

To make penalty assessment reasonably uncomplicated and consistent, while leaving some discretionary judgment in the Regional Administrator, this system requires an initial assignment of a violation to one of four levels of gravity. The initial penalty assessment will be at a fixed amount for each level of gravity. Following the initial assessment several adjustment factors, as specified in the statute, are utilized to raise or lower the initial penalty.

The four gravity levels are as follows:

Level I - This violation is of the type which could cause only localized harm, such as failure to promptly dispose of PCB contaminated rags, minor leaks in stored transformers, etc. The initial assessment for a Level I violation will be \$1000/day/violation. Where such a violation meets the criteria discussed on page E3 for issuance of a Notice of Non-compliance, the penalty may be waived.

Level II - These violations are generally serious in nature. This level may include general recordkeeping and marking violations, and storage violations where exposure is more hazardous than at Level I. The initial assessment for a Level II violation is \$5000/day/violation.

Level III - This level applies to violations of a very serious nature. Such violations may include failure of incinerators to maintain proper temperatures for sufficient periods of time, and leakage from a chemical waste landfill not resulting in permanent environmental damage. In many cases, the differences between Levels II, III and IV violations are largely only ones of degree, depending on such factors as the extent of possible harm. The initial assessment for a level III violation is \$15000/day/violation.

Level IV - These violations are the most egregious, both in terms of blatant disregard for the requirements of the standard and damage caused. Such violations would include significant spilling and dumping of PCBs resulting in large scale contamination and operating an unapproved disposal facility. The initial assessment for Level IV is \$25,000/day/violation.

In determining the gravity level for a violation, the Violation Coordinator, in accordance with regional procedures, should incorporate the statutory factors of nature, circumstances and extent of the violation, i.e., rather than computing separately for nature, circumstances, extent and gravity, all four factors should be considered in the initial level assignment which is termed "gravity". In arriving at this determination, the Coordinator should consider factors such as the extent of exposure, both in terms of numbers, (i.e., number of people, volume of water) and possible severity and permanence of harm. It must be kept in line that the examples of levels of gravity as used above and in the attached Appendix I should not be rigidly applied, since the circumstances behind an otherwise minor violation could render it a more major violation e.g., minor leaks in stored transformers where the leak could degrade

1. there is a PCB spill or leak which poses a risk of injury to health or the environment, and our immediate concern is the cleaning up of the spill or leak rather than the assessment of civil penalties (of course, such an action may also be commenced under the Act's imminent hazard provisions (§7)); or
2. we have reason to believe in the case of a particular violator, based on prior actions or other information, that abatement of his violative practices can only be accomplished by a court order; or
3. the relief desired is that certain PCBs be seized and condemned.

Where the violation coordinator determines that a civil court action is necessary, he must inform the Headquarters Regional Coordination Unit. No such action may be taken without approval from Headquarters.

Criminal Court Action

A criminal court action may be brought pursuant to §16(b), where the alleged violation was a knowing or willful one. These actions will most often be brought where the circumstances of the violation indicates a flagrant disregard for the PCB Regulations. Any contemplated criminal proceeding should be brought to the attention of Headquarters through the Regional Coordinator. Headquarters approval is necessary before a U. S. Attorney is contacted to initiate criminal proceedings.

3. If the Action taken Against the Alleged Violator is Assessment of the Administrative Civil Penalty, How Much Should the Proposed Civil Penalty Be?

This section provides some guidance and sets parameters for the assessment of civil penalties, pursuant to TSCA 16(a), for violations of Section 15(a). The only penalty guidelines provided in Section 16(a) are that penalties of up to \$25,000 may be assessed for each day of each violation, and that in assessing the penalty "the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect or ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." The following guidelines are intended to assure nationwide consistency in penalty assessment, and to assure that violation of TSCA should not only bring no economic benefit to the violator, but should be the cause of some financial loss, i.e., there should be a strong economic disincentive to violate the Act.

This section describes how to compute a penalty for the purpose of serving a written notice of proposed assessment of civil penalty under Section 16(a)(2).

Notice of Non-Compliance

Notice of non-compliance may be issued in lieu of a civil penalty, where:

- a. the violation does not constitute a significant threat to health or the environment;
- b. the violation is the first such violation of the PCB Marking and Disposal Regulation on the part of the particular violator;
- c. the violation is not a by a disposal facility, whether approved or unapproved, of any of the regulatory requirements governing such facilities under the PCB Marking and Disposal Regulation;
- d. the violation does not involve the illegal actual disposal of PCBs on the part of the violator (this does not include insignificant leaks); and
- e. the alleged violation does not appear to have been a willful one.

However, even though the violation satisfies the above tests, the administrative penalty remedy should not be summarily dismissed unless the violation coordinator determines the issuance of a notice of non-compliance will be sufficient to induce the violator to cease violation of the Regulation. The lesser remedy of issuance of a notice of non-compliance should be employed only where the Violation Coordinator determines, in his discretion, that the violation "passes" the above tests and that issuance of a notice of non-compliance will be sufficient to induce the violator to cease violation of the regulation in those respects stated in the notice of non-compliance.

Civil Court Action

A civil court action pursuant to §17 may be brought against an alleged violator, in addition to or in lieu of assessment of administrative civil penalty, where it is determined that the mere issuance of a civil penalty will be insufficient to obtain compliance with the regulation. Section 17 allows the Agency to seek injunctive relief, both to restrain violations of the Act and to compel a person to actually follow the Act. Since this injunctive type remedy is not available under §16 civil penalty actions, a civil court action under §17 will allow the Agency to enforce the regulation against the violator who is willing to pay civil penalties but refuses to continue to comply with the PCB Marking and Disposal Regulation. Thus, a civil court action may be appropriate in the following instances:

1. Is there a probable violation?

To determine whether or not there is a probable violation the Violation Coordinator must examine all the evidence provided in the Inspector's Report. In addition, the Violation Coordinator should take all other reasonable steps (such as speaking with the Inspector, personnel of the laboratory performing any relevant sample analysis, and appropriate Regional attorneys) which he deems necessary for a determination of the existence and extent of a violation. If the Violation Coordinator determines that there is insufficient evidence to indicate a violation he shall take reasonable steps to gather sufficient evidence if he believes that:

1. such evidence may be obtained without unreasonably intensive resource efforts, and
2. the violation, if substantiated, is not an insignificant one.

If the Violation Coordinator determines that there is sufficient evidence to indicate a violation, he shall determine in accordance with the following criteria, what action, if any, should be brought against the alleged violator.

2. What action, if any, should be brought against the alleged violator?

There are several types of actions which may be brought against the alleged violator. These are:

1. notice of non-compliance
2. administrative civil penalty
3. civil court action
4. criminal court action.

The starting point for the Violation Coordinator should be that most violations will be handled via administrative civil penalty. Thus, when the Violation Coordinator determines, based upon review of an Inspection Report and other review, that there is a violation he should assume at the outset that an administrative civil penalty should be assessed against the violator. After making this initial assumption he should comply with the following guidelines in determining whether another enforcement action should be taken in lieu of, or in addition to, administrative assessment of a civil penalty.

A. Wrap-up Activities of the Inspector.

After each inspection the inspector shall write an Inspection Report based upon information on the Violation Worksheet and his Field Notes. The Inspection Report shall detail all violations which the inspector believes he found during the inspection and shall describe all relevant supporting evidence. After completing the Inspection Report, he shall submit that document, a copy of his applicable Field Notes and other relevant supporting documents, in accordance with Regional procedures, to the designated Regional PCB Marking and Disposal Regulation Violation Coordinator. The inspector shall keep the original Field Notes in his files and shall make and keep on file copies of all other material sent to the Violation Coordinator.

B. Wrap-up Activities of the Laboratory.

After the laboratory performs its analysis on the PCB samples collected at the disposal site, the appropriate laboratory personnel shall send a copy of all laboratory records relevant to such sample analysis, along with a copy of the relevant Chain of Custody Record, to the Regional PCB Violation Coordinator. All originals of the above documents shall be maintained by the laboratory as permanent records until required in an enforcement action.

C. Decision Making by the Regional PCB Marking and Disposal Regulation Violation Coordinator.

Each Regional Administrator shall appoint a PCB Marking and Disposal Regulation Violation Coordinator. All PCB Marking and Disposal Regulation Inspection Reports shall be sent to such Violation Coordinator, in accordance with Regional procedures, by the inspector who made the inspection pursuant to the PCB Marking and Disposal Regulation. It should be emphasized that the Violation Coordinator may be any person whom the Region designates for such position. It is anticipated that the Regions shall integrate the function of the PCB Violation Coordinator into existing decision making structures.

The Violation Coordinator shall examine each Inspection Report and determine the answers to the following questions:

1. Is there a probable violation?
2. If yes, what type of action, if any, should be brought against the alleged violator?
3. If the action is one for administrative civil penalty assessment, how much should the proposed civil penalty be?

Criteria and guidelines for decision making in each of the above three areas are provided below.

ENFORCEMENT PROCEEDINGS MANUAL

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Annex VI: Records and Monitoring

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

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(d) when PCB containers or PCB substances or mixture contained in a transformer, are transferred to other storage or disposal facilities, failure to include the identification of the facility to which such PCBs were transferred (§761.45(b)(3)).

Check for the inclusion of all information required.

Document non-compliance in field book.

(f) The total number of any PCB articles or equipment, not in PCB containers, 1) received during the calendar year, and 2) remaining on the facility year, respectively, including the identification of the specific types of PCB articles and equipment received, transferred, or remaining on the facility site.

o When PCB articles and equipment are transferred to other storage or disposal facilities, failure to include the identification of the facility to which such PCB articles and equipment were transferred. (§761.45(b)(4)).

761.45(d):

In addition to the information required to be maintained by §761.45(b) above, each owner or operator of a PCB disposal or storage site collect and maintain, for the period described in #2 above, the following information:

Prior to a records inspection, the site approval file located at the EPA Regional Office should be reviewed for the presence of any documents listed under "regulatory requirements". If the EPA file contains any correspondence or permits not found in the records at the site, a violation exists.

Document non-compliance field book.

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VI: Records and Monitoring

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(2) Failure to include in the annual document:

Check for the inclusion of all information required.

Document non-compliance in field book.

(a) The date when any PCBs are received by the facility during the previous calendar year for storage or disposal, and the identification of the person and facility from whom such PCBs were received (§761.45 (b)(1)).

(b) The date when any PCBs are 1) disposed of at the disposal facility, or 2) transferred to another disposal or storage facility, including the identification of the specific types of PCB substances, mixtures, or articles in containers, PCB transformers, and PCB equipment or PCB articles not in containers which were stored or disposed of (§761.45(b)(2)).

(c) The total weight, in kilograms, of any PCB containers kilograms of any PCB substances or mixtures contained in any PCB transformers, 1) receiving during the calendar year, 2) transferred to other storage or disposal facilities during the calendar year, and 3) remaining on the storage or disposal facility site at the end of the calendar year respectively, including, where applicable, the identification of PCB container contents such as liquids, capacitors, etc.

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Annex VI: Records and Monitoring: Disposal and Storage Facilities (§761.45(b) & (d))

Records and monitoring requirements for storage and disposal facilities are designed to 1) identify the type, amount, and location of PCBs in various storage and disposal facilities, 2) enable EPA to compare storage and disposal records with those of facilities with PCBs in service, for the purpose of detecting discrepancies (which may indicate violations), and 3) to enable EPA to trace back to original user, so that any "in service" facilities that had previously escaped EPA notice may be identified.

<u>REGULATORY REQUIREMENTS</u>	<u>INSPECTION PROCEDURES</u>	<u>DOCUMENTATION</u>
Beginning July 1, 1979, failure of any owner or operator of a facility used for the storage or disposal of PCBs to prepare and maintain, by July 1 of each year, a document which summarizes PCB activities at the facility during the previous calendar year, and to make such documents available at the facility for inspection by EPA. (§761.45(b)).	Check for presence of document. Copy or photograph document for later comparison of records.	Document non-compliance in field book.
Failure to retain such documents at each facility for at least 5 years after the facility is no longer used for the storage or disposal of PCBs, except in the case of chemical waste landfills, where such documents shall be maintained for at least 20 years after the landfill is no longer used for disposal of PCBs (761.45(b)).	Check for presence of document	Document non-compliance in field book.
Failure of the owner or operator of the facility to notify the Agency R.A. of the Region in which the facility is located when the facility ceases storage or disposal operations. (§761.45(b)).	If the facility has ceased operations, check EPA records for presence of the notification and the specification of where all documents are located.	Document non-compliance in field book.

Annex VI: Records and Monitoring

REGULATORY REQUIREMENTS

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- (d) For owners and operators with more than one facility which contains PCBs in the quantities prescribed in #1, and maintaining the records and documents at a single location, failure to insure that the identity of this location is available at each facility containing PCBs that is normally manned for 8 hours a day. (§761.45(a)).

Call all facilities manned for 8 hours a day and ask where records and documents for the facility are kept. This requirement is designed to eliminate the need for EPA to go on "wild goose chases" looking for records. If we know the location of records for a firm, we do not need to determine if all facilities of the firm know the location. If we encounter facilities that do not know the records location and we need to know it, then it should be considered a possible violation.

Document non-compliance in field book.

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I. Records and Monitoring §761.45 Annex VI:

The general purpose of records and monitoring requirements is to (1) enable EPA to keep track of the types, amount, and location of PCBs and (2) to provide further impetus for stores and disposers to keep track of PCBs handled at the particular facility.

Records and Monitoring: PCBs in service or projected for disposal (§761.45(a))

Records and monitoring requirements for PCBs in service projected for disposal are designed to (1) identify the type, amount, and location of PCBs currently in service at a particular location and (2) enable EPA to trace PCBs through storage, transportation and disposal, in order to identify those people/facilities who receive PCBs when they are removed from service. Once receivers are identified, EPA may (a) compare records for the purpose of detecting discrepancies, (which may indicate violations), and (b) discover any storage and disposal facilities that had previously escaped EPA notice.

REGULATORY REQUIREMENT	INSPECTION PROCEDURES	DOCUMENTATION
(1) §761.45(a) PCBs in Service		
(a) Beginning July 2, 1978, for any owner or operator of a facility containing any of the following: (i) 45kg (99.4 lbs) or more PCB chemical substances or PCB mixtures, (ii) one or more PCB transformers, (iii) 50 or more PCB large high or low voltage capacitor, failure to develop and maintain records on the disposition of PCBs. (§761.45(a)).	Determine amounts of PCB chemical substances, mixtures transformers and large high or low voltage capacitors by inquiry and direct observation. If numbers equal or exceed regulatory requirements, check for the presence of records on the disposition of PCBs.	Document non-compliance field book.
(b) Failure to prepare an annual document, based on the above records of disposition, by July 1, covering the previous calendar year, which includes the following information:	Check for (1) presence of document, and (2) the inclusion of all data specified in (a) and (b). Copy or photograph document for later comparison of records.	Document non-compliance field book. When data has been omitted, photograph or copy document if possible.

Annex VI: Records and Monitoring

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(i) The dates when PCBs are removed from service, are placed in storage for disposal, and are placed into transport for disposal.

Obtain copies or make note of locations and names of all storage sites and final disposal sites.

(ii) Total quantities of PCBs remaining in service at the end of the calendar year. The quantities of such PCBs in 2(a) and (b) shall be indicated using the following:

o Total weight, in kilograms, of any PCB substances or mixtures in PCB containers, including the identification of container contents, such as liquids or capacitors;

o total number of PCB transformer and total weight, in kilograms, of PCB substances and mixtures contained in the transformers; and

o total number of PCB large high or low voltage capacitors.
((§761.45(a)(1) & (3)).

(iii) For PCBs removed from service, the location of the initial disposal or storage facility and the name of the owner or operator of the facility (§761.45(a)(2)).

(c) Failure to maintain records and documents for at least 5 years after the facility ceases containing PCBs in the prescribed quantities (H)(§761.45(a)).

If facility has ceased operations, ask former owner or operator where the document is located, and inspect for presence of all information required.

Document non-compliance field book. When data has been omitted, photograph and copy document if possible.

RECORDS AND MONITORING

Annex IV: Decontamination (§761.43)

REGULATORY REQUIREMENTS	INSPECTION PROCEDURES	DOCUMENTATION OF VIOLATIONS
(c) Was the solvent properly disposed of as a PCB mixture (§761.10(b)(2)), when the level of PCBs in the solvent reached 0.5 percent?	Observe procedures to verify compliance.	Document non-compliance in field book. Take sample.
(d) Were all materials used in the decontamination procedures properly disposed of as PCB mixtures (§761.10(b)(2))?	Check to insure that all liquids and solids used in decontamination are placed in a properly marked container and transferred to a storage area that complies with Annex III.	Document non-compliance in field book.
(2) Equipment (§761.43(b))		
(a) Was all moveable equipment used in storage areas decontaminated by swabbing surfaces exposed to PCBs with a solvent meeting the criteria of paragraph (a) above.	Observe procedures to verify compliance.	Document non-compliance in field book.

