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Environmental Protection Agency

Polychlorinated Biphenyls (PCBs);
Manufacture, Processing, Distribution, and
Use in Closed and Controlled Waste
Manufacturing Processes; Proposed Rule

0756051

ENVIRONMENTAL PROTECTION
AGENCY

[40 CFR Part 761]

[OPTS 62017A; TSH FRL 2103-7]

**Polychlorinated Biphenyls (PCBs);
Manufacture, Processing, Distribution,
and Use in Closed and Controlled
Waste Manufacturing Processes**AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On April 13, 1981, the U.S. Court of Appeals for the District of Columbia Circuit issued an order requiring the Environmental Protection Agency (EPA) to undertake a rulemaking for certain chemical manufacturing processes that generate PCBs in low concentrations. In response to the court's order, EPA is proposing to exclude the production of PCBs in closed and controlled waste manufacturing processes from the provisions of section 6(e) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e). Section 6(e) prohibits the manufacture, processing, distribution in commerce, and use of polychlorinated biphenyls (PCBs).

DATES: An informal hearing, if requested, will be held on August 6, 1982, in Washington, D.C. The exact time and location of the hearing will be available through the Industry Assistance Office; which can be reached by calling toll free 800-424-9065 or, in Washington, D.C., by calling 554-1404. Comments on this proposed rule and requests to participate in the informal hearing must be submitted by July 23, 1982.

ADDRESSES: Comments should be submitted to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, D.C. 20460.

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: (800-424-9056); In Washington, D.C.: (554-1404); Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION**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 19627). This proposed rule contains the new designations:

New designation	Former designation
Subpart B	Subpart B
Section 761.166	Section 761.46
Section 761.3	Section 761.2
Section 761.66	Section 761.42
Section 761.70	Section 761.48
Section 761.76	Section 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 regulations to reduce the impact of the ban. EPA promulgated regulations, published in the Federal Register of May 31, 1979 (44 FR 31514), to implement section 6(e) of TSCA. The regulations, among other things, generally excluded from the ban materials containing PCBs in concentrations less than 50 parts per million.

The Environmental Defense Fund (EDF) obtained judicial review of the regulations in the U.S. Court of Appeals for the District of Columbia Circuit. EDF challenged the provisions described above; among others. On October 30, 1980, the court invalidated the regulatory exclusion for 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 Regulations 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. The result would be that many activities in industries throughout the United States would be banned.

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 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 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 the production of PCBs in these processes from the provisions of section 6(e).

EPA attempted to identify and define specifically these processes where there are negligible public health and environmental benefits to be derived from regulation because the processes present such low risks. Two process categories were identified. These are "closed manufacturing processes" and "controlled waste manufacturing processes."

"Closed manufacturing processes" were defined as those in which PCBs are generated but from which no PCBs are released. These processes generate PCBs within closed reaction equipment and the chemical reactions within the processes continuously destroy the PCBs as they are produced.

"Controlled waste manufacturing processes" were defined as processes in which PCBs are generated but from which PCBs are released only as constituents of wastes that are either incinerated, disposed of in EPA-approved landfills, or stored for later incineration or landfilling.

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;

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(2) to promulgate a final rule, within eighteen 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 eleven months after the date of the order (i.e., March 13, 1982), of EPA's plans and schedule for further action on PCBs in concentrations below 50 ppm generated as uncontrolled PCBs.

On May 20, 1981, EPA published two ANPRs on the 50 ppm regulatory cutoff (46 FR 27617 and 46 FR 27619). The ANPRs established bifurcated rulemaking proceedings with respect to PCBs in concentrations below 50 ppm. The first ANPR announced activities that EPA believed may lead to 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. In the ANPRs, EPA stated that it needed to develop a substantial factual basis to support rulemaking on these PCBs.

The comment period for both ANPRs expired on November 18 1981. Approximately 50 public comments were submitted. The most significant submission was filed by the Chemical Manufacturers Association ("CMA"), a trade association whose membership includes many of the nation's principal manufacturers of primary chemicals. As explained further below, EPA has relied on CMA's submission to a significant extent because CMA has collected the most comprehensive set of data on the generation of PCBs in concentrations below 50 ppm.

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. In its report to the court, EPA stated that it could not adequately define its plans for regulatory action for uncontrolled PCBs until it had a reasonable estimate of the number of processes that would be subject to the rulemaking. That number cannot be determined until EPA has defined closed and controlled waste processes and determined the number of processes excluded from the provisions of section 6(e) by the closed and controlled waste process rulemaking. Therefore, 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. EPA also requested that the court extend its stay of mandate until December 1, 1982, to allow EPA time to develop sufficiently detailed plans for regulatory action on uncontrolled PCBs after issues in this rulemaking on closed systems and controlled waste processes are resolved. On April 9, 1982, the court granted EPA's request.

III. Summary of the Available Data on Manufacture of PCBs in Low Concentrations

A. Information Provided by CMA

EPA received about 50 submissions and comments in response to the ANPR. The Chemical Manufacturers Association (CMA) submitted the most comprehensive information to EPA regarding closed and controlled waste manufacturing processes. CMA is a trade association whose membership consists of nearly 200 companies, including some of the nation's largest chemical manufacturers. CMA distributed detailed questionnaires to its membership which were designed to elicit information on the nature and extent of PCBs produced in chemical manufacturing processes in concentrations under 50 ppm. After analyzing the data supplied by its members, CMA submitted its final report, "A Report of a Survey on the Incidental Manufacturing, Processing, Distribution, and Use of Polychlorinated Biphenyls at Concentrations Below 50 PPM" to EPA. This survey represents a major portion of the data base for this rulemaking; therefore, EPA requests comments concerning the data contained in the survey.

Copies of the CMA survey are available for review in the public rulemaking record from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays, in Room E-109, EPA, 401 M St. S.W., Washington, D.C. Copies of the CMA survey, are also available for a fee, by contacting the Industry Assistance Office at (800-424-0065), in Washington, D.C. (544-1404).

CMA found that PCBs are formed in a wide variety of industrial chemical processes. The CMA survey suggests that PCBs can be generated from virtually any starting hydrocarbon structure. Indeed, PCB formation appears to be possible whenever chlorine and carbon are present in a reaction vessel at elevated temperatures. These PCBs are formed as impurities and byproducts in manufacturing processes and constitute

only a very small percentage of process components.

Of 85 respondents to the CMA survey, 28 chemical firms believe that they produce 13,768 pounds of PCBs per year. These PCBs appear as impurities or byproducts in 135 chemical manufacturing processes at concentrations under 50 ppm. The respondents to the CMA survey reported that 9,086 pounds of these PCBs are incinerated, 1,789 pounds are disposed of in surface waters, 1,376 pounds are disposed of in landfills, 550 pounds are disposed of by ground injection and 275 pounds are disposed of in EPA-approved landfills. The respondents also reported that approximately 700 pounds of PCBs are contained in the products of the manufacturing processes.

