensure that releases of PCBs from these processes are actually below the practical limits of quantitation, and that exposure to PCBs as a result of EPA creating this exclusion remains negligible.

EPA believes that for all practical purposes, it would be impossible to determine whether regulation of PCB concentrations below the practical limits of quantitation had any effect on actually reducing releases of PCBs. EPA believes that PCBs present in concentrations below the practical limits of quantitation are of such low concentration, and the total amount of PCBs released would be so low, that it would be impossible to determine if regulation of these levels provided anything greater than trivial benefits. Consequently, EPA has concluded that there would be no measurable gain in protecting the environment or public health by attempting to regulate PCBs at levels that are unmeasurable for all practical purposes.

EPA finds that closed and controlled waste manufacturing processes represent de minimis situations and should not be subject to the prohibitions and other provisions of section 6(e) of TSCA because: (1) releases of PCBs from closed and controlled waste processes (excluding controlled wastes) are below the practical limits of quantitation, (2) the estimated amount of PCBs released from these processes per year is only 0.0006 percent of the estimated 150,000,000 pounds of PCBs present in the environment as free PCBs, (3) controlled wastes are disposed of in a manner that should result in negligible environmental contamination, and (4) manufacturers operating these processes are required to keep records and notify EPA of processes that qualify for exclusion.

C. Determination of No Unreasonable Risk

EPA has concluded that there would be no measurable benefits to public health or the environment by regulating closed and controlled waste processes (as defined in this rule) under section 6(e) of TSCA. Therefore, as previously noted, these processes are eligible for exclusion under the de minimis principle. Nonetheless, the Agency has also considered whether closed and controlled waste processes present an unreasonable risk to human health or the environment. To determine whether a risk is unreasonable, EPA balances the probability that harm will occur from the activity against the adverse effect on society from regulation. In making a determination of whether an unreasonable risk is present from these processes, EPA considered the following factors:

1. The effects of PCBs on human health and the environment.

2. The magnitude of PCB exposure to humans and the environment.

3. The benefits from products containing PCBs, the availability of substitutes, and the ability to prevent the formation of PCBs.

4. The economic impact resulting from the rule upon the national economy, small business, technological innovation, the environment, and public health.

After considering all available information, within the context of the factors listed above, EPA finds that excluding closed and controlled waste processes presents no unreasonable risk to human health or the environment. This finding is based on the following analysis.

1. *Health and environmental effects and exposure to PCBs.* Toxicity and exposure are the two basic components of risk. During this rulemaking, EPA has conducted an analysis of the health and environmental effects of PCBs (see "Response to Comments on Health Effects of PCBs" for details). EPA has concluded that in addition to chloracne, there is a potential for reproductive effects and developmental toxicity as well as oncogenic effects in humans, based on animal data. EPA has also concluded that PCBs do present a hazard to the environment.

However, PCBs are not uniquely toxic, and minimizing exposure to PCBs will minimize any potential risk. EPA evaluated the potential for exposure to PCBs from closed and controlled waste manufacturing processes, and has determined that the exposure to PCBs from closed and controlled waste processes is so low as to be unmeasurable for all practical purposes.

In calculating the practical limits of quantitation of PCBs, EPA considered setting lower levels. While lower numerical cutoffs would theoretically further reduce the risks posed from closed and controlled waste manufacturing processes, it would not be practically possible to measure this reduction in risk afforded by the lower levels of release (see IV.A.3.c.). Thus, regulating PCBs at levels below the practical limits of quantitation provides no measurable benefits to public health or the environment.

As part of the de minimis determination, EPA also considered the public health and environmental benefits of recordkeeping and reporting and their effect on reducing the risks posed from closed and controlled waste manufacturing processes. EPA concluded that recordkeeping and reporting by manufacturers operating closed and controlled waste processes would substantially reduce the likelihood that processes would be mislabeled and, therefore, would result in a reduction in the actual amount of PCBs released to the environment as a result of this exclusion (see IV.D.). Thus, recordkeeping and reporting would help to ensure that only de minimis situations are allowed to operate as a result of this exclusion.

2. *Benefits of products generated in closed and controlled waste processes, the availability of substitutes, and economic impacts.* If the ban on all manufacturing, processing, distribution in commerce, and use of PCBs was made effective for all closed and controlled waste processes, there could be a major disruption of the chemical industry and several other industries in the United States. Since there could be a large number of controlled waste processes, an immediate ban could cost billions of dollars. An immediate ban could disrupt the manufacture of a wide variety of products including paints, varnishes, enamels, agricultural chemicals, adhesives and sealants, printing ink, plastic materials, drugs, and soaps and cosmetics. Such products have great societal value, and a ban of this nature would create great hardship for the public and industry due to the unavailability of these products and would have a severe economic impact. Should such processes be subject to the section 6(e) ban, all manufacturers utilizing closed and controlled waste manufacturing processes which generate PCBs as byproducts would be required to conform with the prohibitions and requirements of section 6(e). Industry has commented that, in general, substitutes are not available for products contaminated with low level PCBs at the same or equivalent costs as PCB-contaminated products, and that processes cannot be modified to prevent the formation of any PCBs. CMA has

commented that research programs to study ways to reduce incidental PCB formation are very costly and have met with limited success. CMA provided an example of a process adjusted to reduce formation of PCBs to below 50 ppm, and estimated that the cost of this project was on the order of $800,000.