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Annex IV: Decontamination (§761.43)

The decontamination requirements are designed to bring the level of PCBs remaining in a container or on equipment after use down to a minimal level, in order to prevent other liquids or articles placed in the container or put in contact with equipment, from becoming contaminated with PCBs.

As decontamination is usually performed when fresh containers or equipment are needed, not at regular intervals, it is unlikely that the inspector will be able to observe decontamination procedures directly. However, it is possible to get a general idea of whether decontamination procedures are conducted in compliance with the regulation by asking "leading" questions such as:

- Are containers and equipment decontaminated after they have been in contact with PCBs?
- What is the normal decontamination procedure?

If the facility representative outlines the procedures listed under "Regulatory Requirements", it can be assumed that he/she is at least familiar with the decontamination requirements of the regulation.

If the representative does not outline the decontamination requirements of the regulation, it is unlikely that he/she is aware of proper decontamination procedures. In this case, the inspector should leave written instructions (based on the "Regulatory Requirements" column) describing proper methods of decontamination.

If, however, decontamination procedures can be observed directly, an inspection should be conducted as outlined below.

REGULATORY REQUIREMENTS	INSPECTION PROCEDURES	DOCUMENTATION OF VIOLATIONS
(1) <u>Containers (§761.43(a))</u>		
(a) Was the container flushed three times with a solvent containing less than 0.05 percent PCB chemical substance in which the solubility of PCBs was five percent or more (by weight)?	Observe procedures to verify compliance.	Document non-compliance in field book.
(b) Was the rinse volume of the diluent equal to approximately ten percent of the container's capacity?	Observe the filling or emptying of solvent into/out of the container. Measure amount of solvent used and determine internal volume of container. Compute to determine whether volume of solvent is equal to 10 percent of container's capacity.	Document non-compliance in field book.

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DECONTAMINATION

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REGULATORY REQUIREMENTS

(iv) Number of PCB articles or equipment not in PCB container received, transported to other storage or disposal facility, and remaining on facility site at end of calendar year. Identification of facility transferred to shall be included.

(j) Special Records Retention

(i) All documents, correspondence and data provided by State or local government agency pertaining to storage.

(ii) All documents, correspondence, and data provided by facility to State or local government agency pertaining to storage.

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Examine facility records.

**Document non-compliance
by noting lack of, or
inadequate records in
Field Book.**

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DOCUMENTATION OF VIOLATIONS

- o Total number of PCB large high or low voltage capacitors.

(i) Owners or operators document on PCB handling at facility for previous calendar year. Effective date of regulation May 1, 1979. Documentation must be available July 1 of each year.

(i) Date PCBs received and identification of person and facility from whom PCBs were received.

(ii) Date PCBs disposed of or transported to another disposal or storage facility, including identification of types of PCBs in containers and not in containers.

(iii) Weight of PCB containers, and weight of PCB chemical substance or mixture contained in transformers received, transported or disposed. Identify PCB containers contents such as liquids, capacitors, etc. Identification of facilities to which PCB containers or PCB chemical substances or mixtures in transformers are transported.

Request copy of report or inspect report at site. Documents must be retained at site for 5 years after facility no longer used for storage.

Obtain copy of records. Document non-compliance in field book.

REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION OF VIOLATIONS**

(g) Owners or operators maintain annual records, effective July 2, 1978.

Inspect records and determine compliance with Annex VI.

Documentation of non-compliance in field book or obtain copy of record

(i) Dates when PCBs removed from service and placed into storage. Quantities indicated as follows:

- o Total weight, in kilogram, in containers and identification of PCB such as liquid or capacitor.

- o Total number of transformers and weight, in kilograms, of any PCB mixture contained in transformers.

- o Total number of PCB large high or low voltage capacitors

(ii) PCBs removed from service, location of initial disposal or storage facility and name of owner or operator.

(iii) Total quantities of PCBs remaining in service at end of calendar year.

- o Total weight, in kilograms, of PCBs in containers including identification of container contents such as liquids or capacitors.

- o Total number of transformers and weight, in kilograms, of any PCB contained in the transformers.

REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION OF VIOLATIONS**

(b) Storage of non-leaking and structurally undamaged PCB large high voltage capacitors on pallets is permitted next to storage facility meeting the requirements of 761.42b until January 1, 1973. Capacitors checked for leaks weekly.

Determine if storage facility has immediate available unfilled storage space equal to 10% of volume of capacitors stored outside of facility. Check all capacitors for leaks.

Calculate volume of unfilled storage space and volume of capacitors. Document all leaks if leaking, capacitor can be placed in unfilled storage space,

(c) Storage areas are marked.

Verify marking to comply with §761.20(a)(6).

Document non-compliance regulation. Photograph (if possible).

(d) Movable equipment handling PCBs which contact PCB chemical substances or mixtures shall not be removed from storage facility unless it has been decontaminated.

Prepare or obtain list of all movable equipment used in storage facility. Inspect for contamination. Verify decontamination procedures.

Document where decontamination procedures deviate from method described in Annex IV. May need to collect samples of solvents.

(e) All PCB containers and articles must be checked for leaks once every 30 days. All such leaking containers and articles and their contents shall be transferred immediately to properly marked non-leaking containers. Any spilled or leaked material shall be immediately cleaned up and disposed of as per the regulation.

Check inspection records. Determine if leaking containers are placed in properly marked non-leaking containers and if spilled or leaked materials are properly disposed of.

Document in field book note compliance of markings, leaking containers, and improper disposal of leak material and absorbents. Collect samples.

(f) PCB containers shall comply with DOT specifications 49CFR173.346 revised Dec. 31, 1976.

Check specification numbers where available. Measure gauge. Compare to DOT specs.

Document non-compliance field notebook. Obtain container equivalent to in non-compliance. Photograph (if possible).

(g) PCB articles and containers must be dated when placed in storage. Storage area must be managed to locate items by date.

Inspect records and storage area.

Document in field book quantity of articles and containers not dated. Obtain photocopies of records

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Storage (Annex III)

Inspection Procedures

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(c) No drains, valves, expansion joints, or other openings within curbed area.

Visual inspection of containment area.
Review all piping and sewer blueprints.

Provide exact locations detail in field book with measurements to station objects. Determine drainage path and ultimate disposal location. Obtain photocopies of blueprint showing openings of area, Verify blueprints by visual inspection. Photograph (if possible).

(d) Floors and curbing constructed of continuous smooth and impervious materials.

Visual inspection material usually concrete or metal (metal storage bins)

Describe material used, exact location of cracks or expansion joints which permit penetration of PCBs. Photograph (if possible).

(e) Storage prohibited at site below 100 year flood water elevation.

Determine from geological records elevation of storage facility.

Obtain of 100 year flood elevation and topographic maps of storage area. Determine accurate elevation of storage area above ground level.

§1.42(c)

(a) Temporary storage of non-leaking PCB articles and equipment permitted for up to 30 days from date of removal from service in area not complying with §761.42(b) (Not containers)

Determine date when equipment or articles removed from service. Inspect all equipment or articles for leaks.

Obtain records when equipment removed from service. Describe leaks, number of containers, condition of equipment, drainage path and ultimate disposition. Photograph (if possible) Collect sample of leaked material.

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G. Storage (Annex III)

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION OF VIOLATIONS

(1) Period of Storage: §761.42(a) PCB article or container stored before January 1, 1973 shall be removed from storage and disposed of before January 1, 1984. PCB article or container stored after January 1, 1983 must be disposed of within one year from date placed into storage.

Check records for date of storage. Confirm that disposal occurred by inspection of storage area.

PCB article or container still in storage area. Record observations in field book, obtain photograph (if possible) of stored material; list quantities of material, type of containers, etc.

(2) Storage Facility: §761.42(a)

Visual inspection for leaks and general condition of structure.

Record observation in detail in field book, provide exact location by measurement from stationary object such as floor, wall, or ceiling where leak occurs, objects water contacts, and drainage path of water. Photographs (if possible)

(a) Adequate shelter to prevent rain reaching PCBs.

(b) Adequate floor with 6 inch high continuous curbing. Containment must provide 2 time internal volume of largest PCB article or container or 25% of total internal volume of all PCB equipment or containers stored therein, whichever is greater.

Determine volume of all stored equipment or containers and volume of largest container by direct measurement or from records. Measure surface dimensions and curb height.

Calculate total volume of containers, largest container, and storage area. If in violation verify all measurements. Obtain photocopies of all records describing container dimensions and volumes.

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INTRODUCTION TO STORAGE INSPECTIONS

Storage areas play a key role in preventing PCBs from reaching the environment prior to their disposal. The function of the storage requirements in the regulations is to assure effective containment of PCBs until they are sent on to a disposal facility. To assure environmental protection, the regulations provide for the construction of protective structures for the storage of PCBs.

The essential concerns of the regulation are that storage facilities avoid potential migration of PCBs into watercourses and that they be able to contain possible spills. These concerns do not necessarily require construction of an elaborate structure. The principle requirements, an adequate roof and walls, impervious flooring and adequate containment capacity, may be met with fairly simple structures and some ingenuity. A steel tub for instance could suffice for meeting the floor and curbing requirements if it were of sufficient capacity. The tub then could be placed in any building for weather protection, and the storage facility requirements would be satisfied.

The operations of the storage facility should comply with the requirements of the §761.20 marking regulation as well as Annex III and Annex IV. With respect to marking, all PCBs which are required to be placed in a storage facility should be marked and dated. In addition, once marked and dated, the PCBs in storage must be carefully organized according to the regulation so as to permit easy access.

At all facilities, PCBs in storage should be accurately recorded in the PCB records for the facility. The quantity of PCBs in storage should relate directly to the quantity of PCBs removed from service or received from other facilities.

As a vital part of each Storage facility inspection the inspector should assess, as a guide to the likelihood of serious violations, the general housekeeping of the facility operation. Poor or non-existent records and sloppy operations are good indicators of breaches of other significant requirements and should be carefully noted in the inspector's field book.

Every facility which owns or uses PCBs should either have an Annex III storage facility or be capable of sending its PCBs directly to a remote storage or disposal site. This suggests that inquiries as to the existence and location of storage facilities should be a part of nearly every PCB inspection.

STORAGE REQUIREMENTS

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STORAGE REQUIREMENTS

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REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION**

(b) Failure to dispose of non-liquid PCBs in the form of a) contaminated soil, rags or other debris, and b) soils and debris contaminated with PCBs as a result of a spill or as a result of placement of PCBs in a disposal site prior to February 17, 1978, in an incinerator that complies with Annex I, or in chemical waste landfill that complies with Annex II (for items specified in a), disposal in a chemical waste landfill is permitted until July 1, 1980. After that date, these items must be incinerated (761.10(b)(2),(3)).

Inspect and sample wastes to determine if non-liquid, (does not flow freely or is not readily pumpable) and contains 500 ppm or greater.

Properly identify sample and analytical results. Field notes on physical nature of wastes (liquid vs. non-liquid).

(c) Failure to dispose of PCB transformers and other PCB articles in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II.

Determine if articles contain PCB mixtures chemical substances. For transformers use direct sampling.

Properly identify sample and analyze results.

Transformer Manufacturers: Inspection Procedures

A. General Procedures: the following facility areas or activities should be inspected.

1. Storage for disposal areas containing any waste PCB liquids or solid wastes generated by manufacturing operations. This applies to most current wastes generated by manufacturers.
2. Materials handling systems used for PCBs. Residual PCBs in the systems could contaminate other substances. Such contaminated substances must be handled as PCB mixtures.
3. Dumps, landfills, or pits used in the past for disposal of manufacturing wastes. Leachate and other indicators of contamination should be sampled.
4. Facility drainage systems should be inspected and sampled for PCB contamination. NPDES or other EPA or state programs may already be examining this problem.
5. Records should be reviewed in accordance with the methods outlined in Chapter 5, Appendix D. (Note: Former manufacturers may not be required to keep records).

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(1) §761.10 Disposal of PCBs

(a) Failure to dispose of liquid PCBs in an incinerator that complies with Annex I. (761.10(a),(b)).

Direct observations of illegal disposal when it occurs would be the most convincing evidence, but it is unlikely this will be possible. Direct observation and sampling of residues from an illegal disposal activity can be achieved in some cases, and such evidence should be obtained whenever possible.

Direct evidence (soils etc.) of illegal PCB disposal should be sampled to determine if dilution was used to get concentrations below 500 ppm. Special samples and notes should be obtained whenever there is suspicion that U.S. waters or adjoining shorelines have been contaminated. Photographs should be taken whenever possible and locations should be precisely referenced and located on maps or plots.

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CC6741

REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION OF VIOLATION**

- (h) Failure to dispose of liquid PCBs resulting from spill incidents in accordance with §761.10(e). (761.10(e)).
- (i) Failure to properly store, prior to disposal, PCB liquid or non-liquids described in 1-10 above, in storage area that complies with Annex III. (761.10(a)(2), (b)(5), (c)(4)(d)(2)).
- (j) For any person who is required to incinerate any PCB and who contends that there is available a means of destroying PCBs which is as efficient as the incineration procedures provided in Annex I, failure to obtain written permission (and failure to comply with any limitations specified therein) from the R.A. before employing any method of disposal of any PCB other than incineration in a facility which complies with Annex I. (761.10(1)).

Follow up spill reports. Direct inspection or contacts with spill official will indicate degree of compliance. Non-compliance will require procedures similar to 1 and 2 except for records review.

See 9 above.

Samples of contamination zones and removed materials. Third party report or direct observation of final disposal.

See 9 above.

ACM CCE74C

Capacitor Manufacturers

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION OF VIOLATIONS

- (d) For any large high or low voltage capacitor owned by any person, failure to dispose in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II, unless it is known from label information, manufacturer's literature or chemical analysis that the capacitor does not contain PCB chemical substances or PCB mixtures. (761.10(c)(2)(i),(ii)).

Similar to A3, except that burden is on owner to furnish other evidence if he contends PCBs are not present. This requirement is intended to force manufacturers of new large capacitors to mark their products "Non PCBs" if no PCBs are used.

Similar to A,3.

- (e) Unless decontaminated in accordance with Annex IV, failure to dispose of PCB containers in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II. (761.10(d)(1)).

Determine that containers contained PCBs by direct samples of residuals or from records review or third party statements.

Field notes, photographs, analytical results, copies of records and statements from employees or third party observers.

- (f) Failure to drain the PCB container of liquid prior to disposal in a chemical waste landfill that complies with Annex II. (761.10(d)(1)).

Observe to determine if any physical evidence of PCBs is present inside or outside of container. If PCBs are observed or if other information suggesting inadequate decontamination is obtained, investigate decontamination process.

Field notes, photographs, statements from employees or third party observers

- (g) For PCB articles other than transformer and capacitors, if incineration is thought to be technologically infeasible, failure to obtain written permission (and to comply with any limitations specified therein) from the R.A. granting permission to use a chemical waste landfill for disposal. (761.10(c)(3)).

Examine documents from R.A. granting permission. Continue investigation to determine if special conditions accompanying R.A. permission are being complied with.

Copies of documents, documentation based on special conditions in R.A. permission.

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REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION**

- (b) Failure to dispose of non-liquid PCBs in the form of a) contaminated soil, rags or other debris, and b) soils and debris contaminated with PCBs as a result of a placement of PCBs in a disposal site prior to February 17, 1978, in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II. (For items specified in a), disposal in a chemical waste landfill is permitted until July 1, 1980. After that date, these items must be incinerated. (761.10(b)(2),(3)).

- (c) Failure to dispose of PCB articles in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II (761.10(c)(3)).

Inspect and sample waters to determine if non-liquid, (does not flow freely or is not readily pumpable) and contains 500 ppm or greater.

Determine if articles contain PCB mixtures or chemical substances. For transformers, use direct sampling. For capacitors, manufacturers reports can be used.

should be taken whenever there is suspicion that U.S. waters or adjoining shorelines have been contaminated. Photographs should be taken whenever possible and sample locations should be precisely referenced and located on maps or plots.

Properly identify sample and analytical results. Field notes on physical nature of waste (liquid vs. non-liquid).

Properly identify sample and analytical results. Copy manufacturers report.

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Capacitor Manufacturers: Inspection Procedures and Documentation

A. General: The following facility areas or activities should be inspected.

1. Storage for disposal areas containing any waste PCB liquids or solid wastes generated by manufacturing operations. This applies to most current manufacturers.
2. Materials handling systems used for PCBs. Residual PCBs in the systems could contaminate other substances. Such contaminated substances must be handled as PCB mixtures.
3. Dumps, landfills, or pits used in the past for disposal of manufacturing wastes. Leachate and other indicators of contamination should be sampled.
4. Facility drainage systems should be inspected and sampled for PCB contamination. NPDES or other EPA or state programs may already be examining this problem.
5. Records should be reviewed. (Note: former manufacturers may not be required to keep records).
6. Any small PCB capacitors owned by manufacturers, past or present, will have to be disposed of in accordance with Annex II(761.10(c)(2)(iv)). These are the only disposal requirements for small capacitors.