CMA believes that in this country a large number of processes, perhaps as many as several thousand, may generate PCBs in concentrations under 50 ppm as impurities and byproducts in industrial chemical manufacturing processes. However, they believe that most of the pounds of PCBs produced in these low concentrations in all chemical manufacturing processes throughout the United States have been accounted for by respondents to the CMA survey. This is because CMA believes that respondents to the survey represents a very high percentage of principle chemical producers.

The respondents identified four processes in which they believe PCBs are generated and continuously destroyed in closed reaction equipment. They indicated that about 0.7 pound of PCBs are found at any one time in these four processes. The respondents also identified forty processes in which PCBs are produced and are released only as constituents of wastes which are incinerated or disposed of in an EPA-approved landfill. Approximately 6,900 pounds of PCBs are reportedly generated in these forty processes. Incineration was defined in the survey questionnaires as incineration in compliance with "applicable" regulations. This definition includes municipal incineration in compliance with local and regional regulations but not necessarily incineration in accordance with EPA's rules for disposal of materials containing PCBs at concentrations greater than 50 ppm (43 FR 7150).

B. EPA Estimates of PCB Generation in Low Concentrations

Since the 85 chemical firms who responded to the survey represents 37.8 percent of industrial chemical sales, EPA has multiplied the amount of PCBs

reported in the CMA survey (13,768 pounds) by 2.6 to obtain an estimate of the total amount of PCBs produced in concentrations under 50 ppm in all processes in the United States (i.e., 35,800 pounds). This figure is considered an upper limit because, as CMA commented, not all chemical firms manufacture chemicals from reactions; many firms conduct formulation only.

Assuming the CMA data are accurate and, as reported by CMA, 50 percent of PCBs produced in concentrations under 50 ppm are produced in processes which meet EPA's initial definitions of closed and controlled waste processes (as they appeared in the May 20, 1981 ANPR), then up to 18,000 pounds of PCBs per year could be produced in the United States in these processes.

C. Additional Data

While section 6(e) of TSCA generally bans the manufacture of PCBs, it also establishes a mechanism for permitting continued manufacture of PCBs in certain situations. This mechanism is the exemption process, whereby persons may petition the Agency for relief from the PCB ban. Approximately forty petitions for exemption from the section 6(e) ban on the manufacture of PCBs were received by EPA following the publication of the May 31, 1979 rule. Data provided in these petitions indicate that about 75,000 pounds of PCBs per year currently are generated in processes in which PCB concentrations at the point of manufacture exceed 50 ppm. In the same way that CMA classified the processes from respondents to its survey, some of these processes can be classified as processes which do not release PCBs or as processes which release PCBs only as constituents of wastes which are either incinerated or disposed of in EPA-approved landfills. By extrapolating from the CMA data covering processes with PCBs below 50 ppm to these cases (i.e. above 50 ppm), EPA estimates that as much as an additional 38,000 pounds of PCBs per year could be generated in processes where the process is considered a closed process or a controlled waste process. EPA does not believe that the percentage of closed and controlled waste processes producing over 50 ppm PCBs will be significantly different from the percentage producing below 50 ppm.

IV. Discussion of the Proposed Rule

A. Overview of the Rule

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.

In this rule, EPA is proposing to exclude 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, as they are defined by EPA in this proposed rule. The basis of this proposed action is that EPA has determined that these processes present de minimis risk to humans and the environment. The proposed rule also requires that the persons who qualify for this exclusion and wish to take advantage of it certify that they qualify and maintain records of the basis for their determination.

This proposal does not mean that the Agency believes that closed and controlled waste processes are necessarily the only situations which present de minimis risks. In future rulemakings, EPA will consider other types of processes which may also present de minimis risks. As discussed in "Background", EPA is developing a plan for rulemaking activities on other than closed and controlled waste processes. EPA intends to consider these other process situations and make a determination on the most appropriate regulatory approach. Regulatory options for other than closed or controlled waste processes will include excluding other de minimis risk situations identified at that time. EPA intends to submit the plan for dealing with other than closed and controlled waste processes to the court on November 1, 1982.

During the course of discussions among EPA, EDF, and industry immediately after the court's decision, closed manufacturing processes and controlled waste manufacturing processes were identified as probably presenting negligible risks. From the 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 and unmeasurable. There would be no benefit from regulating the processes under section 6(e) since there could be

no 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. Therefore, PCBs will be present in very low concentrations in products of these manufacturing processes. Since PCBs will be present in products (at very low concentrations), EPA must also address the processing, distribution in commerce, and use of these PCBs in this rulemaking.

To establish a workable definition of processes subject to this exclusion, it is necessary for EPA to define, in a practical sense, the absence of PCBs in releases to the environment from these processes. Specifically, EPA has to establish how the absence of PCBs will be defined in air emissions, water effluents, products, and wastes from closed processes; and how the absence of PCBs will be defined in air emissions, water effluents, and products from controlled waste processes. Further, it is necessary for EPA to determine appropriate methods for disposal of process wastes from controlled waste processes to insure that PCBs will not be released to the environment from disposal operations.

Therefore, after evaluating ways for determining the absence of PCBs in various releases, EPA proposes to apply this exclusion to: (1) PCBs generated in processes which have no quantifiable releases of PCBs (if EPA's specified analytical technique were used) to products, air emissions, water effluents, or process wastes (closed processes); and, (2) PCBs generated in processes which have no quantifiable releases of PCBs (if EPA's specified analytical technique were used) to products, air emissions, or water effluents, and all other PCBs are disposed of in an EPA-approved incinerator, or in an EPA-approved landfill or stored for such disposal in accordance with certain

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specified criteria (controlled waste processes).

Based on the CMA data, EPA estimates that up to 58,606 pounds of PCBs per year could be exempted from the provisions and prohibitions of section 6(e) by this exclusion, and that on the order of several thousand individual processes could be permitted to operate unregulated by section 6(e). These estimates are derived from the available data on processes which meet the definitions of closed and controlled waste processes as they appeared in the May 20, 1981 ANPR. The estimates are expected to be upper limits, because this proposed rule defines closed manufacturing processes and controlled waste manufacturing processes in a more precise manner than they were defined in the May 20, 1981 ANPR (these definitions are discussed under IV.B. of this preamble). EPA is proposing to revise its definitions from those used in the ANPR because comments indicate that the previous definitions of closed and controlled waste processes were too vague and open to differing interpretations. Thus, some processes categorized by CMA as closed and controlled waste processes may not meet the definition of a closed or controlled waste process as proposed in this rule.

This exclusion would permit the future generation of larger quantities of PCBs as impurities and byproducts in closed and controlled waste processes than are currently produced. However, EPA does not believe that the promulgation of this rule will result in a dramatic increase in the production of PCBs in closed and controlled waste processes because there is no known incentive for such an increase, as PCBs are formed as impurities and byproducts in very low concentrations and are not produced as commercial products.

EPA is developing an enforcement strategy and compliance monitoring program to help to insure that only processes which qualify for this exclusion actually operate unregulated under section 6(e). In addition, EPA intends to conduct periodic audits to monitor the effectiveness of this rule. The purpose of conducting a regulatory evaluation (or audit) is to determine if the rule is accomplishing its objectives. EPA invites comments on the need for such a program.