Although TSCA does provide a mechanism for obtaining relief from the total ban of PCBs, industry has commented that the statutory process for obtaining an exemption is unworkable for the many operations that manufacture, process, or distribute in commerce PCBs in low concentrations. Since TSCA requires a company to obtain an annual exemption, industry representatives indicated that the uncertainty associated with knowing whether they would be able to continue operations and the large cost of submitting petitions each year would be a burden. A quick survey of companies which filed PCB exemption petitions with EPA in the past showed that the annual costs of developing the information required by an exemption petition plus the cost of filing the petition may cost between $16,000 and $132,440 per process. Although EPA does not know precisely how many processes meet the definition of closed and controlled waste processes, if 500 processes were eligible, the avoided cost of submitting petitions for exemption could range from $8 million to $66 million per year. These estimates will vary depending upon the actual number of processes eligible for the exclusion. Administering exemption petitions for closed and controlled waste processes could require extensive EPA resources.

This rule has no significant negative economic impact. Although for those companies who choose to take advantage of it, it imposes additional burdens, it avoids the larger burdens imposed on industry by the prohibitions of section 6(e). As discussed in the following unit, EPA is requiring manufacturers who operate closed and controlled waste manufacturing processes and who desire exclusion to certify that their processes are closed or controlled waste processes, and to notify EPA that the processes qualify for exclusion. EPA has concluded that recordkeeping and reporting by manufacturers affords substantial human health and environmental benefits that greatly outweigh the costs of recordkeeping (see IV.D. for further analysis).

EPA is providing manufacturers the option of conducting a theoretical analysis or of actually monitoring releases for PCB levels. EPA estimates the cost of conducting a theoretical analysis to be on the order of $1,014 per process. EPA estimates the cost of recordkeeping and certification to be on the order of $374 per process per year. If actual monitoring of PCB levels is undertaken, using the EPA recommended method, EPA estimates the costs of monitoring to range between $120 and $770 per sample. Total costs per process range from $844 to $45,990, depending on the frequency of sampling and the actual costs of testing (see support document entitled "Economic Analysis for the Final Rule to Exclude Closed and Controlled Processes from the PCB Ban" for details). The upper estimate of the cost per process of monitoring incorporates $32,000 for air sampling. In adding this amount into its calculation of the upper estimate, EPA assumed that monitoring of air emissions is not currently ongoing for other purposes. Therefore, all costs associated with air emission monitoring have been added to the costs of recordkeeping and reporting under this rule. Since it is unlikely that this is the case for most manufacturing facilities, the upper estimate provided by EPA may be artifically high. For most companies, EPA expects that the costs will not exceed $26,600 per process. This assumes that sampling equipment preparation and data reduction/report writing are the only costs of air emissions monitoring that would be directly attributable to this rule.

3. *Unreasonable risk determination.* EPA has evaluated the human health and environmental effects and exposure to PCBs from closed and controlled waste processes, the benefits of the processes producing the PCBs, and the economic impact of regulating these processes under section 6(e) of TSCA. EPA has concluded that closed and controlled waste processes represent de minimis situations because: (1) The PCBs released from closed and controlled waste manufacturing processes are released at low concentrations, (2) the estimated amount of PCBs released from these processes per year is only 0.0006 percent of the 150,000,000 pounds of PCBs currently in existence in the environment as free PCBs, (3) controlled wastes are disposed of in a manner that should result in negligible environmental contamination, and (4) manufacturers operating these processes are required to keep records and notify EPA of processes operating under the exclusion.

EPA has considered the benefits of closed and controlled waste processes and found them to be substantial. Further, EPA has considered the statutory process of petitioning for yearly exemptions from the TSCA ban and found it to be resource intensive. Finally, EPA has considered the costs of recordkeeping and reporting by manufacturers operating closed and controlled waste processes. EPA has found that these costs do not represent an excessive burden.

Thus, after balancing the risks to human health and the environment created as a result of this exclusion against the benefits afforded by the exclusion, EPA concludes that the exclusion of closed and controlled waste manufacturing processes poses no unreasonable risks to public health and the environment.

D. Recordkeeping and Reporting

1. *Summary of requirements.* In the proposed rule, EPA proposed certain recordkeeping requirements for closed and controlled waste manufacturing processes. EPA proposed that either theoretical assessments or actual monitoring of PCB levels in releases be completed in order to qualify for exclusion, that the records of the analysis be maintained at the facility, and that manufacturers certify that their processes qualify for exclusion. The certification was to be completed by a responsible corporate officer, who was also required to certify that the analysis was true and accurate to the best of his knowledge and that the analysis had been conducted by qualified personnel. The certifications (and records to support the certifications) were to be maintained at the facility for three years after a process ceased operation or for seven years, whichever was shorter. The submission of these records and cerifications to EPA was not required in the proposed rule.