B. Specific Procedures

REGULATORY REQUIREMENTS	INSPECTION PROCEDURES	DOCUMENTATION
(1) <u>§761.10 Disposal of PCBs</u>		
(a) Failure to dispose of liquid PCBs in an incinerator that complies with Annex I. (761.10(a),(b)).	Direct observations of illegal disposal when it occurs would be the most convincing evidence, but it is unlikely this will be possible. Direct observation and sampling of residues from an illegal disposal activity can be achieved in some cases, and such evidence should be obtained whenever possible.	Direct evidence (soils etc.) of illegal disposal should be to determine if any residual concentrations of 500 ppm. or greater are present, or if dilution was used to get concentrations below 500 ppm.

ACM 008737

I. Introduction to PCB Capacitor and PCB Transformer Manufacturing

Manufacturers of PCB capacitors and PCB transformers have been identified as major discharges of PCBs to U.S. waters: the contamination resulting from such discharges has forced the closing of a number of major rivers to fishing. Due to environmentalist pressure and new laws and regulations, the manufacture of PCB capacitors in the U.S. is expected to terminate by mid-1978. As far as EPA is aware, PCB transformer manufacturing has already ceased.

Nevertheless, PCB discharges resulting from complex materials handling systems, poorly constructed drainage systems, and general poor housekeeping practices will probably continue to contaminate U.S. waterways for some time after all PCB transformer and capacitor manufacturing has ceased. Significant volumes of PCB solid wastes, in the form of defective small capacitors, have been disposed of improperly in dumps, and PCB discharges from such dumps continue to contaminate both water systems and municipal sewage sludge.

II. Recommended Approach for Conducting PCB Capacitor and PCB Transformer Manufacturing Facility Inspections

Inspection Priority

The highest inspection priority should be those few capacitor manufacturers who still use PCBs. They will have large amounts of highly concentrated liquid PCBs on hand, and thus have the greatest potential for PCB contamination. Storage and handling of PCB wastes from the manufacturing process will also be a major problem.

The second priority should be former PCB capacitor manufacturers. Transformer manufacturers should be the third priority. All facilities should be physically inspected. Note: Those facilities for which third party reports on illegal disposal or storage have been made should receive priority. Those reports can come from competitors, environmental "watchdogs", transporters, or the general public. These potential sources of information can be effectively used only if the sources are aware of the general requirements of the regulation and the potential harm that can result from non-compliance. Third party reports should be converted into permanent evidence via signed statements or, preferably, affidavits.

INSPECTION PROCEDURES
FOR
TRANSFORMER AND CAPACITOR MANUFACTURERS

ADM CC6735

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(k) Failure to properly store, prior to disposal, any PCB liquids or non-liquids described in 1-10 above, in a storage area that complies with Annex III. (§761.10(a)(5),(c)(4)(1)(2)).

See Chapter on storage for procedures.

See Chapter on storage for documentation.

(1) For any person who is required to incinerate any PCB and who contends that there is available a means of destroying PCBs which is as efficient as the incineration procedures provided in Annex I, failure to obtain written permission (and failure to comply with any limitations specified therein) from the R.A. before employing any method of disposal of any PCB other than incineration in a facility which complies with Annex I. (§761.10(f)).

See 9 above.

See 9 above.

ACM CC8734

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(g) Unless decontaminated in accordance with Annex IV, failure to dispose of PCB containers in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II. (§761.10(d)(1)).

Determine that containers contained PCBs by direct samples of residuals or from records review or third party statements.

Field notes, photographs, analytical results, copies of records, and statements from employees or third party observers.

(h) Failure to drain the PCB container of liquid prior to disposal in a chemical waste landfill that complies with Annex II. (761.10(d)(1)).

Observe to determine if any physical evidence of PCBs is present inside or outside of container. IF PCBs are observed or if other information suggesting inadequate decontamination is obtained, investigate decontamination process. See

Filed notes, photographs, statements from employees or third party observers

(i) For PCB articles other than transformers and capacitors, if incineration is thought to be technologically infeasible failure to obtain written permission (and to comply with an limitations specified therein) from the R.A. granting permission to use a chemical waste landfill for disposal. (§761.10(c)(3)).

Examine documents from R.A. granting permission. Continue investigation to determine if special conditions accompanying R.A. permission are being complied with.

Copies of documents or other documents based on special conditions in R.A. permission.

j). Failure to dispose of liquid PCBs resulting from spill incidents in accordance with 1-9 above. (§761.10(c)(3)).

Follow up spill reports. Direct inspection or contacts with spill officials will indicate degree of compliance. Non-compliance will require procedures similar to 1 and 2, except for records review.

Samples of contamination zones and removed materials. Third party report or direct observation of final disposal.

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REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION**

- | | | |
|---|--|--|
| (c) Failure to dispose of PCB transformers and other PCB articles in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II. (761.10(c)). | Determine if articles contain PCB mixtures or chemical substances. For transformers, use direct sampling. For capacitors, manufacturers reports can be used. | Sample and analytical results should be noted in field book. Copies of manufacturers reports should be included if possible. |
| (d) Failure to, prior to disposal in a chemical waste landfill, drain each transformer of all free flowing liquid, fill the transformer with solvent and allow 18 hours before solvent is drained. (761.10(c)(iii)). | Open drain valves on transformers and collect any free flowing liquid. If liquid volume collected is greater than 5% of the transformer volume, then adequate draining did not occur. If no solvents are present in the liquid, then a solvent flush did not occur. If the facility has not completed adequate draining, they could claim that the disposal site is responsible. Follow up may be necessary. | |
| (e) Failure to dispose of PCB chemical substances and PCB mixtures which are removed from the transformer, (including solvent), in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II (§761.10(c)(ii)). | Interviews with personnel to determine familiarity with proper draining procedures as indicators of proper draining. | Field notes and statements from workers. Obtain serial numbers or other direct identity of transformer. |
| (f) For any large high or low voltage capacitor owned by any person, failure to dispose in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II, unless it is known from label information, manufacturer's literature or chemical analysis used that the capacitor does not contain PCB chemical substances or PCB mixture. (§761.10(c)(2)(i)(ii)). | Similar to A.3. except that burden is on owner to furnish other evidence if he contends PCBs are not present. This requirement is intended to force manufacturers of new large capacitors to mark their products "Non-PCBs" if no PCBs are used.

Capacitors may be found on some new motors and in building electrical systems. Subway systems may have them for power factor correction. | Similar to A.3. |

Railroad and Subway Systems: Specific Inspection Procedures and Documentation

Note: PCBs will generally be found in locomotive and self propelled car maintenance facilities.

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(1) § 761.10 Disposal of PCBs

- (a) Failure to dispose of liquid PCBs in an incinerator that complies with Annex I (761.10(a),(b)).

Direct observations of illegal disposal when it occurs would be the most convincing evidence, but it is unlikely that this will be possible. Direct observation and sampling of residues from an illegal disposal activity can be achieved in some cases and such evidence should be obtained whenever possible.

Direct evidence (soils, etc.) of illegal PCB disposal should be sampled to determine if any residual concentrations of dilution was used to get concentrations below 500 ppm. Special samples and notes should be obtained whenever there is suspicion that watercourses have been contaminated. Photographs should be taken whenever possible and sample locations should be precisely referenced and located on maps or plots

- (b) Failure to dispose of non-liquid PCBs in the form of a) contaminated soil, rags or other debris, and b) soils and debris contaminated with PCBs as a result of a spill or as a result of placement of PCBs in a disposal site prior to February 17, 1978, in an incinerator that complies with Annex I, or in a chemical wastes landfill that complies with Annex II (for items specified in a), disposal in a chemical waste landfill is permitted until July 1, 1980. After that date, these items must be incinerated (761.10(b)(20(3))).

Inspect and sample wastes to determine if non-liquid (does not flow freely or is not readily pumpable) and contains 500 ppm or greater.

Properly identify sample and analytical results. Field notes on physical nature of waste (liquid non-liquid).

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REGULATORY REQUIREMENTS

(j) Failure to properly store and dispose of liquid PCBs resulting from spill incidents.

(k) For any person who is required to incinerate any PCB and who contends that there is available a means of destroying PCBs which is as efficient as the incineration procedures provided in Annex I, failure to obtain written permission (and failure to comply with any limitations specified therein) from the R.A. before other than incineration in a facility which complies with Annex I. (§761.10(f)).

ACM CC673C

INSPECTION PROCEDURES

DOCUMENTATION

Follow up spill reports. Direct inspection or contacts with spill officials will indicate degree of compliance. Non-compliance will require procedures similar to 1 and 2, except for records review.

See 8 above.

Samples of contamination taken and removed materials, third party reports or direct observation of final disposal.

See 8 above.

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(e) Failure to dispose of PCB chemical substances or mixtures which are removed from the transformer, (including solvent), in an incinerator that complies with Annex I, or in a chemical waste.

Interviews with personnel to determine familiarity with proper draining procedures as indicators of proper draining.

Field notes and statements from workers. Obtain serial numbers or other direct identity of transformers.

(f) Unless decontaminated in accordance with Annex IV, failure to dispose of PCB containers in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II. (§761.19(d)(1)).

Determine that containers contained PCBs by direct samples of residuals or from records review or third party reports.

Field notes, photographs analytical results, copies of records, and statements from employees or third party observers.

(g) Failure to drain the PCB container or liquid prior to disposal in a chemical waste landfill that complies with Annex II. (§761.10(d)(a)).

Observer to determine if any physical evidence of PCBs is present inside or outside of container. If PCBs are observed or if other information suggesting inadequate decontamination is obtained, investigate decontamination process. See

Field notes, photographs statements from employees or third party observers

(h) For PCB articles other than transformers and capacitors, if incineration is thought to be technologically infeasible, failure to obtain written permission (and comply with any limitations specified) to use a chemical waste landfill for disposal. (§761.10(c)(3)).

Examine documents from R.A. granting permission. Continue investigation to determine if special conditions accompanying R.A. permission are being complied with. Will seldom apply to transformer repair facilities.

Copies of documents and other documents based on special conditions in the R.A. approval.

(i) Failure to properly store, prior to disposal, any liquids or non-liquid described in 1-8 above, in a storage area that complies with Annex III. (§761.10(a)(2)(b)(5), (c)(4), (d)(2)).

See Chapters on storage for procedures.

See Chapters on storage for procedures.

ACM CC6765

Transformer Repair Facilities

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(b) Failure to dispose of non-liquid PCBs in the form of contaminated soil, rags or other debris contaminated with PCBs as a result of a spill or as a result of placement of PCBs in a disposal site prior to February 17, 1978, in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II (for items specified in (a), disposal in a chemical waste landfill is permitted until July 1, 1980. After that date, these items must be incinerated). (§761.10(b)(3)).

Inspect and sample wastes to determine if non-liquid (does not flow freely or is not readily pumpable) and contains 500 ppm or greater.

Properly identify sample and analytical results. Field notes on physical nature of waste (liquid vs. non-liquid).

(c) Failure to dispose of PCB transformers and other PCB articles in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II. (§761.1)(c)).

Determine if articles contain mixtures or chemical substances. For transformers, use direct sampling. For capacitors, manufacturers reports can be used.

Sample and analytical results and copies of manufacturers reports.

(d) Failure to, prior to disposal in a chemical waste landfill, drain each transformer of all free flowing liquid, fill the transformer with solvent and allow 18 hours before solvent is drained. (§761.10(c)(ii)).

Open drain valves on transformers and collect any free flowing liquid. If liquid volume collected is greater than 5% of the transformer volume, then adequate draining did not occur. If no solvents are present in the liquid, then a solvent flush did not occur. Since transformer facilities can either serve as agents for final disposal or decide to dispose of a transformer after testing or examining it, proper draining of transformers will be an important activity.

9. After July 1, 1978, all PCB transformers at a transformer repair facility will have to be properly marked in accordance with Annex V (see Chapter 5, Appendix C). This also applies to PCB containers storage for disposal areas.

II. Railroad and Subway Systems: All of the above and locomotive and self-propelled car maintenance facilities

B. Specific Inspection Procedures and Documentation

Transformer Repair Facilities

REGULATORY REQUIREMENTS	INSPECTION PROCEDURES	DOCUMENTATION
(1) <u>761.10 Disposal of PCBs</u>		
(a) Failure to dispose of liquid PCBs in an incinerator that complies with Annex 1, (761.10(a), (b)).	Direct observation of illegal disposal when it occurs would be the most convincing evidence, but is unlikely that this will be possible. Direct observation and sampling of residues from an illegal disposal activity can be achieved in some cases, and such evidence should be obtained whenever possible.	Direct evidence (soils, etc.) of illegal PCB disposal should be sampled to determine if there are any residual concentrations below 500ppm. Special samples and notes should be obtained whenever possible and sample locations should be precisely referenced or located on maps or plots.

Railroad and Subway Systems

III. Transformer Repair and Maintenance Facilities: Potential Violations, Inspection Procedures and Documentation

A. General Inspection Procedures

1. Transformer repair and maintenance facilities

For those transformer maintenance and repair facilities selected for inspection, a thorough physical inspection should be performed with records review, as outlined in Chapter 5, Appendix D, as a secondary priority. The following facility areas or activities should be inspected:

1. Storage lot or area where incoming transformers are placed. Inspector should look for leaking units and evidence of significant ground contamination. If storm runoff of PCBs into storm drains or streams is suspected, samples of contaminated soil and stream or storm drain bottom deposits should be taken.
2. Storage for disposal area(s) should be inspected for compliance with 761.42 (see Chapter 5, Appendix A).
3. Scrap metal areas should be inspected for PCB contaminated wiring or other internal parts. No dismantled or intact PCB transformer casing should be here. They must be in storage for disposal areas.
4. General housekeeping conditions should be observed. PCB contaminated rags and other debris must be placed in proper containers for disposal. Poor housekeeping is indicated by PCB contamination of drainage systems and the general facility environment. Drainage systems samples should be taken.
5. PCB storage and handling areas within the facility should be carefully inspected. Although the regulation provisions apply only to storage for disposal, serious hazards can be addressed under emergency powers.
6. The degree of worker knowledge about occupational hazards of PCBs should be determined. The availability of protective clothing should also be determined. These factors are not potential violations per se, but are good indicators of the degree of knowledge that exists regarding environmental concerns.
7. Determine the amount of activity in retrofitting PCB transformers with substitute fluids. If this is a major activity at this facility, then expect large quantities of waste PCBs to be generated.
8. Records as required by Annex III (see Chapter 5, Appendix D), should be reviewed to determine the names and locations of all storage for disposal and final disposal site locations. If outside transformer repair firms are acting as middlemen in the transformer disposal chain from original user to final disposal, adequate records should be available indicating the origin of the transformers or waste PCB fluids.

performed, the facility should be physically inspected. Any facilities for which a third party report or "tip-off" has been made relating to illegal disposal or storage should receive priority. These reports can come from competitors, environmental "watchdogs," transporters, or the general public. These potential sources of information can be effectively used only when these sources are aware of the general requirements of the regulation and the potential harm that can result from non-compliance. Third party reports should be converted into permanent evidence via signed statements or, preferably, affidavits.

ADM CC6725

2. Significant quantities of waste PCBs will be generated, and adequate storage and disposal must be provided for;
3. Since dismantling and repair operations occur in a number of locations within the facility, housekeeping problems can be serious. If wide-spread contamination occurs within the facility, drainage systems can readily become contaminated with PCBs.

Railroad Maintenance Operations

These operations are similar to the transformer repair facilities with two major exceptions:

1. The transformers must be removed from the locomotives or serviced on the locomotives in the same work pits that are used for other locomotive maintenance operations. This often results in very cramped working conditions and an intermixing of PCB operations with other operations.
2. The railroad shops almost never open a transformer for repairs to internal apparatus. For these services, the transformers are sent to outside transformer repair facilities.

Railroad repairs are usually similar to the on-site repair and maintenance operations discussed above. Repair operations unique to the railroad units include repair or replacement of PCB motors used to re-circulate PCBs for cooling, and repair or replacement of cooling radiators that may be damaged by stones or other roadbed projectiles.

The most significant risks at these railroad maintenance facilities are as follows:

1. General housekeeping contamination, particularly in work pits. Drainage to sanitary or storm sewers from the pits could be a significant contamination pathway;
2. Although some quantities of waste PCBs will be generated, increased filtering and reclamation may reduce this.

II. Recommended Approaches for Conducting Transformer Maintenance Repair and Railroad and Subway Facility Inspections.

Inspection Priority

Headquarters is providing a basic list of transformer repair facilities and railroad and subway systems that may handle PCB units. The facilities should be contacted to determine if they are engaged in PCB activities. If there is any possibility or suspicion that PCB maintenance is being

(b) Adding a small amount of PCBs to bring the level up to the full line (topping off);

(c) Replacement or resealing of bushings, insulators, or gaskets (the PCB level of the transformer is lowered below the affected part and then refilled to the full line after repairs have been made);

(d) Removal, filtering (clay filter or paper cartridge) and return of PCB liquids into the transformer (filter media and any waste PCB liquids will require special disposal);

(e) Removal of PCB liquids from a transformer and refilling with new or reclaimed PCB liquids (unusable PCB liquids will require special disposal).