Operators of PCB-generating processes who have determined that their processes are closed or controlled waste processes, as defined by EPA in this proposed rule, and who want to take advantage of this exclusion are also required to certify that they meet the exclusion, keep a record of the basis

for the determination, and make records and data available for review by EPA upon request. EPA is not proposing in this rule to specifically require monitoring of PCB levels in releases from these processes or the submission to EPA of data on PCB levels in releases as conditions for qualifying for the exclusion (see discussion under IV.G. of this preamble). Manufacturers have the option of conducting theoretical assessments or of actually monitoring PCB levels in releases to determine if processes qualify for exclusion. In order to qualify, manufacturers must demonstrate that PCBs would not be quantifiable in releases to other than controlled wastes if the analytical technique specified in § 761.62 were used. This technique is capillary gas chromatography coupled to an electron impact mass spectrometer (GC/C-EIMS).

EPA is developing guidelines to assist manufacturers in making their determinations of whether processes are closed or controlled waste processes. The guidelines developed by EPA will address how to conduct a theoretical analysis and the needed sampling frequency and the need for representative sampling of process streams if actual monitoring of PCB levels is undertaken. In addition, these guidelines will identify the type of quality assurance and quality control procedures which should be developed as an integral part of any program which involves actual monitoring of PCB levels. EPA will follow the guidelines when enforcing this rule. EPA expects that these guidelines will be available during the public comment period for this rule, and their availability will be announced in a separate Federal Register notice.

In judging whether the proposed definitions of closed manufacturing processes and controlled waste manufacturing processes qualified as de minimis situations, EPA considered three factors: (1) The quantity of PCBs that is likely to be released to the environment from these processes; (2) the potential magnitude of exposure and the frequency of exposure to PCBs from these processes; and (3) the benefits from regulating these processes, i.e., the likely reductions in exposure to PCBs that might result if these processes were regulated under section 6(e). EPA also considered whether the exclusion of these processes presented an unreasonable risk.

The evaluation of the issues and factors described above, the basis for EPA's findings, discussions of other options considered by EPA, and EPA's formal conclusion that these processes, as defined by EPA, pose de minimis

risks to public health and the environment follow.

B. Closed and Controlled Waste Processes—Definitional Issues

1. *Defining the absence of PCBs in products, wastes, emissions and effluents.* There are two general approaches the Agency could take to specify how the absence of PCBs is to be determined in air emissions, water effluents, products, and wastes.

First, EPA could select a regulatory cutoff for air emissions, water effluents, products, and wastes at a level where it believes PCBs cannot be practically detected at any lower concentrations. Under this approach, industry would be responsible for selecting analytical methods capable of detecting PCBs at the Agency's selected cutoffs. EPA might give some guidance to industry regarding analytical procedures.

Second, EPA could specify the analytical methods 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 for closed processes), using EPA's methods and procedures, the process would be eligible for exclusion. Under this approach, EPA could give some general guidance concerning the PCB concentrations it expects its procedures to be capable of detecting.

EPA is proposing the second approach, that of establishing an analytical technique. EPA chose this approach for several reasons. The Agency believes that the choice of analytical methods is one of the major sources of variability when attempting to detect PCBs. During the fall of 1981, 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. EPA believes that specifying the analytical technique will eliminate one of the sources of this variability.

EPA also believes that specifying a method is preferable to specifying a cutoff because the difficulty of analyzing products and wastes will vary considerably among processes. If EPA specified a numerical cutoff, some companies would be able to easily detect PCBs in their process streams below the cutoff, and other companies might have extreme difficulty detecting PCBs at the cutoff. In this regard, a numerical cutoff could be considered

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arbitrary. Specifying an analytical procedure mitigates this problem.

The analytical system most often used to monitor PCBs 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 area under the curve on the strip chart. When only the carrier gas is passing the detector, the detector generates a small, slightly variable, electrical signal, referred to as "background" or "noise." Detecting and confirming the presence of 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 that 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 is called the signal-to-noise ratio.

The lowest concentration of a substance that an analytical process can reproducibly quantify with a calculated 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.

At concentrations near the LOD, it is possible to detect that some chemical compound that might be a PCB is present, but it may be impossible to confirm its identity. False negatives and false positives are common. A PCB concentration at or near the LOQ may be needed to confirm the identity of the chlorinated biphenyl. For this reason, EPA proposes that the absence of PCBs be defined as a concentration of PCBs less than the LOQ for the proposed analytical methods. This establishes an easily enforceable condition for judging eligibility as a closed or controlled waste process.

EPA is faced with the problem of deciding the level of sophistication that should be used an analytical techniques. As more sophistication is required for measuring PCBs in very low concentrations, the cost of analysis increases and the availability of facilities and equipment to conduct analyses decreases. Because determining the absence of PCBs in products, air releases, and water releases is critical under this exclusion, the analytical methods selected and referenced by EPA for quantifying PCBs in these media need to be readily

available, have a cost that is reasonable relative to the environmental risks of PCB exposures, result in sufficiently reproducible data, and have adequate sensitivity.

EPA considered a number of techniques for extraction, cleanup, and determination of PCBs in samples. The analysis is extensive and is therefore not reproduced here. It is contained in the support document, "Methods of Analysis for Incidentally Generated PCBs-Literature Review and Preliminary Recommendations," which is available for review and comment.

The proposed method, outlined in § 761.82 and described in "Methods of Analysis for Incidentally Generated PCBs-Literature Review and Preliminary Recommendations," does not use specific extraction protocols or cleanup techniques, but rather, allows the individual laboratory to develop the necessary procedures. This is because these procedures are media dependent. EPA is, however, specifying the method of analysis it will use in enforcing this exclusion. The method specified by EPA is capillary gas chromatography coupled to an electron impact mass spectrometer (CGC/EIMS). CGC/EIMS systems are readily available. CGC/EIMS is cost-effective for multimedia analysis since separation and cleanup procedures for each media will ultimately provide an extract compatible with CGC/EIMS systems. While the reproducibility of the specified method remains to be documented for PCBs, available data from the analysis of other compounds suggests that this method does provide reproducible data. Further, CGC/EIMS does provide confirmatory evidence for PCBs, if present, at a moderate cost, and at an acceptable level of sensitivity (see below). EPA expects the method to supply reliable data of known quality if users implement an appropriate and documented quality assurance program.

The sensitivity of the EPA specified method has been estimated by EPA and is discussed below. The class of PCBs is made up of 209 individual chemical compounds, individually referred to as chlorinated biphenyls. Using EPA's referenced method, each separate resolvable peak or a gas chromatograph may represent a single chlorinated biphenyl, or it may represent all of a group of chlorinated biphenyls.

CGC/EIMS is capable of quantifying PCBs at the level of ten nanograms per resolvable gas chromatographic peak (see support document, "Rationale for Estimate of Level of Quantitation for GC/MS" for discussion). Per peak, this level roughly corresponds to an average of 1-10 micrograms per cubic meter for ten cubic meters of stack gas, 10-100

micrograms per liter for one liter of waste water, and 10-100 micrograms per 100 grams (0.1-1 ppm) in a 100 gram organic process or product stream.