EPA proposed these recordkeeping requirements to: (1) Reduce the likelihood of processes being mislabeled as closed or controlled waste processses, and (2) to aid EPA in monitoring compliance with the rule.

In addition to the recordkeeping requirements of the proposed rule, in the final rule, EPA is requiring: (1) That manufacturers using RCRA-approved facilities for the disposal of controlled wastes certify that the facility qualifies for the disposal of the PCB wastes, and document the basis for the determination, and (2) that EPA be notified of any processes operating under the closed and controlled waste manufacturing process exclusion. Manufacturers are also required to notify EPA of the basis for the determination that a process is

excluded, by indicating whether a theoretical assessment or actual monitoring of PCB levels has been completed. If the process is a controlled waste process, manufacturers are also required to notify EPA of the type, the name, and the location of the disposal facility. Manufacturers have the option, as provided under TSCA section 14(c), of declaring any of this information to be confidential. Manufacturers desiring exclusion would: (1) identify processes which they believe generate PCBs as impurities or by-products; (2) determine if the processes are closed processes or controlled waste processes; (3) place data and records of their determinations in files at the facility: (4) certify that the process qualifies; and (5) transmit a letter to EPA notifying EPA that processes are excluded and the bases of the determinations. Should manufacturers periodically undertake monitoring of PCB levels in processes or in releases from the processes, these data are also retained at the facility. EPA is requiring that such records be maintained for at least three years after the particular process being used at the facility ceases operations or for seven years, whichever is shorter. Further, EPA is requiring that processes be reevaluated and that a new certification be filed upon significant process changes that invalidate the previous certification. Significant process changes include changes that are likely to change the concentration of PCBs in releases from the processes (except in controlled wastes) outside the values in the original assessment and changes in the facility in which PCBs are disposed. The costs of recordkeeping and reporting to manufacturers operating closed and controlled waste manufacturing processes will vary depending upon the nature of the manufacturing process. Processes that are frequently changed or are known to release PCBs in air emissions, water effluents, or products in concentrations that approach the limit of quantitation will probably require more frequent analyses than other types of processes.

Manufacturers are not required to use this rule. They can use the statutory exemption process as an alternative to taking advantage of this exclusion.

2. *Recordkeeping and monitoring requirements.* In the proposed rule, EPA proposed certain recordkeeping requirements. EPA proposed: (1) That either theoretical analyses or actual monitoring of PCB levels be conducted; (2) that the records of the analysis be maintained at the facility: (3) that manufacturers certify that the processes qualify for exclusion; and (4) that all records be maintained for three years after a process ceased operation or for seven years, whichever was shorter.

Certain comments on the proposed rule suggested that EPA should impose a reporting requirement in addition to the proposed recordkeeping requirements (see IV.D.3.). Other comments, however, questioned the need for even the proposed recordkeeping requirements. They maintained that since closed and controlled waste manufacturing processes by definition have been determined to represent de minimis situations, recordkeeping by manufacturers operating such processes creates an unnecessary burden.

However, EPA has concluded that the benefits to public health and the environment of recordkeeping are substantial, and further, that an additional recordkeeping requirement is warranted as a result of the modification to the disposal requirements (see IV.A.5.).

In addition to the recordkeeping requirements of the proposed rule, in the final rule, EPA is requiring that manufacturers disposing of controlled wastes in RCRA-approved incinerators certify that the incinerator is capable of destroying the PCB wastes and maintain records of the basis of the determination. EPA believes that this additional recordkeeping requirement is needed to ensure that controlled wastes are disposed of in qualified RCRA-approved facilities. Manufacturers may use any generally accepted criteria to demonstrate the capability of the incinerator to destroy the PCBs, including the use of heat of combustion values and other parameters addressed in the "RCRA Guidance for Hazardous Waste Incineration."

With recordkeeping requirements in place, fewer processes will be mislabeled by manufacturers as qualifying for exclusion. With fewer processes being mislabeled, less total PCBs will be released to the environment as a result of EPA creating this exclusion. The recordkeeping requirements help to ensure that only situations that have been determined to be de minimis are excluded from regulation under TSCA section 6(e). Further, such recordkeeping is necessary to the development of an effective compliance monitoring program by EPA. Without records (and notification of EPA), EPA will have little or no information upon which to develop an effective compliance monitoring program.

EPA estimates the cost of recordkeeping alone to be on the order of $374 per process per year. This cost does not include the costs associated with conducting the theoretical assessment or monitoring PCB levels in releases.

In view of the substantial benefits afforded public health and the environment described above and the relatively low costs of recordkeeping to manufacturers, EPA has concluded that the benefits, in terms of public health and environmental protection, far outweigh the costs.

In the proposed rule, EPA provided manufacturers the option of utilizing a theoretical assessment to support a determination that a process qualified for exclusion. However, a number of comments criticized the portion of the proposed rule that provided for theoretical assessments in lieu of actual monitoring of PCB levels. Several comments on the proposal maintained that many manufacturers may be either unable to complete a theoretical assessment or uncomfortable with relying on this means of analysis. Other comments suggest that EPA should impose strict monitoring requirements for manufacturers taking advantage of this exclusion.