Off-site operations are conducted at the transformer repair facility and include an operations sequence like the one below.

1. The transformer is delivered to the shop, probably containing PCB liquids;
2. If minor repairs are all that are required, then a series of steps similar to the on-site operations above are performed;
3. For major repairs, the PCB liquids are drained and probably retained for re-use after filtering, unless the liquids are grossly contaminated, particularly with carbon particles from an electrical failure. These contaminated liquids would go to PCB disposal;
4. Before opening the transformer for major repairs, the unit may be flushed with solvent to lower the residual PCB content. The spent solvent should go to PCB disposal;
5. After the top is opened, the internal coils and other electrical apparatus are probably removed for examination and/or repair. These devices may contain significant quantities of residual PCBs;
6. Depending on the condition of the coil, rewinding with new wire may be performed. The scrapwire should be disposed of as a PCB solid. PCB contamination from such transformer salvage operations is considered to be a serious problem;
7. The internal workings are replaced, the transformer resealed, and PCBs (either new or reclaimed) are added to the unit;
8. The transformer is tested and, if satisfactory, returned to service.

The risks these operations pose come from three activities:

1. Newly arriving transformers may be leaking and contaminating transport vehicles, storage areas or building;

E. Introduction to Transformer Maintenance and Repair Facilities and Railroad and Subway Systems.

One of the major sources of PCB exposure for the environment and to workers occurs during transformer repair and maintenance activities, as these operations often involve handling large volumes of highly concentrated liquid PCB's. The internal windings and other electrical apparatus within the transformer can hold significant residuals of PCB's, and major transformer disassembly often results in repeated leakage and drainage of PCB's. As with electrical utility companies, electrified railroads and, to lesser extent, subway systems, perform significant PCB transformer repair and maintenance operations that may be performed by a facility-owned operation or by a contracted outside firm.

Electric railroad locomotives and self propelled commuters receive their electric power from overhead high voltage A.C. current distribution lines. This high voltage current is then reduced to a lower, working voltage by transformers on the locomotives for use by the electric motors that power the locomotives or cars. These transformers are subjected to severe working conditions in that the cramped space available on the locomotives and the heavy electrical load, result in high maintenance requirements when compared to other PCB transformer installations. In addition, many of the railway transformers are located on the undercarriage of the locomotive and are subject to damage from objects thrown up from the track roadbed. This damage may cause a leak of PCBs which will require transferral of the locomotive to a repair facility.

Subway systems are also electrically powered, but receive their power through a third rail which delivers direct current at a working voltage for the electric motors on the subway cars. Transformers are used in the electric distribution system which regulates the voltage to the proper level, and since much of the electrical system is underground, the transformers are often PCB units. The transformers are basically standard distribution system units and are reasonably reliable. The subway systems do not usually have special repair organizations for transformers, but instead contract with transformer repair firms.

Transformer Repair and Maintenance Facility Functions

Transformer repair and maintenance functions are often split between on-site and off-site activities. Since PCB transformers are heavy, bulky units and the transportation of them does pose some risks, many service operations are performed on-site. Some examples of these on-site operations are:

(a) Removing a sample (one pint to one quart of PCBs) for testing dielectric strength (the presence of water, carbon, or other contaminants lowers dielectric strength);

INSPECTION PROCEDURES
FOR
TRANSFORMER MAINTENANCE AND REPAIR FACILITIES
AND RAIL SYSTEMS

ADM CC8721

REGULATORY REQUIREMENTS**INSPECTION PROCEDURE****DOCUMENTATION**

failure to obtain written permission (and failure to comply with any limitations specified therein) from the R.A. before employing any method of disposal of any PCB other than incineration in a facility which complies with Annex I. (\$761.10(f)).

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REGULATORY REQUIREMENTS

INSPECTOR PROCEDURES

DOCUMENTATION

(h) Failure to drain the PCB container of liquid prior to disposal in a chemical waste landfill that complies with Annex II. (§761.10(d)(2)).	Observe to determine if any physical evidence of PCBs is present inside or outside of container. If PCBs are observed or if other information suggesting inadequate decontamination obtained, investigate decontamination process. See	Field notes, photographs statements from employee or third party observers
(i) For PCB articles other than transformers and capacitors, if incineration is thought to be technologically infeasible, failure to obtain written permission (and to comply with any limitations specified therein) from the R.A. granting permission to use a chemical waste landfill for disposal. (§761.10(e)).	Examine documents from R.A. granting permission. Continue investigation to determine if special conditions accompanying R.A. permission are being complied with.	Copies of documents. Other documentation based on special conditions in R.A. permission.
(j) Failure to dispose of Liquid PCBs resulting from spill incidents in accordance with 1-9 above, (§761.10(e)).	Follow up spill reports. Direct inspection or contacts with spill officials will indicate degree of compliance. Non-compliance will require procedures similar to 1 and 2, except for records review.	Samples of contamination zones and removed material Third party reports or direct observation of field disposal.
(k) Failure to properly store, prior to disposal, any PCB liquids or non-liquids described in 1-10 above, in a storage area that complies with Annex III. (§761.10(a) (2),(b),(5),(c)(4)-(d)(2)).		
(l) For any person who is required to incinerate any PCB and who contends that there is available a means of destroying PCBs which is as efficient as the incineration procedures provided in Annex I,	See 9 above.	See 9 above.

ALH CC6715

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(d) Failure to, prior to disposal in a chemical waste landfill, drain each transformer of all free flowing liquid, fill the transformer with solvent and allow 18 hours before solvent is drained. (761.10(c)(11)).

Open drain valves on transformers and collect any free flowing liquid. If liquid volume collected is greater than 5% of the transformer volume, then adequate draining did not occur. This may apply more to disposal sites. If a utility has not completed adequate draining, they could claim that the disposal site is responsible for that operation. Follow up may be necessary.

(e) Failure to dispose of PCB chemical substances and PCB mixtures which are removed from the transformer, (including solvent), in an incinerator or that complies with Annex I, or in a chemical waste landfill that complies with Annex II (§761.10(c)(11)).

Interviews with personnel to determine familiarity with power draining procedures as indicators of proper draining.

Field notes and statements from workers. Obtain serial numbers or other direct identity of transformer.

(f) For any large high or voltage capacitor owned by any person, failure to dispose in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II, unless it is known from label information manufacturer's literature or chemical analysis that the capacitor does not contain PCB chemical substances or PCB mixtures. (§761.10(c)(2)(1),(11)).

Similar to A.3. except that burden is on owner to furnish other evidence if he contends PCBs are not present. This requirement is intended to force manufacturers of new large capacitors to mark their products "non-PCBs" if no PCBs are used.

Similar to A.3.

(g) Unless decontaminated in accordance with Annex IV, failure to dispose of PCB containers in an incinerator that complies with Annex I, or a chemical waste landfill that complies with Annex II.

Determine that containers PCBs by direct samples of residuals or from records review or third party statements.

Field notes, photographs analytical results, copies of records, and statements from employees or third party observers.

REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION**

(b) Failure to dispose of non-liquid PCBs in the form of (a) contaminated soil, rags or other debris, and (b) soils and debris contaminated with PCBs as a result of a spill or as a result of placement of PCBs in a disposal site prior to February 17, 1978, in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II (for items specified in (a), disposal in a chemical waste landfill is permitted until July 1, 1980. After that date, these items must be incinerated) (761.10(b)(2)(3)).

(c) Failure to dispose of PCB transformers and other PCB articles in an incinerator that complies with Annex I, or in a chemical waste landfill that complies with Annex II. (761.10(c)).

Inspect and sample wastes to determine if non-liquid (does not flow freely or is not readily pumpable) and contains 500 ppm or greater PCBs.

Determine if articles contain PCB mixtures or chemical substances. For transformers, use direct sampling. For capacitors, manufacturers reports can be used.

shorelines have been contaminated. Photographs should be taken whenever possible and sample locations should be precisely referenced and located on maps or plots.

Properly identify sample and analytical results. Field notes on physical nature of waste (liquid vs. non-liquid).

Properly identify sample and analytical results in field book. Copy any manufacturer's reports.

-D6-

**Utility Compliances: Potential Violations,
Inspection Procedures and Documentation**

A. General Inspection Procedures

For those utilities selected for inspection, an investigator should (1) go to the central location for PCB records, (2) conduct a records examination as outlined in Appendix D (Annex VI), and (3) based on the findings of this examination, determine the need for physical inspection of utility facilities. If the records are legally sufficient, and do not indicate that the utility has a violation, no further inspection should be performed at the site. If records either do exist or do not meet the minimal legal requirements of the regulation, or indicate that the utility has violated the regulation, a full inspection should ensue.

The records review may indicate specific facilities where violations might be expected, but in the absence of specific leads, inspections should be directed in the following priority.

- (1) Transformer repair and maintenance facilities located at the utility
- (2) Long term PCB storage for disposal facilities
- (3) In use facilities such as major substations and coal fired power generation facilities
- (4) Storage areas for serviceable PCB articles
- (5) Temporary storage for disposal facilities
- (6) PCB transport vehicles

B. Specific Inspection Procedures and Documentation

REGULATORY REQUIREMENTS	INSPECTION PROCEDURES	DOCUMENTATION
(1) <u>§761.10 Disposal of PCBs</u>		
(a) Failure to dispose of liquid PCBs in an incinerator that complies with Annex I. (761.10(a)(b)).	Direct observations of illegal disposal when it occurs would be the most convincing evidence, but it is unlikely this will possible. Direct observation and sampling of residues from an illegal disposal activity can be achieved in some cases, and such evidence should be obtained whenever possible.	Direct evidence (soils etc.) of illegal PCB disposal should be sampled to determine if any residual concentrations are below 500 ppm. Special samples and notes should be obtained when there is suspicion that watercourses are being contaminated.

- (2) Previous inspection histories (TSCA as well as other environmental health statutes) which may indicate corporate attitude toward compliance with environmental regulations.
- (3) Utilities for which a third party report or "tip-off" has been made relating to illegal disposal or storage. These reports can come from competitors, environmental "watchdogs", transporters, or the general public. These potential sources of information can be effectively used only if the sources are aware of the general requirements of the regulation and the potential harm that can result from non-compliance. (Note: all third party reports should be converted into permanent evidence via signed statements, or, preferably, affidavits).

- (c) Replacement or resealing of bushings, insulators, or gaskets (the PCB level of the transformer is lowered below the affected part and then refilled to the full-line after repairs have been made);
- (d) Removal, filtering (clay filter or paper cartridge), and return of PCB liquids into the transformer (filter media and any waste PCB liquids will require special disposal);
- (e) Removal of PCB liquids into the transformer and refilling with another batch of PCB liquids (unusable PCB liquids will require special disposal)

PCB transformer repair and maintenance operations that are performed off site will usually be conducted at a transformer repair facility operated by the electric utility or by a separate transformer service company under contract.

Special Electric Utility Operations Related to PCBs

In addition to the above activities related to the actual use of PCBs, the PCB marking and disposal regulation will probably require electric utilities to perform several ancillary activities. Most utilities will establish long term, (§761.42) and temporary PCB storage for disposal sites (§761.42(c)(1)). Special markings will be required for PCB transformers and large capacitors in use or in storage, for containers of PCBs in use or in storage sites, and for vehicles used to transport PCB transformers and containers to storage.

Special records will have to be kept by utilities on PCB activities. These records will permit the utility to keep track of PCBs to storage for disposal or final disposal. The records will identify locations of storage areas and disposal sites and will enable PCBs to be traced to determine if final disposal is performed in accordance with the regulation.

II. Recommended Approaches for Conducting Electric Utility Inspections

Inspection Priority and Records Review

Before initiating an inspection of an electric utility the following factors should be investigated and evaluated:

- (1) The relative size of the utility in terms of the number of kilowatt hours sold annually should be determined along with scope of activities (as described in the preceding sections) conducted by the utility.

In some cases, the utility may own large capacitors or transformers that are located within buildings or other facilities owned or operated by final users. The capacitors will probably be PCB units and the transformers may also be PCB units because of fire codes. It should be noted that fire codes do not require PCBs in transformers, but rather require fire protection in the event of an electrical failure that could ignite the transformer coolant. A fire proof vault could serve the purpose, but the use of non-flammable coolants has been the simplest solution. Silicon based coolants, other newly developed coolants, or even air cooled transformers (usually much larger than oil cooled units) are alternatives that may be used to meet fire code requirements.

Construction, Maintenance, Repair

Construction, maintenance, and repair activities performed by utilities will be the primary activities involving both direct contact with PCBs and opportunities to comply with the marking and disposal requirements for PCBs. Construction operations will probably not involve the installation of new PCB transformers or capacitors, but the removal or relocation of existing PCB units may occur. PCB disposal may result from these construction activities.

Capacitor Maintenance

PCB capacitor repair and maintenance operations will take place either at the location where the PCB units are used, or at a remote repair facility where the PCB units are delivered for repair or maintenance. Maintenance of large capacitors is relatively straightforward. They either function properly, or they are replaced. When capacitors fail to function properly it is usually because of a short circuit within the unit. This condition may cause the capacitor casing to bulge because of internal pressures due to the short circuit and the casing may rupture, in which case some of the PCB liquid may leak out. Short circuited or damaged capacitors are never repaired, just replaced. The old units are usually disposed.

Transformer Maintenance

Maintenance or repair of PCB transformers is more varied. On-site or in-place maintenance can include the following:

- (a) Removing a sample (one pint to one quart) of PCBs to test dielectric strength (the presence of water, carbon, or other contaminants lowers dielectric strength);
- (b) Adding a small amount of PCBs to bring the PCB level up to the full-line (topping off);

D. Introduction to Electric Utility Operations

Electric utility operations consist of four primary activities: (1) generation of power, (2) distribution of bulk, high voltage power, (3) distribution and sale of electricity to direct users, and (4) construction, maintenance, and repair activities.

Power Generation

Electric power can be generated using a variety of methods, including as hydroelectric units, nuclear reactors, and coal or oil fired generators. Generating methods have little bearing on PCB use except for coal fired generating facilities that use electrostatic precipitators for air pollution control. Precipitators frequently use PCB transformers for voltage control because of the location of the transformers on the roofs of buildings, (fire codes may require non-flammable PCB transformers and large capacitors may be used for other applicat within the generating facilities, but such uses are analogous with those in any other large industrial facility.

Bulk Power Distribution

Bulk power distribution occurs when large electric utilities such as the Tennessee Valley Authority provide power to smaller electric utilities such as Rural electric co-operatives or municipally owned electric utilities. These smaller electric utilities directly distribute and sell power to final consumers. Bulk distributors will probably own fewer PCB transformers, and large capacitors, as they are less involved in providing lower voltage or power factor correction for final customers. Large high voltage capacitors, however, are frequently used in substations that distribute power to small utilities.

Distribution and Direct Sale to Customers

Electric utilities involved in the direct distribution and sale to end users will be the most common type of electric utility. These utilities may generate their own power, but the most important factor is the design of the distribution system. Substations used for voltage changes or other distribution corrections will contain racks of large high voltage capacitors (all will be PCB units except for recent replacements). Small transformers used for will also be found in some substations. Larger PCB transformers are seldom found at substations unless special fire code considerations or unusual space constraints dictate the use of PCB transformer fluids. Power poles within the distribution system will have both large capacitors and transformers. These should contain mineral oil and not PCBs unless special fire requirements or other factors, such as personal preference, dictated PCBs.

INSPECTION PROCEDURES

FOR

ELECTRIC UTILITIES

ACM CC8711

REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION**

(2) Items which must be marked as of January 1, 1970.

(a) All PCB Transformers

(b) All PCB large high voltage capacitors

(c) All PCB equipment containing small PCB capacitors must be marked according to §761.20(a) (4).

(3) As of Oct. 1, 1978 all vehicles for transporting PCBs must be marked.

(4) Certain non PCB equipment (see §761.20(a)(b)) must be marked "No PCB's."

(5) Improper use of Mark M_S

All PCB items shall be checked for required label.

All vehicles includes fork lifts etc. used at facilities

Not expected to arise at presently projected inspections.

Photograph unmarked item explain why mark is required in field notes.

Photographs of vehicles used in transport of PCB

ALM CC671C

C Marking Requirements

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(1) Items to be marked

ML as of July 1, 1978

(a) all PCB containers

(b) PCB Transformers (a) at the time of manufacture (b) at the time of distribution in commerce (c) when removed from service

(c) PCB High Voltage Capacitors (a) at the time of manufacture (b) at the time of distribution in commerce (c) when removed from service.

(d) Equipment containing a PCB transformer or large high voltage capacitor (a) at the time of manufacture (b) at the time of distribution in commerce and (c) when removed from service.

(e) PCB large low voltage capacitors when removed from use.

(f) PCB motors.

(g) PCB Hydraulic systems.

(h) PCB Heat Transfer Systems.