The total amount of unquantified PCBs which could be released from a process will vary, depending on the number of specific isomers present in a particular sample. For example, if a product contains ten different isomers, present at concentrations slightly below 1 ppm, up to 10 ppm PCBs could be released in this product, and yet be unquantifiable by EPA's specified method. Similarly, if a product contains 70 isomers at concentrations slightly below 1 ppm, up to 70 ppm PCBs could be released in this product. EPA does not anticipate that samples will frequently contain greater than 70 isomers. Rather, EPA expects that in most cases samples will contain considerably less than 70 isomers.

EPA has considered other detection systems such as electron capture detectors (ECD) and negative ion chemical ionization mass spectrometry (NICIMS). ECD was found to be very sensitive, readily available and of moderate cost. It is, however, inappropriate because it does not provide confirmatory evidence that the residues detected are PCBs, and not other halogenated organics that are likely to be present in many samples. NICIMS was found to provide confirmatory evidence, but it is inappropriate due to high cost and limited availability.

EPA believes that its approach to analyzing for PCBs satisfies all the requirements of an acceptable method. EPA requests comments on this proposed approach, especially in the areas of confirmability, sensitivity, cost, and availability.

2. *Other options considered by EPA for defining the absence of PCBs in emissions, effluents, products and wastes.* (i) "No quantifiable" PCBs. EPA also considered defining the absence of PCBs as no quantifiable PCBs in air releases, water releases, products, or wastes using any available analytical technique. This option was not selected principally because of the uncertainty it would cause in the regulated community and problems in assuring compliance. In the absence of specified analytical procedures or specific numerical limits, a requirement for "no quantifiable PCBs" in air releases, water releases, products, and wastes would result in the use of many different procedures with vastly different quantification limits. This is particularly true for products and waste streams where the difficulty of analysis varies more than in the case for

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air or water. In addition, state-of-the-art limits of quantification for PCBs will change over time with technological innovation; thus, a floating limit would occur. All of these factors would hinder uniform implementation and enforcement of the rule.

(ii) Not specifically excluding closed manufacturing processes. EPA considered excluding closed processes only if all process wastes were incinerated, disposed of in an EPA-approved landfill, or stored for later incineration or landfilling. The reason EPA considered this alternative is that it has been suggested that it may be particularly difficult to identify universally applicable analytical methods for waste streams.

The CMA survey indicates that only about 3 percent of the processes identified by its members were closed processes. Consequently, EPA believes that if this approach were taken, no more than a few hundred individual processes would be affected nationwide.

This option was not selected because EPA concluded that reasonable analytical procedures for detecting PCBs in waste streams could be established and that manufacturers utilizing closed processes should be able to benefit from the exclusion without having to incinerate or landfill wastes possibly containing no PCBs.

EPA requests comments on the alternatives presented in this section and any other alternatives that may be appropriate. EPA specifically invites comments and data on the extent to which this proposal will affect persons involved in the manufacture, processing, distribution in commerce, and use of PCBs. EPA is particularly interested in receiving comments on the approach selected, i.e., to specify analytical techniques for quantifying PCBs in process streams.

3. Determining appropriate methods for disposal. The May 20, 1981 ANPR defines acceptable methods of handling wastes from controlled waste processes as incineration, disposal in EPA-approved chemical waste landfills, and storage for such incineration or landfilling. An EPA-approved chemical waste landfill is a facility approved under § 761.75. However, EPA did not specifically define "incineration" or "storage for incineration or landfilling." After further consideration, EPA believes that additional clarification of the acceptable methods of disposal is needed under the definition of a controlled waste manufacturing process.

Certain methods that may meet the general definitions of "incineration" and "storage for incineration or landfilling" could result in releases of PCBs to the

environment. Since EPA is proposing to exclude controlled waste manufacturing processes from the provisions of section 6(e) based on the de minimis risk principle, EPA must be reasonably confident that the wastes from controlled waste processes are disposed of in a manner which will result in negligible environmental contamination. Therefore, EPA is proposing to specify acceptable methods of disposal for wastes from controlled waste processes.

EPA is proposing that eligibility for exclusion as a controlled waste process requires incineration by a facility approved under § 761.70, landfilling in a landfill approved under § 761.75, or storage for incineration or landfilling in compliance with the criteria specified in § 761.65(b)(1).

The criteria specified in § 761.70 require that the incinerator used for destruction of PCBs be approved by the EPA Regional Administrator and that it meet certain standards related to efficient combustion. Incineration in compliance with these standards has been shown by extremely sensitive tests to result in essentially no release of PCBs to the atmosphere.

The criteria specified in § 761.65(b)(1) for the storage of PCBs require that storage facilities meet standards including adequate flooring with continuous curbing, no drain valves or floor openings, and construction of floors and curbing with impervious materials.

EPA already has in effect a Disposal and Marking Rule (43 FR 7150), which requires PCBs in concentrations over 50 ppm to be disposed of in accordance with the criteria prescribed under §§ 761.70, 761.75, and 761.65. These are the same disposal criteria being proposed for controlled waste processes. Consequently, this proposal of requiring stricter criteria for disposal of wastes than was implied in the definition of controlled waste process in the ANPR will effect only persons using processes which release PCBs to waste streams at concentrations between the limit of quantification and 50 ppm.

EPA invites comments and data on the extent to which this proposal or alternate requirements for incineration, landfilling, and storage will affect persons involved in the manufacture, processing, distribution in commerce and use of PCBs.

C. The Likely Magnitude of Releases of PCBs and Exposure To PCBs From Closed and Controlled Waste Processes

1. Routine operations. As discussed earlier, CMA speculates that many processes may meet the definitions of closed and controlled waste processes

as they appeared in the May 20, 1981 ANPR. An upper estimate from CMA data and CMA and EPA assumptions about the data (see unit III) suggests that up to 56,000 pounds of PCBs per year could be generated in these processes.

In this rule, EPA is proposing to define closed and controlled waste processes by specifying the absence of PCBs in releases and specifying appropriate methods of disposal. Therefore, EPA anticipates that fewer processes may actually qualify for exclusion than was suggested by EPA calculations based on the CMA data and extrapolations from those data to the entire chemical industry. EPA anticipates that, based on current production, less than 56,000 pounds of PCBs per year would actually be excluded from the provisions of section 6(e) under this proposed exclusion.

It is theoretically impossible to preclude the release of some PCBs from manufacturing processes in which PCBs are generated. Therefore, extremely small quantities of PCBs will be released from closed and controlled waste processes to the environment, as free PCBs, contained in air emissions, water effluents, wastes, and products. Actual environmental releases from products are expected to be even less, since the PCBs in many products are bound in solid matrices (i.e., paints and polymers). Although wastes from controlled waste processes will contain higher levels of PCBs, the proposed requirements for handling these wastes will prevent significant releases to the environment.

Workers may be exposed to PCBs that are produced in closed and controlled waste manufacturing processes through a variety of activities involving manufacture, processing, distribution in commerce, and use. Exposures may occur through: (1) Direct handling of products, wastes, or other materials containing low level PCBs, (2) handling of containers for these materials; (3) maintenance of equipment, and (4) handling of laboratory samples containing PCBs.