EPA does not agree that monitoring of process releases is necessary in all process situations. EPA believes that theoretical assessments which correctly conclude that PCBs are not released above the practical limits of quantitation will be possible in some process situations and that it would be unreasonable to require actual monitoring of PCB levels when reason and logic alone clearly dictate that a process qualifies for exclusion. Further, EPA has concluded that it is not reasonable for EPA to eliminate this option for all manufacturers simply because certain manufacturers have commented that they would be uncomfortable relying on a theoretical analysis.

The objective of conducting a theoretical assessment is to use reason, logic, and chemical/mathematical calculations to make a correct determination of whether a manufacturing process is a closed or controlled waste manufacturing process and, therefore, qualifies for exclusion. Specifically, the objective is to determine if PCB levels in releases from a process to other than controlled wastes exceed certain levels (the practical limits of quantitation of PCBs) without actually monitoring these releases. Obviously, if the expected concentration of PCBs in releases (derived through a theoretical calculation) approaches the level set as the regulatory cutoff, actual monitoring

of PCB levels would be advisable. The need to actually undertake monitoring of releases can be determined only by each manufacturer and will depend upon the expected level of release, its relationship to the cutoff, and the level of confidence placed in the accuracy of the estimate. The ultimate burden of making a correct decision to rely on theoretical analyses rests on each manufacturer.

A primary consideration in completing a theoretical assessment is determining the probable point(s) of manufacture of PCBs, the likely mechanism(s) of formation, and the probable identity and concentrations of the PCB congeners formed. Once these have been determined, the fate of the PCBs is traced from the point(s) of manufacture, through the process, to the point(s) of release. Factors to be considered in projecting the movement of the PCBs through the process include: (1) The concentrations of PCBs at different points in the manufacturing process, (2) the solubility, volatility, and density of the PCB congeners relative to the other process components, (3) the temperatures and pressures at different points in the process, (4) the potential for the PCBs to be transformed into other compounds or destroyed prior to release, and (5) the physical characteristics of the process and the processing equipment used within the process. Additional guidance on conducting a theoretical assessment is provided in a support document to this rulemaking entitled: "Guidance for Conducting a Theoretical Assessment." This document is available in the rulemaking record, and by contacting the Industry Assistance Office (see FOR FURTHER INFORMATION CONTACT).

A theoretical assessment is to address: (1) The reaction or reactions believed to be producing the PCBs, (2) the levels of PCBs generated and released, (3) the bases for estimates of PCB concentrations in releases, and (4) the name and qualifications of the person or persons performing the analysis.

If actual monitoring of PCB levels is undertaken, records are to be maintained and must include: (1) The method(s) of analysis, (2) the results of the analysis for PCB levels in releases, including data from the quality assurance plan, (3) the name of the analyst or analysts, and (4) the date and time of the analysis.

A determination that PCBs are absent by actual monitoring of PCB levels should take into account the statistical variability in analytical results which will always occur. Recognizing that there will be variation in results of a series of samples taken from a particular stream, EPA is recommending a sampling procedure that uses a sequential sampling scheme. (See support document entitled "Guidance for Sample Collection.")

This approach should result in a considerable savings over standard statistical sampling methods without adding to the risks of making incorrect decisions. Sequential sampling is a procedure where, unlike other statistical methods, the sample size is not fixed in advance. After every sample or group of samples is analyzed, the sequential sampling procedure indicates whether sufficient samples have been gathered to make a decision or whether additional samples are needed. On the average, fewer samples are required for this procedure than with other methods.

In general, for any statistical method, two decision errors are possible: (1) declaring processes which are qualified for an exclusion to be not qualified for exclusion, and (2) declaring processes which are not qualified for exclusion to be qualified for exclusion. The sequential sampling scheme recommended by EPA eliminates any significant likelihood of committing an error of the first type. The recommended maximum number of samples (seven) was chosen because, when several PCB peaks are present, it results in an acceptably low probability of the second type of error without necessitating an excessive amount of sampling to declare a process qualified for exclusion.

Manufacturers are required to certify that their processes qualify for exclusion, certify that the analysis completed is accurate to the best of their knowledge, and maintain these records and certifications for three years after a process ceases operation or for seven years, whichever is shorter.

EPA estimates that cost of conducting a theoretical analysis to be on the order of $1,014 per process. EPA estimates the cost of certification without actual monitoring of PCB levels in releases to be on the order of $374 per process per year. If actual monitoring of PCB levels is undertaken, using the EPA-recommended method, EPA estimates the costs of monitoring to range between $120 and $770 per sample. Total costs per process are estimated to range from $844 to $45,990, depending upon the frequency and actual cost of sampling (see "Economic Analysis for the Final Rule to Exclude Closed and Controlled Processes from the PCB Ban" for detailed assessment).

3. *Reporting requirement.* In the proposed rule, EPA did not propose that reporting of data to the Agency be required. However, in response to the proposed rule, EPA received several comments that suggested that a reporting requirement should be imposed in addition to the proposed recordkeeping requirements. These comments maintain that the cost to manufacturers of notifying EPA that certain processes qualify for exclusion is trivial (less than $1.00 per process), and the benefits to EPA of developing an effective compliance monitoring program far outweigh these trivial costs. Other comments, however, question the need for even the proposed recordkeeping requirements (see IV.D.1.) for situations that have been determined to be de minimis. These comments suggest that reporting and recordkeeping requirements impose unnecessary burdens on industry.