(i) PCB Article containers containing marked PCB items.

(j) PCB Storage Areas.

Look for unmarked PCB items. Obtain legal justification for failing to mark any PCB item where requirement exists, and item is not marked, document violation. Many PCB items must be marked upon removal from service but need not be marked while in service until January 1, 1978. Between July 1, 1978.

Photograph, to document lack of label. Sample or otherwise establish that item is a PCB item, Note in field book reasons why items should be marked, and status of item which imposes marking requirement.

ACM CC67C9

MARKING REQUIREMENTS

ALP CC6708

REGULATORY REQUIREMENTS

(ii) Date PCBs disposed of or transported to another disposal or storage facility, including identification of types of PCBs in containers and those not in containers.

(iii) Weight of PCB containers, and weight of PCB chemical substance or mixture contained in transformers received, transported or disposed of. Identify PCB container contents such as liquids, capacitors, etc. Identification of facilities to which PCB containers or PCB chemical substances or mixtures in transformers are transported.

(iv) Number of PCB articles or equipment not in PCB containers received transported to other storage or disposal facility, and remaining on facility site at end of calendar year. Identification of specific type PCB article and equipment and identification of facility transferred to shall be included.

(c) Special Records Retention

(i) All documents, correspondence and data provided by facility to State or local government agency pertaining to disposal are retained at the site for appropriate length of time.

ALM CC87C7

INSPECTION PROCEDURES

DOCUMENTATION

Examine Facility records.

Document non-compliance.

REGULATORY REQUIREMENTS

- (ii) PCBs removed from service, location of initial disposal or storage facility and name of owner or operator.
- (iii) Total quantities of PCBs remaining in service at end of calendar year.
 - o Total weight in kilograms of PCBs in containers including identification of container contents such as liquids or capacitors.
 - o Total number of transformers and weight in kilograms of PCB contained in the transformer.
 - o Total number of PCB large high, or low voltage capacitors.
- (b) Owners or operators document on PCB handling at facility for previous calendar year. Effective date of regulation May 1, 1979. Document must be available July 1 of each year and include:
 - (1) Date PCBs received and identification of person and facility from whom PCBs were received.

ACM CC87C6

Request copy of report or inspect report at site. Documents must be retained at site for 5 years after facility no longer used for storage.

Document non-compliance.

Chemical Waste Landfills - Section 761.41

REGULATORY REQUIREMENTS

- o Site shall be operated and maintained in a manner to prevent safety problems or hazardous conditions resulting from spilled materials or wind blown materials.

(3) Particular Record Keeping Requirements for Chemical Waste Landfills

(a) Owners or operators maintain annual records, effective July 2, 1978.

- (i) Date when PCBs removed from service and placed into storage. Quantities indicated as follows:

- o Total weight in kilograms of PCBs in containers including identification of containers contents such as liquids or capacitors.

- o Total number of transformers and weight in kilograms of any PCB mixture contained in transformers.

- o Total number of PCB large high, or low voltage capacitors.

ACM 006705

INSPECTION PROCEDURES

DOCUMENTATION

Inspect operations for general good housekeeping as specified in the operational plan

Observe and photograph violations and make detailed field notes.

Inspect records and determine compliance with Annex VI.

Document non-compliance in field book or obtain copy of records.

Inspect records and determine compliance with Annex VI.

Document non-compliance in field book or obtain copy of records.

Chemical Waste Landfills - Section 761.41

REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(vii) Chemical Waste Landfill

Operations

- o PCBs shall be placed in the landfill in a manner that will prevent damage to containers and articles. Other wastes, incompatible with PCBs and PCB containers, shall be segregated from PCBs throughout the waste handling and disposal process. (§761.41 (b)(7)(1)).

Visually observe handling operations. Check for broken or ruptured containers in holding and disposal areas.

Operations observed that could damage containers is observed (e. g. dropping them, pushing them, pushing them with bulldozer, inappropriate stacking unless transferring, malfunctioning handling equipment), actual damaged containers seen. Puddles of PCBs seen in areas. Analysis of surface soil shows excessive PCB content. Incompatible wastes identified in PCB areas. Take soil samples in areas or leaks from containers. Identify other wastes in handling and disposal areas. Make detailed notes in field book.

viii) Supporting Facilities

- o A six-foot woven mesh fence, wall, or similar device shall be provided around the site.

Inspect the fence or barrier for integrity.

Fence or barrier is in disrepair or is damaged. Photographs and detailed field book notes as appropriate.

- o Roads shall be maintained to and on the site adequate to operate and maintain the site without causing nuisance, or hazards. (§761.41(b)(8)).

Inspect road visually for ruts, bumps. Road surface is inadequate so that it is too muddy in raining weather. It is not properly cleaned of snow. It is properly surfaced

Photograph conditions of roads. Make detailed notes in field book.

so as to minimize dust control.

ACM CC67C4

Chemical Waste Landfills

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

(iv) If landfill is above the 100-year floodwater elevation; the operators shall provide diversion structures capable of diverting all surface water runoff from a 24-hr, 25-yr storm. (§761.41(b)(3)(iii)).

Examine permit for 100 year floodwater elev. and diversion requirements. Inspect diversion structures if appropriate.

Photographs showing that structure does not meet requirements of permit, maintenance is poor, or structures have been damaged, or erosion has occurred. Make detailed notes in field book.

(v) Monitoring Systems. Monitor wells shall be cased and the annular space between zone of saturation and surface shall be completely backfilled or plugged with cement to prevent intrusion of surface water into well zone. The well shall have removable cap. (§761.41(5)(ii)(5)).

Check general integrity of wells. Check for cover. Insure that well is not plugged or filled with soil or debris. Take samples from wells.

Annular space is not completely backfilled or concrete in space is cracked or crumbling. Well is plugged, buried, damaged flooded, or otherwise unuseable. Samples cannot be retrieved from well. Analysis of well indicating excess PCBs content. Obtain photos. Make detailed notes in field book.

(vi) Leachate Collection must be monitored monthly for quality of leachate produced. (§761.41(b)(6)).

Check permit to determine leachate collection requirements. Check general integrity of leachate collection system.

Leachate system is not properly maintained. There is visible evidence that system is plugged, or damaged. Samples cannot be retrieved from system. Analysis of system sample show excess PCBs content. Take samples from system. Photo as appropriate. Make detailed field note.

ACM 000703

Chemical Waste Landfills

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

- (1) For any person who disposes of PCBs under an exemption from chemical waste landfilling, failure to give at least 30 days prior written notice of such disposal to the State and local governments within whose jurisdiction the disposal is to take place. (§761.10(g)(2)).

Request copies of notice.
Verify receipt if necessary.

Note absence of actual notice in field notes.

(2) Sec. 761.41 Operation Requirements for Chemical Waste Landfills

- (a)(i) Soils meet certain parameters (parts i through vi). Liners shall be compatible with PCBs and liner integrity maintained. Soil underlining shall be provided as well as soil cover. (761.41(b)(1)).

Check to see if cover has been put on completed burial areas or does not cover entire area used to bury PCBs to an adequate depth, or if soil cover has been eroded, damaged, or removed. Photographs of incomplete cover should be taken. Note in field book.

Photograph inadequate cover. Note in field book details of cover appearance.

- (ii) Hydrology. There shall be no hydraulic connection between site and standing or flowing surface water. Site shall have monitoring wells and leachate collection (§761.41(b)(2)).

Inspect site for flowing or standing surface water and for existence of useable monitoring wells and leachate collection systems.

Photographic documentation that flowing or standing surface water exists. Make detailed notes in field book show that monitoring wells or leachate system is not workable.

- (iii) Flood Protection if landfill is below 100 year floodwater elevation; operator shall provide division dikes around landfill a minimum height of 2' above 100 year flood elev. §761.41

Inspect for 100 year floodwater elevation and dike requirements. Inspect integrity of dikes if appropriate, and determine height.

Photographic documentation and field book note stating that dike maintenance is poor, or that dike has been eroded or damaged by operations so that gaps, cracks, or height loss has resulted.

Chemical Waste Landfills

REGULATORY REQUIREMENTS	INSPECTION PROCEDURES	DOCUMENTATION
(i) Failure to store, prior to disposal, any PCB liquids or non-liquids described above, in a storage facility that complies with Annex III. (§761.10(a)(2), (b)(5), (c)(4)).	See storage procedures.	See storage procedures.
(j) Failure to store and dispose of liquid PCBs resulting from spill incidents in accordance with 1-5 above. (§761.10(e)).	See storage and disposal procedures.	See storage and disposal procedures.
(k) For each operator of a chemical waste landfill or alternative to incineration approved under (6) above, failure to give the following written notices to the State and local governments within those jurisdiction the disposal facility is located:	Check records of PCB disposal, ask to see copies of written notices.	Obtain copies of records written notices. Note discrepancies in field book.
(i) Notice at least 30 days before a facility is first used for disposal of PCBs, and		
(ii) At the request of any State or local government, annual notice during the time the facility is used for disposal of PCBs of disposed of during the year, not more than 30 days after the end of the year covered. (§761.10 (g)(1)(i)(ii)).		

ACM C067C1

Chemical Waste Landfills

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

- | | | |
|--|---|--|
| (e) Failure to properly dispose of PCB chemical substances and PCB mixtures, which are removed from transformers. (§761.10(c)(11)). | Check on procedures for handling drained mixtures from transformers. Observe transformer drainage operation. | Photographic documentation of improper procedures. Record detailed observations in field notebook. |
| (f) Unless decontaminated in accordance with Annex IV, failure to properly dispose of PCB containers. (§761.10(d)(1)). | See incineration, chemical, and waste landfill procedures. | See incineration and chemical waste landfill procedures. |
| (g) Failure to drain the PCB container of liquid and flush it if necessary so that remaining PCB chemical substances and PCB mixtures constitute no more than 0.5 per cent of the total volume of the container, prior to disposal in a chemical waste landfill that complies with Annex II. (§761.10(d)(1)). | Check landfill site for PCB containers that contain noticeable amounts of residual materials. Obtain samples of material. Measure the size of the container and the total volume of residual. | Calculate volume of residual as percent of volume of container. Document samples. Determine if residual volume exceeds 0.5 per cent of total container volume. |
| (h) For all PCB articles other than transformers, and capacitors; if incineration is thought to be technologically infeasible, failure to obtain written permission (and failure to comply with any limitations specified therein) from the R.A. to use a chemical waste landfill for disposal. (§761.10(c)(3)). | Check landfill site for PCB articles other than transformers or capacitors. Ask to see R.A.'s written permission to use chemical waste landfills. | Obtain photographs of PCB articles disposed in landfill. Obtain copies of records. Record observations in detail in field book. |

ACM CCE7CC

B. Chemical Waste Landfills

REGULATORY REQUIREMENTS

INSPECTION PROCEDURES

DOCUMENTATION

1. Sec. 761.10 Disposal of PCBs

(a) Failure to properly dispose of liquid PCB Chemical Substance and PCB Mixtures in an incinerator that complies with Annex I. (761.10(a)(b)).

Observe for liquid PCB wastes designated for disposal, and for improper disposal of liquid PCB.

Photograph and sample suspected areas of illegal disposal.

(b) Failure to properly dispose of non-liquid PCBs in the form of a) contaminated soil, rags or other debris (permitted until July 1, 1980), b) soils and debris contaminated with PCB as a result of a spill or of placement of PCBs in a disposal site prior to February 17, 1978, and c) sewage treatment sludges that are PCB mixtures. (761.10(b)(2)(3)(4)).

Determine whether PCB items are placed in areas of the site which are approved for PCB disposal. Look for peculiarly placed items.

Note or copy records which indicate items are improperly placed. Photograph items or sample areas suspected of being contaminated.

(c) Failure to properly dispose of PCB articles. (§761.10(c)).

Look for anomalous discarded and improperly placed items.

Photograph improperly placed items. Locate on map

(d) Failure to, prior to disposal in a chemical waste landfill, drain each transformer of all free flowing liquid, fill the transformer with solvent, and allow 18 hours before solvent is drained. See (§761.10(c)(1)).

Check on procedures for handling transformers at the landfill. Observe transformer handling operation. Check transformer draining areas, solvent filling areas. Check landfill notes for undrained transformers.

Photographic documentation of improper procedures. Record detailed observations in field book.

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INSPECTION PROCEDURES

FOR

CHEMICAL WASTE LANDFILLS

ACM CC5698

Liquid PCBs - Incineration

REGULATORY REQUIREMENTS

- (c) Total weight in kilograms of any solid residues generated by the incineration of PCBs during the calendar year, the total weight in kilograms of any solid residues disposed of by such facility in chemical waste landfills, and the total weight in kilograms of any solid residues remaining on the facility site shall be retained for 5 years.
- (d) When PCBs are being incinerated, additional periodic data shall be collected and maintained as specified by the Regional Administrator pursuant to Annex I. (§761.40(d)(4)).
- (e) A document shall be prepared on any suspension of the operation of any incinerator by the owner or operator thereof, as required in Annex I - (§761.40(a)(3)). The document shall, at a minimum, include the date and time of the suspension and an explanation of the circumstances causing the suspension of operation. The document shall be sent to the appropriate Regional Administrator.

ACM 006657

INSPECTION PROCEDURES

DOCUMENTATION

REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION**

(b) In addition to the records and monitoring requirements specified in Annex VI, (See §761.45(b)) failure of each owner of a PCB Incineration facility to collect and maintain the following information.

(i) When PCBs are being incinerated, the following continuous and short-interval data shall be collected and maintained for a period of 5 years from the date of collection.

Check records.

Note discrepancies in field book. Obtain copies of any data or records available over the interval in question.

- o Rate and quantity of PCBs fed to the combustion system, as provided in Annex I. (§761.40(a)(3)).

- o Stack emission products including O₂, CO₂, and CO, as provided in Annex I. (§761.40(a)(7)).

(ii) When PCBs are being incinerated, data and records resulting from the monitoring of stack emissions as required in Annex I - (§761.40(d)(8)), shall be collected and maintained for 5 years.

ACM CCECSE

REGULATORY REQUIREMENTS**INSPECTION PROCEDURES****DOCUMENTATION**

Water scrubbers shall meet any performance requirements specified by the Regional Administrator. (§761.40(a)(9)).

- (i) Combustion efficiency shall be at least 99 per cent computed as follows:

$$\text{Combustion eff} = \frac{\text{Cco}_2 - \text{Cco} \times 100}{\text{Cco}_2}$$

Where Cco_2 = Conc. of carbon dioxide

Cco = Conc. of carbon monoxide

Section 761.40(a)(2)

- (j) Additional requirements that the Regional Administrator finds necessary must be met. (761.40(d)(4)).

Obtain concentration data from step 1. Calculate the combustion

Check the approval document for additional requirements.

(5) Particular Record Keeping Requirements for Incineration Facilities

- (a) Failure to prepare and maintain all documents required by Annex VI. (§761.45(b)).

Request opportunity to inspect PCB records.

of the water scrubber. Inspector must obtain copies of records showing non-compliance with scrubber requirements. If not possible, note the suspected violation in field book.

Combustion efficiency less than 99 per cent. Inspector must obtain a copy of appropriate records show combustion products concentrations. Show calculations in field book.

Note failure to produce, or production of inadequate records in field book

REGULATORY REQUIREMENTS

(§761.40(a)(8)(iii)).

Failure to maintain at least this dwell time causes automatic suspension of incinerator operations.

- (g) The flow of PCBs into the incinerator must stop automatically if the combustion temperature drops below the value in the selected combustion criteria.

ACM
C08654

- (h) Water scrubbers shall be used for HCL control during PCB incineration.

INSPECTION PROCEDURES

Material in the combustion chamber during PCB incineration. Calculate the maximum flow rate possible that would stay within the limits of the dwell time.

Have the operator show the temperature limit detection mechanism and the linkage to the automatic shut-off valve controlling PCB input. If possible, have the operator test the unit using off-line testing mechanisms incorporated in the devices. Review records of flow rate and combustion temperatures and locate any periods in which the temperature fell below the specified limit.

Check the approval letter for the performance requirements for the water scrubber, and verify compliance requirements.

DOCUMENTATION FOR VIOLATION

tain copies of the records showing the times when the flow rates or the chamber velocity exceeded the rates that correspond to minimum dwell time. The inspector should also show the appropriate dwell time calculations. If not possible, note suspected violation field book.

No shut-off mechanism exists, or no actuation of the shut-off mechanism occurred during a period in which the time fell below the specified limit. Inspector must obtain copies of records showing the temperature drop and no corresponding cessation of flow. If no mechanism exists, the inspector should take photographs of the feed mechanism that attests to the absence of such a shut-off mechanism, and record nature of component parts and model numbers. If not possible, note the suspected violation in field book.

No water scrubber is being used. The Inspector must take photographs of the emission control system that attest to the absence

REGULATORY REQUIREMENTS**INSPECTION PROCEDURE****DOCUMENTATION**

(b) PCBs feed rate and quantity of PCBs fed into combustion systems must be measured and recorded at least every 15 minutes. (§761.40(a)(3)). Failure to comply results in immediate suspension of incinerator operations. (§761.40(a)(11)).