EPA evaluated occupational exposure to PCBs by first identifying six generic activities which are likely to occur during routine operations in chemical manufacturing plants, and then calculating the anticipated exposure to PCBs from these activities. These activities are: (1) The sampling of process streams, (2) the cleaning of reactors, (3) removing spent filters, (4) repairing equipment, (5) removing still bottoms, and (6) handling, storage and loading of products. EPA anticipates that the handling, storage and loading of

products in a continuous operation will result in the lowest levels of exposure, while cleaning reactors in a batch operation will result in the highest levels of exposure (see support document entitled "Occupational Exposure to Inadvertently Produced PCBs" for more details).

Industry representatives have commented that the chemical industry employs proper protective clothing and good management practices to protect workers from exposure to process components. Safety glasses, gloves, and long-sleeved shirts were reported as being generally used when contact with a toxic or corrosive chemical may occur. In addition, comments were received that indicated that additional protection, including splash goggles, shields, gloves, and protective outer clothing is usually required during waste handling operations. EPA has concluded that exposure levels during routine operations are not expected to result in significant exposure because of measures already instituted in the industry to reduce exposures.

EPA specifically requests additional comments on exposure to PCBs, particularly the degree of absorption of PCBs that might occur during routine operations in chemical manufacturing plants.

2. Accidental and unplanned releases.

Accidental releases may occur when pipes, lines, or hoses rupture. Unintentional spills can occur during the transfer and transport of products and wastes. These unplanned events may expose unprotected workers, the general public, and fish and wildlife to higher PCB levels than routinely occur during normal plant operations. EPA has little information from industry indicating the frequency of unplanned events, and the likely releases during these events. However, industry representatives have contended that scheduled maintenance activities and process engineering and design considerations minimize the potential for accidental releases. Comments indicated that it is in the best interest of companies to work to minimize the loss of process components from accidental releases, because large or frequent accidental releases would seriously harm production and profitability. EPA's independent exposure assessment confirms this, as major accidents (resulting in large releases or process components) are expected to be rare (on the order of once every sixty years per facility).

EPA requests comments and data on: (1) The types of accidental releases that might occur and their frequency, (2) the likelihood of releases of PCBs to the environment from such accidents, and

(3) measures being taken by industry to prevent accidents or to control releases and exposures when accidents do occur.

D. Conclusion: Processes Covered by This Rule Present de Minimis Risks

TSCA section 6(e) specifically bans the manufacture, processing, distribution in commerce, and use of PCBs in other than a totally enclosed manner. The adverse effects of PCBs were described in considerable detail in various documents which were part of the rulemaking record for the May 31, 1979 rule. While substantial comments have been submitted to EPA rebutting the conclusions made with respect to the toxicity of PCBs, the Agency does not agree that this information proves that PCBs do not pose any serious risks to human health or the environment. EPA believes however, that the risks posed from exposure to PCBs are reduced as exposure to PCBs is reduced; and, that an unmeasurable level of exposure to PCBs can be considered to pose de minimis risks to public health and the environment.

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 emissions are not quantifiable if EPA's specified analytical technique were used. For closed manufacturing processes, releases of PCBs in wastes also must not be quantifiable by EPA's specified analytical technique. EPA also is proposing to require wastes from controlled waste processes to be disposed of by incineration in a facility approved under § 761.70; landfilling in a landfill approved under § 761.75; or stored for incineration or landfilling in compliance with the standards and requirements prescribed in § 761.65(b)(1).

Precluding releases of PCBs above the limits of quantification will insure that only negligible releases of PCBs occur. Further, disposal of wastes in compliance with the above standards will prevent the release of PCBs in anything but negligible quantities. EPA does not believe that any significant harm will result from releases of PCBs to the environment or exposure to humans at unmeasurable levels. Since the releases are not measurable by reasonably available methods, it would be impossible to determine whether regulation had any effect on reducing the releases. Also, EPA does not know of any reasonable way to regulate releases of PCBs below measurable levels in order to reduce the releases further. Consequently, there would be

no gain in protecting the environment or public health by attempting to regulate unmeasurable levels. Finally, EPA's upper estimate of the amount of PCBs which currently would be excluded from the prohibitions and requirements of section 6(e) by this exclusion is 56,000 pounds of PCBs per year. Of the tiny fraction of these PCBs that are not destroyed in the process or handled as a controlled waste, some will be bound in products, further limiting the actual quantity of free PCBs that are likely to enter the environment. Although this proposed rule would not prevent these amounts from increasing, EPA is not aware of any reason why these quantities should increase significantly. It is possible that some companies may institute engineering modifications to their processes to qualify for the exclusion. This would, however, benefit public health by reducing overall releases of PCBs to the environment. The amount of PCBs expected to be released annually from these excluded processes is only a tiny fraction of the estimated 150,000,000 pounds of PCBs that currently exist in the environment as free PCBs.

Therefore, EPA finds that if releases of PCBs from closed and controlled wastes processes (excluding controlled wastes) are unquantifiable by EPA's specified analytical techniques, and controlled wastes are disposed of as specified by EPA, then these processes represent de minimis risk situations and should not be subject to the prohibitions and other provisions of section 6(e).

E. 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 reasons discussed below.

1. *Health and environmental effects and exposure to PCBs.* EPA has determined that exposure to PCBs from closed and controlled waste processes is so low as to be reasonably unquantifiable. Since the risks posed from exposure to PCBs decrease as levels of exposure decrease, EPA believes that exposure to PCBs at nonquantifiable levels from closed and controlled waste processes poses de minimis risks to public health and the environment.

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 exemptions 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 \$128,000 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 \$63 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 since it imposes no additional burdens but rather, avoids some of the burdens imposed on industry by the prohibitions of section 6(e). As discussed earlier, EPA is proposing in this rule to require manufacturers who operate closed and controlled waste manufacturing processes and who desire exclusion to certify that their processes are closed or controlled waste processes. EPA is proposing to give manufacturers the option of conducting a theoretical analysis to demonstrate that PCBs would not be quantifiable by EPA's specified technique in releases other than to controlled wastes, or of actually monitoring releases for PCB levels. EPA estimates the cost of certification without actual monitoring of PCB levels in releases to be on the order of \$84.00 per process per year. EPA estimates the cost of conducting a theoretical analysis to be on the order of \$800 per process. If

actual monitoring of PCB levels is undertaken, using the EPA-specified method, EPA estimates the costs of monitoring to range between \$200 and \$2,000 per sample. Total costs per process range from \$1,200 to \$72,000, depending on the frequency of sampling and the actual costs of testing (see support document entitled "Cost Analysis for the Proposal to Exclude Closed and Controlled Waste Processes from the PCB Ban" for details). This exclusion substantially reduces the cost to industry associated with the expense and problems of annually developing, analyzing, and preparing petitions for exemption from the section 6(c) ban and the cost of EPA of processing these petitions.