After considering these comments, EPA is instituting a reporting requirement in the final rule. The final rule requires manufacturers to notify EPA that closed and controlled waste processes are operating at their facilities. Further, manufacturers are required to indicate, in the notification letter, whether a theoretical assessment or actual monitoring of PCB levels was used to make the determination that the processes qualify for exclusion. If the manufacturing process is a controlled waste process, the manufacturer must also notify EPA of the type, the name, and the location of the disposal facility. Manufacturers have the option of declaring this information to be confidential, under TSCA section 14(c). Manufacturers also have the option to sending a copy of the actual assessment to EPA.

EPA has concluded that requiring notification of EPA that processes are excluded and submission of information on the general bases for the determinations that the processes are excluded provides a relatively low cost incentive for manufacturers to carefully evalute their processes for eligibility for exclusion. Further, EPA believes, as several comments have suggested, that such a reporting requirement would provide benefits which greatly outweigh the costs to manufacturers of transmitting letters to EPA. Specifically, the letters could be used by EPA in developing an enforcement strategy and in monitoring compliance with the rule. EPA agrees with these comments and has concluded that establishing a reporting requirement of the nature described here does not place unreasonable burdens on the regulated community.

E. The EPA Recommended Analytical Method for Quantifying PCBs

For purposes of this rule only, EPA has designated capillary gas chromatography coupled to an electronic impact mass spectrometer (CGS/EIMS) as the EPA recommended analytical technique for quantifying PCBs in air emissions, water effluents and product/process streams. (Different analytical techniques may be more appropriate for other situations). This is the analytical technique which EPA will use in monitoring compliance with this final rule and which manufacturers may very well choose to use. To qualify for the closed and controlled waste process exclusion, PCBs must be below practical limits of quantitation for PCBs in air, water, and products (and wastes from closed processes). It should be emphasized that actual monitoring of releases is not required as a condition for exclusion (theoretical analyses are acceptable), and this method is not required if monitoring is elected.

1. *Chemical analytical methodology.* True confirmation of chlorinated biphenyls (PCBs) in specimens which may contain other chlorinated aromatic compounds can reliably be accomplished by capillary gas chromatography coupled to mass spectrometry. In order to obtain the selectivity to use this analytical technique, specific separation, extraction, and cleanup steps are a necessary part of the chemical analysis process. There are many analytical procedures for separation, extraction, cleanup, and detection which can successfully be used to indicate the presence of PCBs. Some suggested protocols appear in the support document: "Analytical Methods for Incidentally Generated PCBs—Initial Validation and Interim Methods."

2. *Quality assurance plan for measurement of incidentally generated chlorinated biphenyls.* An integral part of CGC/EIMS analysis is the quality assurance program (QAP). QAPs insure the integrity of the data produced.

A QAP includes the following: (1) History and disposition of samples, (2) sampling and sample collection procedures and (3) extraction and instrumental analysis procedures. A QAP documents how a laboratory intends to demonstrate its capability to produce data of acceptable quality. A QAP is essential for establishing the validity of the analytical data generated. In monitoring compliance, EPA will use CGC/EIMS in conjunction with a QAP to verify the accuracy of the data generated.

3. *Guidelines.* EPA has issued guidance on: (1) Sample collection and homogenization of the sample, (2) addition of surrogate compounds to the sample, (3) extraction and cleanup, (4) concentration or dilution of the extract, (5) analysis of the final extract, (6) reporting the results of the chemical analysis as specific PCB isomers or total PCBs, (7) developing a QAP, and (8) performing a theoretical assessment. In addition, the "RCRA Guidance for Hazardous Waste Incineration" is also available. These guidance documents are support documents for this rulemaking and are available by contacting the Industry Assistance Office (see FOR FURTHER INFORMATION CONTACT).

F. Relationship of the Final Rule to Other PCB Rules

1. *Disposal and marking rule.* The Disposal and Marking Rule, published in the **Federal Register** of February 17, 1978 (43 FR 7150), as Part 761 of Title 40 of the Code of Federal Regulations, requires that when PCBs and PCB items are removed from service, disposal be in accordance with specific criteria. Briefly, PCBs in concentrations below 50 ppm are not required to be disposed of in any special manner; liquid PCBs in concentrations between 50 ppm and 500 ppm are required to be disposed of in an incinerator which complies with certain standards, in a chemical waste landfill, or in a high efficiency boiler; non-liquid PCBs are required to be disposed of in an incinerator which complies with certain standards or in a chemical waste landfill; and liquid PCBs in concentrations at or above 500 ppm are required to be disposed of in an incinerator which complies with certain standards.

This rule has no direct effect on the existing marking and disposal regulations. PCBs created in other than closed and controlled waste manufacturing processes in concentrations between the LOQ and 50 ppm are not required by this rule to be disposed of in any special manner. This rule simply excludes PCBs generated in controlled waste manufacturing processes from the section 6(e) ban when all PCBs generated and released above the LOQ are handled in a manner specified in this rule.