Check the PCB feed rate and quantity records. Look for differences in the recording intervals of greater than 15 minutes during PCB incineration. Hold data on rate and quantity for use in dwell time determination.

Monitoring intervals greater than 15 minutes during PCB incineration
Inspector must note this in field book.

(c) The temperature of the incineration process shall be continuously recorded. (§761.40(a)(8)(11)).

Check the PCB incineration and temperature records making sure that the temperature was continuously monitored throughout the PCB incineration process.

No temperature recorded for periods of PCB incineration. Inspector must note this in his field book.

(d) Depending on the selected combustion criteria, the temperature must be maintained at 1200° (+100°C) or 1600° (+100°C) (§761.40(a)(1)(i)&(11)). Failure to comply results in immediate suspension of incineration operations.

Check the temperature records against the selected combustion criteria temperature. Make sure that the temperature is maintained within the 100° range throughout the PCB incineration process.

Temperature falls below above the specified limits
Inspector must note this in his field book.

(e) Depending on the selected combustion criteria, the oxygen concentration must be maintained at 2% or 3% excess oxygen. (§761.40(a)(1)). Failure to maintain excess oxygen at the level specified causes automatic suspension of incinerator operations. (§761.40(a)(8)(iii)).

Check the combustion products, monitoring results. Make sure that oxygen concentration was maintained at the appropriate level during PCB incineration. Verify automatic cut-off.

Oxygen concentration fall below specified excess oxygen level. Inspector must obtain a copy of the monitoring records that show this violation. If not possible, note the suspected violation in field book.

(f) Depending on the selected combustion criteria, the dwell time must be maintained for at least 1-1/2 or 2 seconds.

Obtain feed rate data from step 2. Have the operator provide the calculations he used to determine dwell time of the

Dwell time is less than time specified in the selected combustion criteria. Inspector must obtain record of dwell time.

REGULATORY REQUIREMENTS

(c) Unless decontaminated in accordance with Annex IV, failure to dispose of PCB containers in an incinerator that complies with Annex I or in a chemical waste landfill that complies with Annex II. (§761.10(d)(1)).

(d) Failure to drain the PCB container of liquid and flush it if necessary so that remaining PCB chemical substances are removed.

(3) Sec. 761.20 Marking of PCBs

(a) Failure to mark as specified with Mark M_L as described in Annex V each of the following items in existence on or after July 1, 1978:

- (i) PCB Containers
- (ii) PCB article containers
- (iii) Such storage area used to store PCBs

(4) Sec. 761.40 Incineration

(a) Continuously monitor and record the combustion products whenever PCBs are being incinerated. At a minimum O₂, CO₂ and CO are monitored. (§761.40(a)(7)). Failure to monitor results in automatic suspension of incinerator operations. (§761.40(a)(9)(L))

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INSPECTION PROCEDURES

DOCUMENTATION

Determine procedure for disposition of used PCB containers, articles, and equipment. Look for containers which have residues. Look for marked and or dated containers which have not been disposed but are contaminated.

Note in field book source of statement on improper procedures. Photograph marked containers which are improperly disposed.

Same as above.

Same as above.

Check PCB containers, article containers and storage areas for appropriate marking.

Photograph items that are unmarked. Obtain sample from unmarked containers. Note discrepancies in field book.

Check the incinerator records and the combustion products monitoring records. Make sure that O_2 , CO_2 , and CO were monitored at all times during the PCB incineration period. Hold data on CO_2 , CO for use in combustion efficiency determination.

No combustion products monitoring records are available for periods of PCB incineration.
Inspector must note this in field book.

O.

REGULATORY REQUIREMENTS

(c) For any person who disposes of PCBs under an exemption from incineration, failure to give at least 30 days prior written notice of such disposal to the State and local governments, within whose jurisdiction the disposal is to take place. (\$761.10(g)(2)).

(d) For any person who is required to incinerate any PCB and who contends that there is available a means of destroying PCBs which is as efficient as the incineration procedure provided in Annex I, failure to obtain written approval of the Regional Administrator before employing any method of disposal of any PCB other than incineration with Annex I. (\$761.10(f)).

(2) Sec. 761.10 Disposal Of Non-liquid PCBs

(a) Failure to properly dispose of non-liquid PCBs in the form of contaminated soil, rags, or other debris (761.10(b)(2)), soiled or contaminated with PCBs as a result of a spill or as a result of placement of PCBs in a disposal site prior to February 17, 1978 (761.10 (b)(3)).

(b) Failure to properly dispose of PCB articles. (761.10(c)).

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INSPECTION PROCEDURE

DOCUMENTATION

Determine whether exemption is required, i.e. whether disposal other than by incineration takes place. Verify notice.

Obtain copies of notice letters. Verify by phone or letter that letters were sent or received by agencies.

Ask to see approval documentation determine whether disposal methods require approval beyond customary site approval.

Inspector should note in field book that PCBs are being handled in a manner such that all PCBs are not incinerated. Verify by examining approval document.

In areas where PCB items are used, processed, transported, stored or decontaminated, or otherwise handled, check for likelihood of PCB contamination. Observe for oily residues, discoloration etc.

Sample, if necessary. Investigate source of contamination. Note observations in field book. Photograph obvious contamination and sources of contamination.

Assess whether facility procedures assure incineration of all PCBs or sending them to proper disposal.

Photograph PCB items which are not incinerated or sent to disposal.

A. Incineration

REGULATORY REQUIREMENTS

(1) §761.10 Disposal of Liquid PCBs

- (a) Failure to comply with any conditions and/or limitations stated in the written approval document.**

- (b) For each operation of an incinerator or alternative to incinerator, failure to give the following written notices to the State and local governments within whose jurisdiction the disposal facility is located.**
 - (i) Notice at least 30 days before facility is first used for incineration of PCBs.
in an approved incinerator.**
 - (ii) At the request of any State or local government, annual notice during the time the facility is used for disposal of PCBs or disposed of during the year, not more than 30 days after the end of the year covered.
(§761.10(g)(1)(i),(ii))**

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INSPECTION PROCEDURES

DOCUMENTATION

Compare operation to conditions and/or limitations specified in the approval documents.

Obtain copies of record and charts that show that that operation exceeds specific limits. Photograph if possible. Document in field book.

Check records of PCB disposal operation. Ask to see copies of notices.

Obtain copies of records written notices. Note discrepancies.

also provide for sending the PCB items to incinerators which are approved to incinerate them. An assessment of the facilities general procedures for receiving and disposing of the PCBs received can often provide significant clues as to whether the facility is careful in disposing of items in accordance with its approval document.

A portion of the inspection should consider whether the facility is fastidious in disposing of all its PCBs. Many items such as rags old containers and even sweepings from floors may be disregarded as insignificant trash or waste. The inspector should explore the facilities diligence in PCB housecleaning and assure that such contamination is not left unaddressed.

A third but not necessarily final area of concern is the information in the facilities PCB records. The list of parties transporting PCBs to the a disposal facility should be copied. This may provide new information concerning PCB users. The inspector should also assess whether the facility is keeping all of the data which is required under Annex VI and their approval or waiver documents. In addition, the monitoring records for the facility should be reviewed to determine whether the facility is operating within its prescribed limits and whether these limits have been properly monitored. Some of the monitoring requirements in the regulations require continuous monitoring. Some require intermittent monitoring. These monitoring methods should be reflected in the monitoring records which have been retained by the facility. The data should conform to the requirements of annexes I or II and VI as well as any requirements imposed by approval waiver documents.

UNAPPROVED SITES

The above discussion concerned only approved PCB disposal facilities. Inspections of suspected illegal or unapproved disposal facilities present two problems: First of all the inspector must establish the presence of PCBs at the facility. Second it must be established that the act of disposal occurred after April 18, 1978.

Establishing the presence of PCBs may be accomplished by locating PCB labels or PCB items by sampling or by other methods such as comparing serial numbers to manufacturers records. Determining that disposal occurred after April 18, 1978 presents a more difficult problem. This may require direct observation of acts of disposal; unless other approaches are available. In the instance of PCBs which have at one time been in a proper storage facility, the items should be dated. Many other PCB items may be dated for one purpose or another. Where the operation of an unapproved site is suspected the inspector should make every effort to gather all relevant evidence to ensure complete enforcement against the facility.

Introduction to Disposal Site Inspections

When inspecting PCB disposal facilities there are at least three investigations which should be pursued. 1) are the PCB disposal processes functioning properly. 2) are all of the PCBs sent to an approved disposal process, and 3) are the PCB records properly kept.

The first concern in inspecting a disposal facility is whether the facility effectively disposes of PCBs in a manner which is permitted in the site's approval document. For incinerators and chemical waste landfill facilities there are specific minimal performance criteria which are incorporated as part of their facility approval documents (see requirements detailed below). Additionally the site approval document may apply further restrictions, requirements or waivers to the operation of the facility.

Whenever an alternative method of disposal is authorized under the regulations the authorization will usually also specify performance standards for the alternative method to meet. The inspector should collect the performance standards from the various approval and authorization documents and use them for comparison with the facility's operating data.

Many of the performance requirements in the regulation are supported by requirements for related monitoring equipment. A necessary first part of the inspection process is to determine whether all of the required monitoring equipment for the facility is in place and is operating properly. In addition to determining whether all of the equipment is measuring their required parameters properly, some equipment, measuring vital criteria, may be required to incorporate automatic shut off mechanisms. The inspector should establish that these mechanisms work as required.

Another priority during an inspection is to determine if the facility properly receives and sends all of the PCBs that it receives to an approved disposal process. The basic issues are whether the facility is diligent in identifying the types of PCBs being received, and whether the facility is sending these PCBs to a disposal process which is in accordance with its approval document. A simple example of this would occur when liquid PCBs are received at a chemical waste landfill transformers or containers and the landfill fails to remove the liquid PCBs from the items before disposal. The liquids would then have to be either properly stored or directed to an approved incinerator. This situation will occur where transformers, containers, or equipment are sent to landfills by users who have failed to drain the PCBs. Another example would occur where incinerators receive PCB equipment or articles for disposal and their approval document does not permit them to dispose of those particular items. Landfills receiving liquid PCBs should have observable procedures for recognizing liquid PCBs when they are received and for sending them on to an appropriate disposal facility. Incinerators should have similar procedures for identifying PCB items which may not be disposed of under their approval document. The procedures must

INSPECTION PROCEDURES

FOR

INCINERATION FACILITIES

ACM 008667

Appendix VI

Environmental Protection Agency
Toxic Substances Control Act
PCB Marking and Disposal Regulation

CHAIN OF CUSTODY RECORD

Name of Person Taking Sample:

Signature:

Inspector's Number:

<u>Type of Sample</u>	<u>Date Taken</u>	<u>Time Taken</u>	<u>Place Taken</u>	<u>Required Analysis</u>
-----------------------	-------------------	-------------------	--------------------	--------------------------

Relinquished by:

Received by:

Date:

Time:

Relinquished by:

Received by:

Date:

Time:

Relinquished by:

Received by:

Date:

Time:

Dispatched by:

Date:

Time:

Received for Laboratory by:

Date:

Time:

Method of Shipment:

Distribution: Original to Accompany Shipment (inside locked shipment container). One copy from laboratory to Regional PCB Violation Coordinator upon completion of analysis.

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Appendix V

U.S. Environmental Protection Agency

Receipt for Samples

Regional Address:

Name of Plant Manager
or Similar Official:

Firm Name:

Firm Address:

Sample Numbers:

Samples Collected: (Describe fully the time, place, date and type of
sample, number of containers for each type of sample)

Acknowledgement of Plant Manager or Similar Official

The undersigned acknowledges that the samples described above have
been collected:

Signature:

Title:

Duplicate Samples for each Type of Sample Taken:

Sample #

Requested and provided

Not requested

Name of person who
collected samples:

Title of Collector:

Signature of Collector:

Distribution: one copy to Facility Plant Manager
original to PCB Violation Coordinator
one copy for Inspector's Records

Appendix IV

SAMPLE TAG

USEPA, TSCA PCB Marking and Disposal Regulation Field Sample

Inspector's Name

Type of Samples

Date Taken

Time Taken

Place Taken

Name of Person
Taking Sample

(written & signed)

Analysis Required:
(Determination of PCB Content)

Sample Number:

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Appendix III
TSCA INSPECTION CONFIDENTIALITY NOTICE

United States Environmental Protection Agency

Regional Address: _____

Facility Inspected:

Name of person at the facility
to whom this notice given:

Date Inspected:

Address of Facility:

TITLE

Name of chief officer
of business:

Name of EPA Inspector:

Address:

Date mailed to chief
officer:

It is possible that EPA will receive public requests for release of the information obtained by inspectors during inspection of the facility indicated above. Such requests will be handled by EPA in accordance with provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552, EPA regulations issued thereunder, 40 CFR Part 2, and the Toxic Substances Control Act Section 14. EPA is required to make inspection data available in response to FOIA requests unless the Administrator of the agency determines that the data contains information entitled to confidential treatment.

In order to facilitate the Agency's timely response to any public inquiries, while giving due consideration to your company's right to request confidentiality, please provide us with a statement specifying any information which our inspection of the above indicated facility may reveal which you believe should be entitled to confidential treatment.

Your statement should be addressed to _____
(RESPONSIBLE EPA OFFICIAL) and should reach this address no later than 30 days after your receipt of this notice. Failure by your firm to submit, within the 30 day time period, a written request that information be characterized as confidential or privileged will be treated by EPA as a waiver by your company of any claims for confidentiality regarding the inspection data and the data will be made available to the public without further notice to you.

date received by owner/operator

signature of Plant Manager

Distribution: one copy Plant Manager
one copy Chief Officer of Business
one copy PCB Violation Coordinator
one copy Inspector's Files

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Reverse Side- Notice of Inspection

TSCA Notice of Inspection Authority to Conduct Inspections

By authority of Section 11 of the Toxic Substances Control Act (15 USC 2601) an authorized representative of the Administrator of the United States Environmental Protection Agency may enter and inspect, at reasonable times, any establishment facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance used to transport chemical substances, mixtures, or such articles in connection with distribution in commerce.

Scope of Inspections

Inspections conducted under Section 11 of the Toxic Substances Control Act (15 USC 2601) extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing upon whether the requirements of the Toxic Substances Control Act applicable to the chemical substances or mixtures within the premises or conveyance have been complied with.

However, inspections shall not extend to the following types of data unless the nature and extent of such data are described with reasonable specificity in the written notice presented to the owner, operator, or agent in charge of the premises or conveyance:

1. financial data
2. sales data (other than shipment data)
3. pricing data
4. research data (other than research data required by the provisions of the Toxic Substances Control Act or under a rule promulgated thereunder)
5. personnel data.

Penalties for Failure to Allow Inspection

Section 15 of the Toxic Substances Control Act makes it unlawful for any person to fail or refuse to permit entry or inspection as required by Section 11 or to fail or refuse to permit access to or copying of records. Section 16 provides for both civil and criminal penalties for violations of Section 15. Section 17 authorizes specific enforcement, including the obtaining of an injunction to restrain any violations of Section 15.

Appendix II

U.S. Environmental Protection Agency
NOTICE OF INSPECTION
UNDER THE TOXIC SUBSTANCES CONTROL ACT

Name of Firm:
Firm Address:

Date Inspection Commenced:
Hour:
EPA Regional Office Address: (type)

Reason for Inspection:

☐ For the purpose of inspecting (including taking samples, photographs and other inspection activities) an establishment, facility, or other premises in which chemical substances or mixtures or articles containing same are manufactured, processed or stored, or held before or after their distribution in commerce (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of the Act applicable to the chemical substances, mixtures or articles within or associated with such premises have been complied with.

☐ For the purpose of inspecting (including taking samples, photographs and other inspection activities) a conveyance being used to transport chemical substances, mixtures, or articles containing same in connection with their distribution in commerce (including records, files, papers, processes, controls and facilities) bearing on whether the requirements of the Act applicable to the chemical substances, mixtures or articles within or associated with the conveyance have been complied with.

☐ In addition, this inspection extends to (circle appropriate letters):

- A) Financial data
- B) Sales data
- C) Pricing data
- D) Personnel data
- E) Research data

The nature and extent of inspection of such data specified in A through E above is as follows:

Name of Person to Whom
Notice of Inspection Was Given:

Signature of EPA Employee:

_____ DATE _____

TITLE _____

TITLE _____

Distribution: one copy Plant Manager
one copy PCB Violation Coordinator
one copy Inspector's Files

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Appendix I

TSCA Inspection Credentials

UNITED STATES OF AMERICA

ENVIRONMENTAL PROTECTION AGENCY

This is to certify that

whose signature and photo appear below is an authorized representative of the Administrator of the U.S. Environmental Protection Agency.