F. Relationship of the Proposed 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, or 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 proposed rule has no effect on the existing marking and disposal regulations. It simply excludes PCBs generated in controlled waste manufacturing processes from the section 6(e) ban when all PCBs generated are handled in ways prescribed under the existing disposal 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 prohibited 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, EPA requested an extension of this stay of mandate until December 1, 1982. Prior to that time, EPA intends to 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 until the rulemaking is completed.

G. Determining Eligibility for Exclusion

Persons producing PCBs as impurities or byproducts in manufacturing processes need a means of determining whether they are eligible for this exclusion. Further, EPA is naturally concerned that only processes which meet the proposed definitions of closed or controlled waste processes are permitted to operate unregulated under section 6(e).

To accomplish these objectives EPA is proposing an amendment to Subpart J which would require that persons who produce PCBs and who consider themselves eligible for the exclusion certify that their processes meet EPA's definition of a closed or controlled waste process, i.e., PCBs are not quantifiable in releases from these processes (in other than controlled wastes) by the EPA-specified analytical technique. They would be required to develop and maintain records on the basis for their certification. Manufacturers are given the option of developing a theoretical assessment which demonstrates this, or of actually monitoring PCB levels to support certification. If actual monitoring is undertaken, those persons are required to maintain a record of any analytical data that they obtain on PCB levels in the processes or in releases from their processes. If monitoring is elected, this proposed rule does not require that the EPA-specified method be used. Any technique can be used, but the standard that must be met is still that PCBs are not quantifiable in releases (except in controlled wastes) if the EPA-specified technique were used. This section specifies the format for such a self-certification and the recordkeeping necessary to support this certification.

The primary purposes of this self-certification program are (1) for persons to determine if the rule is applicable to them and (2) to aid EPA in monitoring compliance. This approach would provide reasonable assurance that only processes which actually meet the definitions for exclusion operate unregulated under section 6(e). By being able to self-certify, industry avoids the costs of petitioning for exemptions under section 6(e).

The self-certification process begins with compiling data to show that a process meets EPA's definition for exclusion. This may include actual monitoring of PCB levels in releases, or it may consist solely of preparing information for use in a theoretical assessment. EPA considered establishing rigid requirements for the type of data needed to support a manufacturer's determination that a process is closed or controlled waste manufacturing process. EPA considered requiring monitoring of releases from processes to air, water, products, and wastes (of closed processes). EPA evaluated the feasibility of specifying the frequency of sampling and places for sampling in manufacturing facilities.

EPA determined that it was not feasible to develop and propose a detailed monitoring program of broad applicability because of the extreme variability among processes and manufacturing facilities. Rather, EPA is proposing to allow manufacturers to select either theoretical assessments or actual monitoring of PCB levels to support certification. EPA intends to develop guidelines to assist persons in the evaluation of manufacturing processes for eligibility under the closed and controlled waste process exclusion. These guidelines will identify processes likely to produce PCBs and specify the types and nature of data that would be considered acceptable to support a determination that a process is closed or controlled waste process. These guidelines will address how to prepare a theoretical assessment, as well as how to conduct actual monitoring of PCB levels in releases. In addition, these guidelines will describe the type of quality assurance and quality control procedures which should be developed as an integral part of any program which involves actual monitoring of PCB levels.

A determination that PCBs are absent by actual monitoring of PCB levels must take into account that statistical variability in analytical results which will always occur. Recognizing that there will be variation results of a series of samples taken from a particular

stream, EPA will attempt to develop a sampling procedure that uses a sequential sampling scheme.

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. The sequential sampling procedure indicates, after every sample or group of samples is analyzed, 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. The sequential sampling scheme used by EPA will insure that the decision that the level of PCB concentration exceeds a quantifiable level will be incorrect for approximately 5 percent of the streams sampled (95 percent confidence level). EPA believes that a high level of confidence is desirable to insure that incorrect decisions that a process should be excluded from the ban will occur infrequently. EPA specifically requests comments on the appropriateness of a 95 percent confidence level for this decision.

The guidelines developed by EPA can be used as reference tools by manufacturers when they evaluate their processes to determine if they are eligible for exclusion. They will be used by EPA in monitoring compliance with this rule. EPA expects that the guidelines will be available during the public comment period to this rule. EPA intends to announce their availability through a Federal Register notice.

EPA considered requiring reporting data to the Agency on a semi-annual or an annual basis. EPA also considered requiring reporting one time with recertification being required upon significant process changes. EPA is proposing that no reporting be required. With no requirement to report to EPA that certain processes qualify for exclusion, some processes may be mislabeled as qualifying for the exclusion when in reality the manufacturer should be petitioning for an exemption. To help reduce the likelihood of this occurring, EPA is developing an enforcement strategy. EPA's enforcement strategy will include identifying processes which are likely to generate PCBs as impurities and byproducts. EPA intends to use the petitions for exemption, among other sources of information, to identify generic processes which are likely to generate PCBs. This information would accompany the analytical guidance to

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be distributed for this rule. After developing the enforcement strategy, EPA will then determine if companies manufacturing similar products have petitioned for exemptions. If petitions have not been submitted by particular manufacturers, EPA will examine company records of persons who claim their processes are closed or controlled waste processes. Through these means, EPA believes it can effectively assure that the exclusion is not being abused.

With the proposed approach, manufacturers would identify processes which they believe generate PCBs as impurities or byproducts, determine if the processes are closed processes or controlled waste processes, and place data and records of their determinations in records at the facility. Should manufacturers periodically undertake monitoring of PCB levels in processes or in releases from the processes, these data would also be retained. EPA is proposing to require that such records be maintained for seven years, or for at least three years after the particular process being used at the facility ceases operations, whichever is shorter. Further, EPA is proposing to require that processes be reevaluated and that a new certification be filed upon significant process changes that invalidate the previous certification. A significant process change is one which is likely to change the concentration of PCBs in releases from the processes (except in controlled wastes).

In addition, EPA intends to develop and conduct an audit program to monitor the effectiveness of this rule. The purpose of this program is to determine if the rule has accomplished its objectives, and to identify potential areas where revisions or modifications are needed.

Other alternatives that EPA considered but rejected are discussed below.

1. Certification by EPA. Under this alternative, every company desiring to classify a process as a closed or controlled waste process would be required to submit theoretical or analytical data to EPA with a request for certification as a closed or controlled waste process. After EPA reviewed the submitted data and the request, it would send the company a determination of eligibility for exclusion from the requirements of section 6(e) under the closed and controlled waste process exclusion. This approach would be very costly and burdensome to industry and EPA. It would require the development of data and submittal of data to EPA from everyone in the chemical industry and other industries who generate PCBs to prove that they are closed or

controlled waste processes (or petition for exemption). It would require EPA to expend substantial resources reviewing the applications for exclusion. By setting up such an annual certification procedure, in effect industry and EPA would be subject to monitoring, reporting, and reviewing requirements similar to those incurred under the regular exemption process. One of the main reasons for this rule is to relieve manufacturers and processors of the burdens imposed by an exemption process when the potential exposure to PCBs from their processes is very low. However, this approach would probably provide the greatest assurance that only companies that are truly eligible for the exclusion operate unregulated under section 6(e).