2. *Regulatory exclusion at 50 ppm.* The PCB Manufacturing, Processing, Distribution in Commerce, and Use Prohibition rule, published in the **Federal Register** of May 31, 1979, (44 FR 31514), as Part 761 of Title 40 of the Code of Federal Regulations basically prohibits the manufacture, processing, distribution in commerce and use of PCBs in concentrations above 50 ppm in other than a totally enclosed manner. As discussed under the Background unit in this preamble, this exclusion of PCBs in concentrations below 50 ppm was successfully challenged by the Environmental Defense Fund. The court granted a stay of mandate with respect to the 50 ppm cutoff, and persons manufacturing, processing, distributing in commerce and using PCBs in concentrations below 50 ppm were permitted to continue these activities. The initial stay of mandate was scheduled to expire on October 13, 1982. However, in its report to the court on uncontrolled PCBs, filed in March of 1982, EPA requested and was subsequently granted an extension of this stay of mandate until December 1, 1982. Prior to that time (but no later than November 1, 1982), EPA will submit a plan to the court for rulemaking on uncontrolled PCBs. EPA anticipates that its plan will include a schedule for rulemaking for uncontrolled PCBs and a request for an additional extension of the stay of mandate for processes covered by the rulemaking until it is completed.

V. Official Rulemaking Record PCB Regulations for Closed and Controlled Waste Manufacturing Processes

In accordance with the requirements of section 19(a)(3)(E) of TSCA, EPA is publishing the following list of documents constituting the record of this rulemaking. This list does not include public comments, the transcript of the rulemaking hearing, or submissions made at the rulemaking hearing or in connection with it. These documents are exempt from **Federal Register** listing under section 19(a)(3).

A. Previous Rulemaking Records

1. Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Disposal and Marking Final Regulation," 43 FR 7150, February 17, 1978.

2. Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions Rule," 44 FR 31514, May 31, 1979.

3. Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Electrical Equipment," 47 FR 37342, August 25, 1982.

B. Federal Register Notices

1. 46 FR 27617, May 20, 1981, USEPA, "Polychlorinated Biphenyls (PCBs); Manufacture of PCBs in Concentrations Below 50 Parts Per Million; Possible Exclusion From Manufacturing Prohibition; Advance Notice of Proposed Rulemaking."

2. 46 FR 27615, May 20, 1981, USEPA, "Polychlorinated Biphenyls (PCBs); Court Order Regarding PCBs in Concentrations Below 50 Parts Per Million."

3. 47 FR 24976, June 8, 1982, USEPA, "Polychlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution in Commerce, and Use in Closed and Controlled Waste Manufacturing Processes, Proposed Rule."

4. 47 FR 25555, June 14, 1982, USEPA, "Polychlorinated Biphenyls (PCBs): Manufacture, Processing, Distribution, and Use in Closed and Controlled Waste Manufacturing Processes, Correction."

5. 47 FR 30082, July 12, 1982, USEPA, "Notice of Availability of Guidelines for the Analysis of PCBs."

C. Support Documents

1. USEPA, OPTS, CCD, "Summary of Comments [on ANPR] Received Concerning the Exclusion of PCBs in Concentrations Below 50 ppm, and in Closed Manufacturing Processes from Regulation Under Sections 6(e)(2) and 6(e)(3) of Toxic Substances Control Act" (undated).

2. USEPA, OPTS, EED, "Occupational Exposure to Inadvertently Produced PCBs—Preliminary Report" (April 22, 1982).

3. USEPA, OPTS, EED, "Methods of Analysis for Incidentally Generated PCBs Literature Review and Preliminary Recommendations. Draft Interim Report, Revision 2" (April 21, 1982).

4. USEPA, OPTS, ETD, "Draft: Cost Analysis for the Proposal to Exclude Controlled Processes from the PCB Ban" (April 1982).

5. USEPA, OPTS, ETD, "Cost Analysis for the Proposal to Exclude Controlled Processes from the PCB Ban–2nd Draft" (May, 1982).

6. USEPA, OPTS, ETD, "Economic Analysis for the Final Rule to Exclude Closed and Controlled Processes from the PCB Ban" (September 1982).

7. USEPA, OPTS, HERD, "Review of Studies of Health Effects of PCBs" (December 31, 1981).

8. USEPA, OPTS, HERD, "Proposed Rule on (PCBs) Use in Electrical Equipment. Review of Potential Health Effects in Humans from Exposure to PCBs and Related Impurities" (April 12, 1982).

9. USEPA, OPTS, EED, "Quality Assurance Guidelines" (April 22, 1982).

10. USEPA, OPTS, EED, Memo from Redford to Halper, "Rationale for Levels of Quantitation for CGC/EIMS" (April 21, 1982).

11. USEPA, OPTS, EED, "Estimation of Releases from Spills of Inadvertently Produced PCBs" (April, 1982).

12. USEPA, OPTS, EED, "Analytical Methods for Incidentally Generated PCBs—Intitial Validation and Interim Protocols. Preliminary Draft, Draft Interim Report #4" (June 24, 1982).