Date issued:

Expiration Date:

Name:

Title: Inspector

(Photo)

This Inspector is authorized under the Toxic Substances Control Act to conduct inspections (including taking samples, photographs and other inspection activities) of establishments, facilities, or other premises in which chemical substances

or mixtures or any articles containing same are manufactured, processed, stored or held before or after their distribution in commerce, and any conveyance being used to transport chemical substances, mixtures or such articles in connection with distribution in commerce.

Signature of Inspector

Signature of the Administrator

No. _____

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Couriers picking up samples at the airport, post office, etc. shall sign jointly with the laboratory custodian. If samples are delivered to the laboratory when appropriate personnel are not there to receive them, the samples must be locked in a designated area within the laboratory in a manner so that no one can tamper with them. The same person must then return to the laboratory and unlock the samples and deliver custody to the appropriate custodian.

d. Immediately upon receipt, the custodian will place the sample in the sample room, which will be locked at all times except when samples are removed or replaced by the custodian. To the maximum extent possible, only the custodian should be permitted in the sample room.

e. The custodian shall ensure that heat-sensitive or light-sensitive samples, or other sample materials having unusual physical characteristics, or requiring special handling, are properly stored and maintained.

f. Only the custodian will distribute samples to personnel who are to perform tests.

g. The sample analyst will record, in his laboratory notebook or analytical worksheet, identifying information describing the sample, the procedures performed and the results of the testing. The notes shall be dated and indicate who performed the tests and they should note any abnormalities which occurred during the testing procedure. In the event that the person who performed the tests is not available as a witness at time of trial, the government may be able to introduce the notes in evidence under the Federal Business Records Act.

h. Standard methods of laboratory analyses shall be used as described in the "Guidelines Establishing Test Procedures for Analysis of Pollutants", 38 F.R. 28752, October 16, 1973. If laboratory personnel deviate from standard procedures, they should prepare the justification for the deviation in the laboratory notebook.

i. Once the sample testing is completed, the unused portion of the sample, together with all identifying tags and laboratory records, should be returned to the custodian. The returned tagged sample will be retained in the sample room until it is required for trial. Strip charts and other documentation of work will also be turned over to the custodian.

j. Upon completion of laboratory PCB sample analysis, the custodian shall send a copy of all laboratory records and a copy of the appropriate chain of custody record to the Regional PCB Violation Coordinator. The laboratory should retain the originals as permanent records.

k. Alterations in or deviation from this chain of custody procedure must be approved, by the Regional Office of General Counsel and/or the Headquarters Enforcement Office, prior to implementation.

- a. In your physical possession, or
- b. In your view, after being in your physical possession, or
- c. After being in your physical possession was locked by you in a manner so that no one could tamper with it.

The following procedures should be followed:

(1). Samples will be accompanied by a Chain of Custody Record (Appendix VI) which includes, the name of person taking the sample; inspector's number; type of sample taken; analysis required. If the person who takes the sample is required to transfer possession of the sample prior to dispatching it to the appropriate laboratory for analysis, the transferor and transferee will sign, date and time the sheet.

(2). The inspector taking the sample, or the person who rightfully receives possession of the sample directly or through a chain originating with the inspector who took the sample, has the responsibility of properly packaging and dispatching samples to the proper laboratory for analysis. As a matter of policy, the inspector taking the sample should not relinquish possession of the sample prior to dispatch to the appropriate laboratory except in circumstances where to do so would be highly impractical. In any event, the person who dispatches the sample to the appropriate laboratory for analysis should fill in the "Dispatch" portion of the Chain of Custody Record.

(3). Samples will be properly packed in shipment containers such as ice chests to avoid breakage. The shipping containers will be padlocked for transfer to the receiving laboratory.

(4). All packages will be accompanied by the Chain of Custody Record showing identification of the contents. The original will accompany the shipment (inside the locked shipment container) and will remain on record in the laboratory performing the analysis.

(5). If sent by mail, the person who dispatches the sample to the laboratory must send the package certified mail with return receipt requested. If sent by common carrier, a government bill of lading should be obtained. Receipts from post offices and bills of lading will be retained as part of the permanent Chain of Custody documentation.

2. Laboratory Custody Procedures

a. The laboratory shall designate a "Sample Custodian". An alternate will be designated in his absence. In addition, the laboratory shall set aside a "sample storage security area". This should be a clean, dry, isolated room which can be securely locked from the outside.

b. All samples should be handled by the minimum possible number of persons.

c. All incoming samples shall be received only by the custodian who will indicate receipt by signing the Chain of Custody Record Sheet accompanying the samples and retaining the sheet as permanent records.

is a "Duplicate Sample". Of course, the fact of having prepared a duplicate sample should be reflected in the Inspector's Field Notes. If you provide a duplicate sample, make the appropriate notation on the chain of custody record, described below.

C. Special Category of Samples - Photographs

During an inspection, you may want to photograph various parts of the facility, certain operations in the facility or locations where a sample was taken. In all cases where you take a photograph during an inspection, write the following in your Field Notes for each photograph taken.

1. Nature of object or process photographed
2. The sequential number of that photograph for the inspection.
3. Inspector's Number
4. Inspector's Name
5. Time, date and place of taking photograph.

When the photographs are developed, transpose the information recorded in your fields notes onto the back of the photograph at your first opportunity.

4. Post - Sampling Procedure

A. Identification of Samples

Each unit of the sample is to be tagged in the Inspector's handwriting in ballpoint (waterproof) ink. The tag (See Attachment IV) shall contain, at a minimum, the following information: Inspector's Name, type of sample, sample number, name of person taking sample, and the type of analysis required. This tag should be completely filled out by the inspector and attached to the sample container.

B. Receipt of Samples

After taking a sample, prepare a Receipt for Samples Form in triplicate (See Appendix V). Give one copy to the Plant Manager or similar official at the facility, include one copy in your Inspection Report and retain one copy for your own records. You may record all the samples taken during the inspection of a facility on one Receipt for Samples Form.

E. Chain of Custody Procedures

1. Inspector to Laboratory

The inspector who collects samples is responsible for the care and custody of the samples until properly dispatched to the receiving laboratory or turned over to an assigned custodian. You must assure that each container is:

unless the situation is such that it is impossible for you to do so or to force the issue would provoke a scene creating embarrassment to or bring discredit on the government.

- B. Make no private promises of any kind which may be construed as binding upon the Agency since a Government employee by his private word cannot bind the Government.
- C. Never use any information coming to you confidentially in the performance of governmental duties as a means for making private profit.
- D. During an inspection do not speak of any product, process, facility or person in a derogatory manner.

Taking Samples

1. Responsibility

Samples should be collected and prepared in accordance with procedures outlined in this Manual. Keep in mind that you may have to testify in court regarding a sample you have taken. You may be required to identify the sample collected and to explain that you followed the sampling procedures provided in this Manual. Mistakes or deficiencies in procedures may damage the Government's case in this regard. However, if you make a mistake in sampling, do not, under any circumstances, attempt to cover up the mistake. Record the mistake in your Field Notes and re-take the sample as appropriate.

2. When to Sample

Take a sample only under the circumstances indicated in this Manual and only during the course of an inspection of a facility covered by this Manual.

3. How to Sample

A. Taking Samples

When taking a sample during an inspection of any facility covered by this Inspector's Manual you should follow the specific sampling techniques appropriate for each type of facility you inspect. Deviation from the Standard Methods and procedures for a sample might cause problems in introducing your sample into evidence during an enforcement proceeding. If there is any deviation from established procedures, explain the deviation in your Field Notes.

B. Duplicate Samples

If a responsible agent of the facility being inspected requests a duplicate sample, it should be collected and marked in the same manner the official samples, with an indication on the extreme left hand corner of the Sample Tag to be attached thereto that the sample

the allowable scope of your inspection, remind the person that such prohibition is unlawful but do not argue with the person who prohibits your inspection. Simply ask the person why you are not being allowed to inspect the particular thing or process and note all the particulars in your Inspection Diary, along with the name of the person who refused to let you inspect. Then, continue the remainder of your inspection of the facility. Following the inspection, contact the designated TSCA Enforcement Attorney for the regions for instructions concerning the area where you were not allowed to inspect.

- D. If an authorized representative of the facility being inspected wishes to accompany you during the inspection allow him to do so.
- E. Be alert for any statements made by employees of the facility being inspected which may be construed to be admissions of acts of violation of the regulation.

Prohibited Activities

The following activities may not be engaged in by an EPA inspector before, during or after an inspection of a facility under the PCB Marking and Disposal Regulation. These prohibitions are based upon and derived from material in the EPA Pesticides Inspections Manual.

- A. Never discriminate by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for yourself or anyone else, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of your government duties. The EPA handbook entitled "Responsibilities and Conduct for EPA Employees" specifies that an employee shall not accept anything of value from the trade, public or consumers for or because of any official act he has performed or will perform. Each inspector should refer to the above referenced handbook for amplification of this policy.

In this regard one area of concern to inspection personnel which generates more questions than any other is the matter of handling a situation where, during a facility inspection, you have lunch with plant officials and/or personnel and find your lunch paid for by them, or there is no way you can pay for your portion of the luncheon. EPA regulations cover this by providing an exemption whereby you can accept food and refreshments of nominal value on infrequent occasions in the ordinary course of an luncheon or dinner meeting or other meeting or on an inspection tour where you may be properly in attendance.

Under no circumstances shall you interpret this to allow acceptance of meals or refreshments when it is proper and feasible for you to pay for your own. You must avoid such situations when possible and must make every effort to pay your part.

reports, they must contain only facts and observations. Language should be objective, factual and free from personal feelings or terminology which might prove inappropriate. The Field Notes are part of EPA's files and should not be considered the inspector's personal property.

The government's case in a formal hearing or criminal prosecution hinges on the evidence gathered by the inspector. It is likely that inspectors will be called to testify in enforcement hearings. Therefore, it is imperative that each inspector keep detailed records of inspections in his Field Notes. This data will serve as an aid in giving testimony, in determining the conduct of the prosecution of the alleged violator, and in helping the inspector prepare his Inspection Report.

Personal Demeanor During Inspection

An inspector must conduct an inspection with the highest degree of honesty and is expected to perform his duties in a professional and responsible manner. At the very least, the inspector must conduct himself at all times in accordance with the regulations prescribing Environmental Protection Agency Employee Responsibilities and conduct which were published in the Federal Register (Vol. 38, No. 73) on April 17, 1973, codified at 40 CFR Part 3, and reissued in the EPA handbook "Responsibilities and Conduct for EPA Employees". In addition, the inspector must:

- A. Develop and report facts of inspections completely, accurately and objectively.
- B. Inspectors should at all times wear such safety equipment as is customary in the facility being inspected. Inspectors should wear a hard hat, safety glasses or gloves if the owner or his agent so advises.
- C. Know the limits of your inspection authority. If you have presented the appropriate credentials and written notice of inspection, your inspection of the facility may extend to all things within the premises being inspected (including records, files, papers, processes, controls and facilities) bearing on whether the requirements of the PCB Marking and Disposal Regulation have been complied with. Although you may not on your own authority take anything belonging to the facility other than a sample out of the facility, you may copy any relevant records and take the copies with you as part of your inspection report. You should remember that if you want to inspect financial data, sales data (other than shipment data), or most research data you need to describe the nature and extent of such data you wish to inspect in the written notice of inspection. If at any time during the inspection you are prohibited from inspecting particular things or processes which you believe are within

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for such conclusions. Also note such observations about the appearance of the facility as are possible. If there is a belief that an immediate inspection of the facility is imperative, call the Headquarters Regional Coordination Unit at 202-755-1212. Where immediate inspection is desired, a search warrant may be required by law. The Regional Coordination Unit will aid the inspector in obtaining a warrant where appropriate.

D. Inspection Procedures

1. Conduct During Inspection

**Inspector's Instructions, Violation Worksheet
and Maintenance of Diaries and Field Notes**

The Inspection Manual for the PCB Marking and Disposal Regulation is divided into several sections. In addition to the sections dealing with Legal Requirements for Inspections and the Enforcement Proceedings Manual, the Inspection Manual contains instructions on how to conduct inspections at the various categories of facilities subject to the regulations. For each category of facilities, there are separate instructions. Thus, for example, if you are inspecting an electric utility company facility, turn to the Electric Utility Company portion of the Inspector's Manual and follow the instructions provided there. While conducting an inspection of a particular facility, the inspector should closely follow the instructions in the Inspection Manual for inspecting facilities of that type to the extent that they apply to the circumstances of the particular facility.

Each inspector must maintain legible and detailed Field Notes providing an accurate and inclusive documentation of inspection activity. Entries in an Inspector's Field Notes should include, but not be limited to, the following:

- (i) Name and location of facility inspected
- (ii) Explanation of what parts of the facility were inspected
- (iii) Summary of inspection related conversations with facility employees, along with names of employees with whom the conversations occurred
- (iv) Place in the facility where samples were taken, along with explanation of the sampling technique employed, including, but not limited to:
 - (1) Number of samples collected
 - (2) Description of origin of sample (transformer, PCB container, etc.)
 - (3) Detailed analysis of method of obtaining the samples, including description of sample container.
- (v) Nature of suspected violation, including place and time of discovery, and including explanation of why you think your discovery is a violation.

Inspection Confidentiality Notice, shown in Appendix III. You will have four copies of the TSCA Inspection Confidentiality Notice. At the time you present a copy of this Notice to the facility official, place a copy in an envelope addressed to the Chief Officer of the business whose facility you are inspecting. You should determine the name of such Chief Officer before your arrival at the inspection site. Mail the envelope at your earliest opportunity via certified mail. The envelope should be mailed no later than two days after your inspection of the facility.

As indicated in the Enforcement Proceedings Manual, when you submit your Inspection Report to the person indicated in the Enforcement Proceedings Manual, also submit one copy of the TSCA Inspection Confidentiality Notice. Retain one copy for your own records.

6. Opportunity to Accompany Inspector During Inspection

At the time you present the appropriate facility official with the Notice of Inspection, tell him that company representatives may accompany the inspector during the inspection for the purpose of:

- (a) indicating to the inspector which processes, facilities, operations, records, etc. of the facility should be treated as confidential, and
- (b) any other reasonable purpose.

7. Opportunity to Obtain Duplicate Samples

At the time you present the appropriate facility official with the Notice of Inspection tell him that you may be taking samples during your inspection and inform the official that he has the right to request and receive duplicate samples.

C. What To Do If You Are Denied Entry

1. If you are denied entry, first make sure that you have provided the appropriate facility official with all of the material which must be presented prior to inspection. If you have not presented this official with such material, do so.

2. If you have followed all the appropriate procedural steps prescribed above and you are still denied entry, ask the person who denied you entry his or her reason for denying you entry into the facility. If the response indicates that you failed to adequately show your credentials show the person your credentials again.

3. If the person adamantly refuses to admit an inspector, make no further attempt to enter.

Upon leaving the premises make appropriate notes concerning any relevant observations which may have been noted concerning the refusal. If there are any reasonable bases for suspecting that refusal was based upon a desire to cover up regulatory violations note the bases

3. Written Notice of Inspection

You must present the appropriate person at the facility to be inspected (preferably the Plant Manager or other similar official) with written notice of your intent to inspect the facility. Present the written notice at the time you appear at the facility to conduct the inspection. As a general rule advance notice of an inspection should not be given. However, a general notice to a company or an industry that it may be subject to inspection in the next several months is permissible. There may even be instances where specific advance notice of inspection would be warranted. The giving of any such specific advance should first be cleared through the Headquarters Regional Coordination Unit. Presentation of this notice will allow you to inspect most things in operation in the facilities. However, if you wish to inspect any of the following:

- (1) Financial data;
- (2) Sales data (other than shipment data);
- (3) Pricing data;
- (4) Personnel data, or
- (5) Most research data

The written notice of inspection which you present to the appropriate official at the facility to be inspected must also contain a description of the nature and extent of the data in the above categories which is to be inspected. As a general rule, you will know in advance if you are going to inspect such data at the facility, in which case you should ensure that the notice of inspection describes the nature and extent of that data. An example of a written notice of inspection is shown in Appendix II.

4. Credentials

You must bring with you and present to the appropriate person at the inspection site (Plant Manager or similar official having responsibility for operations at plant) credentials which indicate that you are a lawful representative of the Administrator of the Environmental Protection Agency and that you are authorized to perform the inspection which you are to undertake. Sample credentials for making inspections of facilities under TSCA are shown in Appendix I.

5. Confidentiality

During the inspection of a facility, you may come across information which should be treated as confidential by the Environmental Protection Agency. To help protect bona fide business trade secrets from public disclosure, you must adhere to the following procedure at the time you present your credentials and notice of inspection to the appropriate official at the facility you are about to inspect.

At the time you present the facility official with the Notice of Inspection, also present such official with one copy of the TSCA

B. Pre Inspection Considerations

1. General Preparation for Inspections

Certain Documents and data should be obtained and reviewed prior to performing on site inspections. Whenever practicable the inspectors should obtain relevant Federal State and Local permits and authorizations which have been obtained by the facility for the purpose of operating the facility. These permits should be reviewed to determine whether PCBs have been at issue with other regulatory programs. In addition, where possible the record for compliance with other relevant regulatory programs should be investigated by obtaining pertinent data.