2. No documentation. EPA also considered not requiring recordkeeping by manufacturers utilizing what they consider to be closed or controlled waste manufacturing processes. Under this alternative, manufacturers would not be required to maintain any records of their determinations that processes operating at their facilities were closed or controlled waste manufacturing processes. This alternative eliminates the costs and burdens associated with documenting determinations that processes are closed or controlled waste processes.

Clearly, with no requirement to document determinations that certain processes qualify for exclusion, many processes may be automatically labeled as closed or controlled waste processes and operate unregulated under section 6(e). Further, a large amount of resources would have to be expended by EPA to verify manufacturers' claims that processes generating PCBs without specific exemptions are closed or controlled waste processes. This is because in many cases EPA would have to develop a verification strategy tailored to individual processes, and there would be no records for EPA to review to determine how the company concluded that it was eligible for the exclusion. It would be extremely difficult for EPA to identify anyone but the most flagrant violators. It is very likely that companies would not spend much effort to ensure that they actually met the criteria for exclusion since the likelihood of being identified as not complying with the rule would be very small.

H. Discussion of Analytical Method For Detecting PCBs

Section 761.82 designates capillary gas chromatography coupled to an electron impact mass spectrometer (CGC/EIMS) as the EPA specified analytical

technique for quantifying PCBs in air emissions, water effluents and product/process streams. CGC/EIMS is the analytical technique specified under the definitions of closed manufacturing process and controlled waste manufacturing process. To qualify for the closed and controlled waste process exclusion, PCBs must not be quantifiable by this technique in releases to air, water, and products (and wastes from closed processes). Although 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, if actual monitoring is undertaken, manufacturers may wish to use the method specified in § 761.82 to insure that they are in compliance with the rule. EPA will use this technique in conjunction with the yet to be published guidelines to determine whether processes are closed or controlled waste processes.

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 (CGC) coupled to mass spectrometry (MS). 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. These methods are useful in identifying the presence of materials which may require the confirmatory analysis outlined in § 761.82. For enforcement purposes EPA will use the analytical approach described in § 761.82.

2. Quality assurance plan for measurement of incidentally generated chlorinated biphenyls (PCBs). 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. For enforcement purposes EPA will use CGC/EIMS in conjunction with a QAP

to verify the accuracy of the data generated.

3. *Guidelines.* The guidelines EPA is developing will include 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, and (7) developing a QAP. Sample collection should be representative of the process to be characterized. Increased variation in the components of the process will increase the necessity to sample more frequently or to composite samples taken concurrently from several locations. The samples will then pass through a decision tree where pertinent procedures in the analytical method will be selected, based on the nature of a specific sample. As an example, for the homogenization step, aqueous samples free of suspended or settled solids would pass on to the extraction step. Aqueous samples with suspended matter would be stirred during subsampling and extraction. Aqueous samples with settled material, which could not be stirred into a suspension, would require pulverization of the solids and then could be treated as the aqueous sample which contained suspended matter. In the guidelines, other portions of the decision tree will be described for non-aqueous samples and for the other steps in analyzing for PCBs.

V. Summary of Issues

EPA specifically requests comments, data, and information relevant to:

1. The data presented in the CMA survey.
2. The appropriateness of excluding closed and controlled waste processes from the section 8(e) ban including EPA's rationale that closed and controlled waste processes pose de minimis risks to public health and the environment; and that the benefits of allowing these processes to be excluded outweigh the de minimis risks posed.
3. The need to specify criteria for determining the absence of PCBs in products, air emissions, water discharges, and wastes to define adequately processes subject to the exclusion; the desirability of one criterion for all releases or separate criteria for air, water releases, products, and wastes of closed processes; the suitability of the proposed analytical method for purposes of judging whether a process should be eligible for the exclusion. In particular, EPA seeks information relating to the effect that the

proposed method would have on persons involved in the manufacture, processing, distribution in commerce and use of PCBs.

4. The appropriateness of using limits of quantification versus limits of detection for defining the absence of PCBs in releases from processes.

5. The appropriateness of requiring controlled wastes to be sent to facilities in compliance with standards in §§ 761.70, 761.75, and 761.85. In particular, EPA seeks information relating to the effect that this requirement would have on persons disposing of waste from controlled waste processes, and on the environmental/health risks of not disposing of PCBs in this manner.

6. The need for a program whereby manufacturers demonstrate that their processes do qualify for exclusion; the desirability of a self-certification program versus one where the manufacturers report to EPA and the Agency determines whether they qualify. In particular, EPA seeks information relating to the effect that self-certification or other programs would have on persons who inadvertently manufacture PCBs, and on the problems or risks associated with not requiring certification and recordkeeping.

7. The suitability of allowing manufacturers to use best theoretical analyses in lieu of actual monitoring of PCB levels. In particular, EPA seeks information relating to the effect that requiring monitoring data or theoretical analyses would have on persons inadvertently manufacturing PCBs.

8. The retention time for records (7 years or 3 years after a process ceases operation, whichever is shorter).

9. The cost and economic impact of this exclusion policy. Specifically:

- a. The costs of EPA's recommended analytical technique for determining the absence of PCBs, including sampling and storage costs.
- b. The costs of recordkeeping and reporting which might be required for eligibility for the exclusion.
- c. The availability of testing equipment to perform testing in-house and/or the availability of outside laboratories to perform tests.
- d. The costs to manufacturers of performing "best theoretical analyses" in lieu of actual monitoring of PCB levels.
- e. The costs of incinerating wastes in EPA-approved incinerators, landfilling in EPA-approved landfills, and storage for incineration or landfilling under this exclusion.
- f. The costs of filing for an exemption petition, including the costs of making

and documenting a "good faith effort to develop substitutes for PCBs" and the cost of determining and documenting that "no unreasonable risk" exists.

VI. Authority

Section 8(e) of TSCA [15 U.S.C. 2805]. The Administrator of EPA has delegated 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), to the Assistant Administrator for Pesticides and Toxic Substances.

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 proposed 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 proposed 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 proposed rule excludes certain uses of PCBs that would otherwise be prohibited by section 8(e) of TSCA and, therefore, reduces the overall costs and economic effect of section 8(e).

The proposed rule was submitted to the Office of Management and Budget (OMB) prior to publication, as required by the Executive Order. Any comments from OMB to EPA and any response by EPA to those comments are available for public inspection as part of the public record of this rulemaking.

VIII. Regulatory Flexibility Act

Under section 805(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 proposed 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 proposed rule, I certify that this rule will not, if promulgated, 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 proposed 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 proposed rule (if adopted in the final rule) will be submitted to OMB under section 3504(b) of the Act.

X. Official Rulemaking Record

Proposed 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 proposed rulemaking. A supplementary list or lists may be published at any time on or before the date the final rule is issued. However, no such list will 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 full list of these materials will be available on request from the Document Control Officer listed under "ADDRESSES."

A. Previous Rulemaking Records

1. Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions Rule" 44 FR 31514, May 31, 1979.
2. Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Disposal and Marking Final Regulation" 43 FR 7152, February 17, 1978.

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."