13. USEPA, OPTS, EED, "Guidance for Sample Collection, Preliminary Draft" (July 8, 1982).

14. USEPA, OPTS, CCD, "Response to Comments on the Closed and Controlled Waste Rule" (October 12, 1982).

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24. USEPA, OPTS, EED, Memo to CMA from Smith "Sample Collection" (July 26, 1982).

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44. USEPA, "EPA Report in Accordance with this Court's April 13, 1982 Order Concerning EPA Proposal for Action on Polychlorinated Biphenyls in Concentrations Below 50 Parts Per Million Resulting From Uncontrolled PCBs and Motion for Extension of Stay of Mandate as to EPA Action on Uncontrolled PCBs Until December 1, 1982" (March 11, 1982).

45. CMA, Letter to Gunter (EPA) from Fensterheim (CMA), "Summary of Discussion on Erickson Testimony" (July 13, 1982).

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51. USEPA, OPTS, EED, "Methods of Analysis for Incidentally Generated PCBs Literature Review and Preliminary Recommendations, Draft Interim Report, Revision #3" (June 17, 1982).

52. USEPA, OPTS, EED, "Methods of Analysis for Incidentally Generated PCBs Literature Review and Preliminary Recommendations, Final Report" (October 12, 1982).

53. USEPA, OPTS, EED, "Methods of Analysis for Incidentally Generated PCBs-Synthesis of ^{13}C-PCB Surrogates, Draft Interim Report #3" (June 29, 1982).

54. USEPA, OPTS, EED, "Methods of Analysis for Incidentally Generated PCBs Preliminary Validation and Interim Methods" (October 12, 1982).

55. USEPA, Memo from R.G. Bell to Don Clay, "OTS Obligations Under the Environmental Research, Development and Demonstration Authorization Act of 1978" (July 30, 1982).

D. Reports

1. Chemical Manufacturers Association, "A Report of a Survey on the Incidental Manufacture, Processing, Distribution, and Use of Polychlorinated Biphenyl at Concentrations Below 50 ppm."

2. Chemical Manufacturers Association, "The Analysis of Chlorinated Biphenyls."

3. Ecology and Environment, Incorporated, "Summary of the Health Effects of PCBs."

VI. Authority

Section 6(e) of TSCA [15 U.S.C. 2605]. The Administrator of EPA has authority to amend or modify the PCB Manufacturing, Processing, Distribution in Commerce and Use Prohibition Rule (40 CFR Part 761), published in the Federal Register (44 FR 31514, May 31, 1979).

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 final rule is not a major rule as the term is defined in section 1(b) of the Executive Order. Therefore, EPA has not prepared a Regulatory Impact Analysis for this proposed rule.

EPA has concluded that this final rule is not "major" under the criteria of section 1(b) because the annual effect of the rule on the economy will be 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 significant adverse effects on competition, employment, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. In fact, this final rule allows certain uses of PCBs that would otherwise be prohibited by section 6(e) of TSCA and, therefore, reduces the overall costs and economic impact of section 6(e).

VIII. Regulatory Flexibility Act

Under section 605(b) of the Regulatory Flexibility Act, 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. The amendment to the PCB rule excludes persons who manufacture PCBs in closed and controlled waste manufacturing processes from the ban on manufacture of PCBs. For those persons who qualify for the exclusion, the effect of this rule is to avoid the economic impact associated with the ban. Since no negative economic effect is expected upon any business entity from the promulgation of this rule, I certify that this rule will not have a significant economic impact on small entities.

IX. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq* (the Act), authorized the Director of the OMB to review certain information collection requests by Federal agencies. EPA has determined that the recordkeeping and reporting requirements of this rule constitute a "collection of information," as defined in 44 U.S.C. 3502(4). In accordance with the Act, the recordkeeping and reporting requirements of this rule have been submitted to OMB under section 3504(b) of the Act. OMB has assigned the control number 2070–0008 to this final rule.

List of Subjects in 40 CFR Part 761

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

Dated: October 12, 1982.

Anne M. Gorsuch,

Administrator.

PART 761—POLYCHLORINATED BIPHENYLS (PCBs) MANUFACTURING, PROCESSING, DISTRIBUTION IN COMMERCE, AND USE PROHIBITIONS

Therefore, 40 CFR Part 761 is amended as follows:

1. Paragraph (f) is added to § 761.1, to read as follows:

§ 761.1 Applicability.

* * * * *

(f) Persons who manufacture, process, distribute in commerce, or use PCBs generated as byproducts, impurities or intermediates in closed and controlled waste manufacturing processes (as defined in § 761.3 (jj) and (kk)) are exempt from the requirements of Subpart B. To qualify for this exclusion, such processes must also fully comply with § 761.185.

2. Paragraphs (jj), (kk), (mm), and (nn) are added to § 761.3, to read as follows:

§ 761.3 Definitions

* * * * *

(jj) "Closed manufacturing process" means a manufacturing process in which PCBs are generated but from which less than 10 micrograms per cubic meter from any resolvable gas chromatographic peak are contained in any release to air; less than 100 micrograms per liter from any resolvable gas chromatographic peak are contained in any release to water; and less than 2 micrograms per gram from any resolvable gas chromatographic peak are contained in any product, or any process waste.