C. Support Documents

1. USEPA, OTS, "Summary of ANPR Comments."
2. USEPA, OTS, "Occupational Exposure to Inadvertently Produced PCBs."
3. USEPA, OTS, "Methods of Analysis for Incidentally Generated PCBs Literature Review and Preliminary Recommendations."
4. USEPA, OTS, "Cost Analysis for the Proposal to Exclude Closed and Controlled Waste Processes from the PCB Ban."
5. USEPA, OTS, "Internal Memorandum of EPA Review of CMA Submitted Toxicity Data."
6. USEPA, OTS, "Quality Assurance Guidelines."
7. USEPA, OTS, "Rationale for Estimating Level of Quantification for CCG/EMIS."
8. USEPA, OTS, "Estimation of Releases from Spills of Inadvertently Produced PCBs."

D. Reports

1. Chemical Manufacturers Association, "A Report of a Survey on the Incidental Manufacture, Processing, Distribution, and Use of Polychlorinated Biphenyls 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."

EPA will identify the complete rulemaking record on or before the date of promulgation of the final rule, as prescribed by section 19(3) of TSCA. EPA will consider for inclusion in the record additional material submitted at any time between the publication of this notice and the date the Agency identifies the final record. The final rule will also permit persons to point out any omissions or errors in the record.

XI. Additional Information

The comment period for this rule is limited to thirty days because EPA is under court order to promulgate a final rule by October 13, 1982.

EPA requests that comments be submitted in triplicate. Comments should include the docket number, OPTS 62017A. Comments on this proposed rule will be available for review from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays, in Rm. E-107 Environmental Protection Agency, 401 M St., SW., Washington, D.C.

Requests to participate in the informal hearing should be made in writing to the Industry Assistance Office at the address given above. All requests for participation must include, at least, a detailed outline of the topics to be addressed in the opening statement, the amount of time requested for the statement, and the names of the participants. Statements should not

repeat information already presented in written comments but should address additional information or issues. All hearings will be conducted in accordance with EPA's "Procedures for Rulemaking Under Section 8 of the Toxic Substances Control Act" (40 CFR, Part 760).

List of Subjects in 40 CFR Part 761

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

Dated: June 2, 1982.

Anne M. Gorsuch,
Administrator.

Therefore, it is proposed that 40 CFR Part 761 be amended to read as follows:

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

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 § 761.3 (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) and (kk) are added to § 761.3, to read as follows:

§ 761.3 Definitions.

(jj) "Closed manufacturing process" means a chemical manufacturing process in which PCBs are generated but from which no quantifiable PCBs are released to air, water, products, or in process wastes if the analytical method specified in § 761.82 were used.

(kk) "Controlled waste manufacturing process" means a chemical manufacturing process in which PCBs are generated but from which no quantifiable PCBs are released to air, water, or products if the analytical methods specified in § 761.82 were used, and the remainder of PCBs generated are incinerated in an incinerator approved under the provisions of § 761.70, landfilled in a landfill approved under the provisions of § 761.75, or stored for such incineration or landfilling in accordance with the requirements of § 761.85(b)(1).

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3. A new Subpart E, consisting at this time of § 761.82, is added to read as follows:

SUBPART E—METHOD OF ANALYSIS

§ 761.82 Analytical method and quality assurance plan for quantifying PCBs in air, water, products, and closed process waste streams.

(a) *Analytical approach.* This section is the Agency's designated analytical approach for non-Aroclor PCB analysis. This technique is the method specified under the definitions of closed manufacturing process and controlled waste manufacturing process. The approach includes a description of the analytical technique and a description of the necessary quality assurance program (QAP). This is the analytical technique and QAP which EPA will use in determining whether a process falls within the closed and controlled waste manufacturing process exclusion (see § 761.1(f)).

(b) *Analytical technique.* (1) A specified number of samples is taken according to a suggested procedure. Each sample, if too large to go directly to extraction, would be thoroughly homogenized and a representative subsample would be removed.

(2) Each sample (or subsample from paragraph (b)(1) of this section) then has surrogate compounds, e.g., several ^{14}C PCB isomers, incorporated into it. These surrogates are used in quantitation and to document recovery rates.

(3) Each sample is then subjected to an extraction and/or cleanup procedure. Through this procedure, the original sample would have any contaminants and interfering compounds removed from it, and ideally an extract with only PCBs would remain. The extraction procedure would vary for different media (air, water, solid) and matrix (chlorinated, non-chlorinated, etc.).

(4) Each sample extract would be concentrated or diluted to a known volume. This known volume is used in the quantitation procedure.

(5) A known amount of the prepared extract is then removed and introduced into a capillary gas chromatograph (CGC) coupled to an electron impact mass spectrometer (EMIS).

(6) The instrumental response is then integrated so that the levels are described by PCB homolog (mono-, di-, and trichlorobiphenyls, etc.) and each PCB homolog is quantitated based on the known responses of the ^{14}C surrogates (see paragraph (b)(2) of this section).

(7) All 10 homolog concentrations are then summed to obtain a "total PCB" value.

(c) *Quality assurance program.* A quality assurance program includes:

(1) An accurate trace or history of the life of a sample (to be chemically analyzed for PCBs) including a description of the scheme for sample collection including a written description of what happens to the sample, schedules and timetables, disposition and handling.

(2) Details of the sample collection procedure including:

(i) Reasons for using a particular sample selection process and reasons for not using other processes.

(ii) Estimates of how well the selected samples represent the medium to be characterized.

(3) A full, detailed description of the extraction and chemical analysis procedures.

(4) The results of laboratory participation in round robin analytical programs, the results of performance audits, the results of systems audits, and analytical results of performance audit specimens.

4. Section 761.185 is added to read as follows:

§ 761.185 Self-certification program and retention of special records by persons incidentally 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 chemical 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 facility: (1) Collects data on the process and performs either a theoretical analysis of PCB levels in releases or conducts actual sampling of PCB levels in releases.

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

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

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

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

(D) Any additional information relevant to the analysis of the process for PCBs.

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

(B) The results of the analysis, including data from the QAP.

(C) The name of the analyst or analysts.

(D) The date and time of the analysis.

(E) Any additional information relevant to the analysis of the process for PCBs.

(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) If the analytical method specified in § 761.82 were used, PCBs could not be quantified in air releases and water releases from the manufacturing process, or in products of the manufacturing process.

(4)(i) If the analytical method specified in § 761.82 were used, PCBs would be below the limits of quantification in process wastes.

(ii) All process wastes are either incinerated in accordance with § 761.70, 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 include the name and location of the disposal facilities (if the process is a controlled waste process). The certification must be signed by a responsible corporate officer. For the purpose of this section, a responsible corporate officer means: (i) 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.

(ii) 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. This certification process must be repeated whenever process conditions are significantly modified to make the previous certification no longer valid. This certification must be filed at each facility in which a closed or controlled

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waste process is operating for a period of seven years or for three years after a process ceases operation, whichever is shorter, and must be made available to EPA upon request.

(d) 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 person 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 _____

(FR Doc. 82-15088 Filed 6-7-82; 8:45 am)

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