(kk) "Controlled waste manufacturing process" means a manufacturing process in which PCBs are generated but from which less than 10 micrograms per cubic meter from any resolvable gas chromatographic peak are contained in any release to air; less than 100 micrograms per liter from any resolvable gas chromatographic peak are contained in any release to water; less than 2 micrograms per gram from any resolvable gas chromatographic peak are contained in any product, and the remainder of PCBs generated are incinerated in a qualified incinerator, landfilled in a landfill approved under the provisions of § 761.75, or stored for such incineration or landfilling in accordance with the requirements of § 761.65(b)(1).

(ll) [Reserved]

(mm) "Manufacturing process" means all of a series of unit operations operating at a site, resulting in the production of a product.

(nn) "Qualified incinerator" means one of the following:

(1) An incinerator approved under the provisions of § 761.70.

(2) A high efficiency boiler approved under the provisions of § 761.60(a)(3).

(3) An incinerator approved under section 3005(c) of the Resource Conservation and Recovery Act (42 U.S.C. 6925(c)) (RCRA). The manufacturer seeking to qualify a process as a controlled waste process by disposing of wastes in a RCRA-approved incinerator must make a determination that the incinerator is capable of destroying less readily burned compounds than the PCB homologs to be destroyed. The manufacturer may use the same guidance used by EPA in making such a determination when issuing an approval under section 3005(c) of RCRA. The manufacturer is also responsible for obtaining reasonable assurances that the incinerator, when burning PCB wastes, will be operated under conditions which have been shown to enable the incinerator to destroy the less readily burned compounds.

3. Section 761.185 is added to read as follows:

§ 761.185 Certification program and retention of special records by persons generating PCBs in closed manufacturing processes and controlled waste manufacturing processes.

(a) In addition to meeting the basic requirements of § 761.1(f), PCB-generating manufacturing processes shall be considered "closed manufacturing processes" or "controlled waste manufacturing processes" (and thus, be excluded from the TSCA section 6(e) ban on manufacture), only if the owner/operator of the manufacturing facility:

(1) Performs either a theoretical analysis of PCB levels in releases or conducts actual sampling of PCB levels in releases.

(2) Determines that the disposal facility is qualified for the disposal of controlled wastes under § 761.3(nn) (for controlled waste processes only).

(3) Maintains (for a period of 3 years after a process ceases operations or for 7 years, whichever is shorter) records containing the following information on the processes:

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

(B) The basis for all estimations of PCB concentrations.

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

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

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

(C) The name of the analyst or analysts.

(D) The date and time of the analysis.

(iii) *Qualifications of the disposal facility.* (A) The type of disposal facility.

(B) The name of the disposal facility.

(C) The location of the disposal facility.

(D) If the disposal facility is a RCRA-approved incinerator, the basis for the determination that the incinerator qualifies for the destruction of the PCB wastes to be destroyed.

(b) The data collected, and the analysis performed under paragraph (a) of this section must support the following certification if the processes are to be excluded under the closed manufacturing process and controlled waste manufacturing process exclusion. Persons desiring exclusion of a PCB-generating process under the closed and controlled waste process exclusion shall certify that:

(1) An analysis of the manufacturing process for PCB levels and releases (either theoretical or through actual monitoring for PCBs) has been completed.

(2) The analysis of the manufacturing process is on record at the facility.

(3) The concentration of PCBs in air emissions is below 10 micrograms per cubic meter per resolvable gas chromatographic peak; in water effluents, below 100 micrograms per liter per resolvable gas chromatographic peak; and in products, below 2 micrograms per gram per resolvable gas chromatographic peak.

(4) Either:

(i) The concentration of PCBs in process wastes is below 2 micrograms per gram resolvable gas chromatographic peak.

(ii) All process wastes are either incinerated in a qualified incinerator (see § 761.3(nn)), landfilled in a landfill approved under § 761.75, or stored for such incineration or landfilling in accordance with the requirements of § 761.65(b)(1).

(c) The certification must be signed by a responsible corporate officer. This certification must be filed at each facility in which a closed or controlled waste process is operating for a period of three years after a process ceases operation or for seven years, whichever is shorter, and must be made available to EPA upon request. For the purpose of this section, a responsible corporate officer means:

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

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

(d) This certification process must be repeated whenever process conditions are significantly modified to make the previous certification no longer valid. Significant modifications include changing disposal mechanisms or facilities for the disposal of controlled wastes.

(e) Any person signing a document under paragraph (b) (1) through (4) of this section shall also make the following certification:

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

Dated: ———————.

Signature ———————.

(f) Manufacturers operating closed and controlled waste manufacturing processes shall transmit a letter to EPA notifying EPA of:

(1) The number, the type, and the location of the closed and controlled waste manufacturing processes.

(2) Whether the determinations that the processes qualify for exclusion are based on theoretical assessments or on actual monitoring of PCB levels in releases.

(3) The type, the name, and the location of the waste disposal facility, if the process is a controlled waste manufacturing process.

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