The inspector should at all times obtain all PCB related approval documents, authorizations, exemption documents prior to arriving at an inspection site.

Where these documents contain operating conditions and requirements these conditions and requirements should be noted and serve as the basis for specific inquiries during the inspection. The inspector should then verify that the facility is complying with these conditions and requirements.

After review of the above documents and any available PCB records the inspector should prepare the Notice of Inspection. The scope of the Notice should, at a minimum, cover the specific areas that the office review indicated may be potential problems.

2. Records Review

Prior to conducting a physical inspection the PCB records for the subject facility should be examined. In some instances the records inspection may be conducted prior to the physical inspection by requesting the facility to send the records to the Regional Office. Conducting the records inspections early might make the conduct of the physical inspection less difficult.

The arithmetic related to records inspections is fairly simple: PCBs removed from service should equal the PCBs stored plus the PCBs disposed. In addition to striking an appropriate balance, the records should adequately describe the disposition of all of the PCB items connected with the particular facility. The inspector should be able to determine the name and location of all storage and disposal facilities used, including the final disposal site.

The value of the records inspection lies in forcing the PCB facility to account for their PCB items in a fairly accurate manner. An inspector, by using the recorded information, should be better able to conduct physical inspections. Where records are kept properly, the inspector's observations of facility processes should serve to uncover sources of imbalance in the PCB equation. In addition to forming the basis of a violation in itself, inadequate or inaccurate record keeping serves as a flag to areas of concern in inspecting facilities.

A. INTRODUCTION

1. GENERAL AUTHORITY TO CONDUCT INSPECTIONS

Section 11 of the Toxic Substances Control Act (15 U.S.C. 2601) provides the basic authority for inspection of establishments and conveyances. It authorizes an inspector to enter, at reasonable times, any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance used to transport chemical substances, mixtures, or such articles in connection with distribution in commerce.

Inspections may be made only upon the presentation of appropriate credentials and written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. Section 11 provides that a separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection.

2. SCOPE OF TSCA SECTION 11 INSPECTIONS

Inspections conducted under Section 11 extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing upon whether the requirements of TSCA applicable to the chemical substances or mixtures within the premises or conveyance have been complied with. However, inspections shall not extend to the following types of data unless the nature and extent of such data are described with reasonable specificity in the written notice presented to the owner, operator, or agent in charge of the premises or conveyance:

- a. financial data
- b. sales data (other than shipment data)
- c. pricing data
- d. research data (other than research data required by the provisions of TSCA or under a rule promulgated thereunder)
- e. personnel data

3. PENALTIES FOR FAILURE TO ALLOW INSPECTION

Section 15 of TSCA makes it unlawful for any person to fail or refuse to permit entry or inspection as required by Section 11 or to fail or refuse to permit access to or copying of records. Section 16 provides for both civil and criminal penalties for violations of Section 15. Section 17 authorizes specific enforcement, including the obtaining of an injunction to restrain any violations of Section 15, or to compel taking of any action required under TSCA.

LEGAL REQUIREMENTS OF INSPECTOR'S PROCEDURES

ADM 000000

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TOXIC SUBSTANCES CONTROL ACT

PCB MARKING AND DISPOSAL REGULATION

INTERIM INSPECTION GUIDANCE



ACM CC8666

a waterway could very well make the violation attain a higher level of gravity. Upon making the level of gravity determination, the indicated penalty should be used as a base from which adjustments should be made according to the following additional statutory criteria:

1. Violator's ability to pay. This factor may be difficult to consider at the time of penalty assessment, since the inspector ordinarily will not examine violators' financial records (See Section 11(b)(2)(A)). Thus, the inability of a violator to pay probably would not be fully considered until raised by the violator after issuance of the complaint. However, several factors can be evaluated at the initial stages of penalty determination. The inspector should inquire of the person-in-charge the size of the business being inspected. Gross annual revenue is probably the best indication. In addition, the inspector or violation coordinator can consult Dun & Bradstreet, even prior to the inspection, to determine gross annual revenue. In determining a violator's ability to pay, the fact that a company is a subsidiary of a parent corporation should be considered, i.e., it is appropriate to look at the resources of the parent. A reduction of penalty amount of up to 20% may be allowed where gross annual revenues are below \$250,000 and up to 10% where gross annual revenues are between \$250,000 and \$1,000,000. No reduction will be allowed for larger companies.

2. Inability of a violator to continue in business. This category is intertwined with "ability to pay". A substantiated claim of inability to continue in business if a large penalty is sustained may require negotiation of the penalty to an amount lower than would otherwise be assessed under these guidelines. Since such a claim will not normally be raised until after the initial penalty assessment, it is discussed below.

3. History of prior such violations. Where a violator has no prior history of violation of EPA regulations or statutes, penalties may be reduced up to 20%. A violator with a prior history of EPA violations, but with no prior violations of TSCA receives no penalty adjustment. If a violator has any previous TSCA violations his penalty should be increased 10% for each prior TSCA violation. If a violator has violated the same standard previously, the repeated nature of this violation requires that the penalty be raised 25% for Levels I and II, and 50% for Levels III and IV (up to \$25,000 total) - these figures should be doubled in cases where the same standard is violated for the third time. For the purpose of this "repeat" policy, a company with more than one facility can be assessed for a repeat violation if the second violation takes place at a different facility than did the initial violation.

4. Degree of culpability. The degree of culpability of a violator should also be considered in the penalty assessment. A reduction of up to 20% may be allowed where the violation was substantially contributed to by persons outside the violator's company, or where the violator has made a good faith effort to comply with the regulation.

Conversely, a person who negligently and/or willfully violates the Act suffers an upward penalty adjustment. Thus, a negligent violator can be assessed up to an additional 20% penalty, depending on his degree of negligence. A willful violator should be assessed an additional 25% penalty. The maximum adjustments for culpability are down 20% or up 25% - i.e., if a violator is willful and negligent the willful 25% upward adjustment only is assessed. Of course, such a violator may be the subject of criminal proceedings.

Computation of Penalties - In calculating the adjusted initial penalty, the adjustments should be added together prior to being applied to the initial level of gravity figure. For example, with a level II violation the penalty based on that level alone is \$5000 if the violation was for one day. If the company's revenues are between \$250,000 and \$1,000,000 it is entitled to a 10% reduction; if the company has a previous TSCA violation 10% is added on; and if the violation occurred in spite of some good faith efforts by the company it may be entitled to a reduction of, say, 10%. The adjustment factors are, -10, +10, and -10, for a net reduction of 10%, which when applied to the \$5000 initial penalty, results in a \$4500 proposed penalty assessment sent to the violator. Do not compute the penalty piecemeal, i.e., do not deduct 10% of \$5000 for size, then add 10% of the remainder for history, and then subtract 10% of the remainder for culpability.

In computing duration of a violation generally only count the days on which the violation was actually observed. Thus if a violation is observed during an inspection, and the complaint is not served for a month, compute the penalty as if the violation lasted one day, not a full month. However, if reliable evidence exists that the violation was present before the inspection, an assessment for multiple days of violation may be appropriate.

D. Disclosure of Information - Confidentiality

TSCA Section 14 addresses the protection of trade secrets and confidential information. Section 14 provides that any information reported to or otherwise obtained by EPA under this Act, which is exempt from disclosure pursuant to subsection (a) of Section 552 of Title 5, United States Code, by reason of subsection (b)(4) shall not be disclosed by the Administrator or by any officer or employee of the United States.

Exceptions from this prohibition are also provided. Disclosure of information described in Section 552(b)(4) of Title 5 may be made in the following situations:

1. to officers or employees of the United States in connection with their official duties to protect health or the environment, and for specific law enforcement purposes.
2. to contractors with the United States when the Administrator determines it to be necessary for the satisfactory performance of their duties in connection with this Act and under such conditions as may be necessary to preserve confidentiality as the Administrator may specify.

3. if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.
4. When relevant under a proceeding under TSCA, except that disclosure under such proceeding under this Act shall be made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

Disclosure of any health or safety study, or any information obtained from such study, on any substance or mixture which is already being distributed, or for which testing is required under Section 4, or for which notification is required under Section 5, is not prohibited. Data in such a study, however, which discloses manufacturing processes or the proportions of a mixture may not be disclosed if such processes or proportions would otherwise be entitled to protection from disclosure.

Section 14(c) of TSCA provides that a manufacturer, processor or distributor in commerce of a toxic substance may:

- A. designate the data which such person believes is entitled to confidential treatment under subsection (a) of the same section, and
- B. submit such designated data separately from other data submitted under this Act.

Designation by a manufacturer, processor, or distributor that certain information is entitled to confidential treatment must be made in writing.

Section 14(c)(2)(A) states that where the Administrator proposes to release for inspection data which has been designated by the manufacturer, processor, or distributor as being entitled to confidential treatment, the Administrator shall notify in writing and by certified mail, the manufacturer, processor, or distributor who submitted such data, of the intent to release such data and that if release of such data is to be made pursuant to a request made under the Freedom of Information Act, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release the data before the expiration of 30 days after the manufacturer, processor, or distributor submitting such data has received the notice of the Administrator's intent to release such data.

Section 14(c)(2)(B) states an additional requirement that where disclosure of data is warranted by a determination by the Administrator that such disclosure is necessary to protect the health or the environment against an unreasonable risk of injury to health or the environment, the Administrator must notify each manufacturer, processor, and distributor who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.

EPA regulations dealing with confidentiality of business information appear in 40 CFR Part 2, Subpart B.

Handling Inspection Data

For the purposes of: (1) assuring Agency compliance with Section 14 of the Toxic Substances Control Act; (2) limiting the likelihood of inadvertent disclosure of confidential business information; (3) affording businesses a fair opportunity both to assert a confidentiality claim and to substantiate the claim prior to an EPA ruling on the claim; (4) protecting the interests of members of the public who request disclosure of business information under the Freedom of Information Act, 5 U.S.C. 552; and (5) furnishing assistance to those EPA officers and employees who must deal with confidentiality claims and requests for information obtained by the Agency pursuant to its inspection authority, the following procedures will be employed in handling inspection data:

- A. At the time an inspector presents the TSCA Notice of Inspection (see Appendix II) to the appropriate official at a facility which is about to be inspected, he shall also present one copy of the TSCA Inspection Confidentiality Notice (See Appendix III). At the time the inspector presents a copy of said TSCA Inspection Confidentiality Notice to the facility official, he shall place a second copy in an envelope addressed to the chief officer of the business whose facility he is inspecting. The inspector should determine the name and address of such chief officer before his arrival at the inspection site. The inspector shall mail the envelope at his earliest opportunity, via certified mail return receipt requested. In any event, the envelope should be mailed no later than 2 days after completion of the inspection of the facility.
- B. When an inspector submits his Inspection Report, via Regional procedures, to the PCB Violation Coordinator, the inspector shall include a third copy of the TSCA Inspection Confidentiality Notice along with his Inspection Report and shall keep a fourth copy for his own records.
- C. The business concern which receives the TSCA Inspection Confidentiality Notice must make its confidentiality claim within 30 days after the chief officer receives the Notice.
- D. When a business concern asserts a timely claim of confidentiality for inspection data, the inspection data for which confidentiality was claimed shall be removed, in accordance with Regional procedures, from the main file of the Inspection Report. Such data shall be placed in a locked file cabinet and shall be accessible only to EPA employees and contractors in the exercise of their official duties and responsibilities. If such a claim is received before the PCB Violation Coordinator receives the Inspection Report on the facility for which the claim is made, the appropriate Inspector shall remove such data and keep it in a locked file. He shall turn over such data (marked as "Claimed TSCA Inspection Confidential Data") to the PCB Violation Coordinator with his Inspection Report. If the confidential-

ity claim is received after the PCB Violation Coordinator has possession of the Inspection Report he shall be responsible for separating such data, for maintaining it in a locked file, and for marking it "Claimed TSCA Inspection Confidential Data".

- E. If a formal or informal request for data claimed as confidential is made by any person other than an EPA employee or contractor the person in possession of the data claimed as confidential shall forward such data, in accordance with Regional procedures, to the person designated in the Region to handle such requests. Such person shall follow established procedures for granting or denying the request for information.
- F. If a person other than an EPA employee or contractor requests data obtained during an inspection and no claim of confidentiality has been asserted with respect to such data, the following procedures shall be followed:
 - 1. If the request for information is received by EPA before the expiration of 30 days from the date when the chief officer of the business concern whose facility was inspected received the TSCA Inspection Confidentiality Notice, it shall be presumed that a claim of confidentiality will be made within the thirty day period. The information request shall be initially denied and the chief officer of the business whose data was requested shall be notified and required to substantiate any claims of confidentiality which he may make, in accordance with procedures stated in 40 CFR Section 2.204.
 - 2. If the request for information is received by EPA after expiration of such 30 day period, the requested data shall be treated, in accordance with procedures stated in 40 CFR Part II, Subpart B, like any data for which no claim of business confidentiality has been made.

SAMPLE PLEADINGS

1. Sample letter for Civil Penalty Action
2. Complaint for Civil Penalty Action
3. Default Order for failure to request hearing
4. Consent Agreement-Final Order
5. Condemnation and seizure pleading
6. Complaint for Injunction
7. Motion for Temporary Restraining Order
8. Preliminary Injunction Order

ACM CC8773

Complaints, Pleadings and Related Documents

This section gives examples of the complaints, affidavits, verifications, pleadings and other documents that may be used to initiate actions under TSCA Sections 16 and 17 for violations of the PCB Marking and Disposal Regulation.

1. Section 16 provides for the assessment of civil penalties for TSCA violations. As indicated in Section III of this Enforcement Proceedings Manual. It is anticipated that most TSCA enforcement actions will be prosecuted under Section 16 and that an administrative civil penalty will be assessed. Such an action is initiated under Section 16(a)(2) by the issuance of a Complaint and Notice of Opportunity for Hearing. The following is a sample of such a document, with cover letter. Please note that the question of who issues Default Judgements has not been finally determined pending development of the Consolidated Rules of Practice.

ACM CC8774

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. X
Chief Corporate Officer
(when not in Region -
Registered Agent)
25 River Drive
Alton, Michigan

RE: TSCA Complaint and Notice
of Opportunity for Hearing
Docket No. _____
B.G. Power Industries, Inc.
Alton, Michigan

Dear Mr. X:

Enclosed please find a Complaint and Notice of Opportunity for Hearing concerning violations of the Toxic Substances Control Act, 15 U.S.C. §2601, discovered by EPA inspectors at the above-captioned facility.

It is recommended that the enclosed Complaint and Rules of Practice, 40 C.F.R. § , be carefully read and analyzed to determine the alternatives available in responding to the alleged violations, proposed penalties, and opportunity for a hearing. Please note that each day the violations cited herein continue constitutes a new violation for which additional penalties may be imposed.

Regardless of whether you choose to request a hearing within the prescribed time limit of fifteen (15) days following service of this Complaint, you are extended an opportunity to request an informal settlement conference. To request a conference, please write to Mr. Attorney, Enforcement Division United States Environmental Protection Agency, etc., or telephone him at

Failure to respond to this Complaint and Notice of Opportunity to Hearing by specific answer within 15 days of your receipt of this Complaint constitutes your admission of the allegations made in the Complaint. Such failure shall result in the issuance of a Default Order imposing the penalties proposed herein without further proceedings.

Very Truly Yours,

Enforcement Division Director

ACM CC8775

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

IN RE

TSCA - V - 001

B. G. DISPOSERS, INC.,
Respondent

COMPLAINT AND NOTICE
OF OPPORTUNITY FOR
HEARING

1.

COMPLAINT

This is a civil administrative action instituted pursuant to Section 16(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. §2615(a). The complainant is the Director, Enforcement Division, Region , United States Environmental Protection Agency (U.S. EPA). The Respondent is B.G. Disposers, Inc., which is and at all times hereinafter referred to was a corporation incorporated under the laws of the State of Michigan, and has a place of business at 100 North Nowhere, Alton, Michigan.

This Complaint serves as notice of the Director's preliminary determination that Respondent has violated Section 6 and Section 15 of TSCA, 15 U.S.C. §§2605 and 2614, as follows:

Count 1

1. The above-referred facility of B.G. Disposers, Inc., operates an incinerator (as defined at 40 C.F.R. §761.2(j)) intended to destroy and dispose of liquid PCB.
2. 40 C.F.R. §761.40(a)(1) of Annex I, incineration, requires that liquid PCB introduced into an incinerator for a 2-second dwell time at three percent excess oxygen in the stack gas be maintained at 1200 degree C (+ 100 degrees C) for destruction.
3. On March 31, 1981, a temperature of 950 degrees C was being maintained in the incinerator at B. G. Disposers, Inc., during the attempted disposal of liquid PCB, in violation of Section 6 of TSCA and regulations promulgated thereunder. 15 U.S.C. §2605; 40 C.F.R. §761.40(a)(1)(i).

ADM CCE776

Count 2

1. 40 C.F.R. §761.40(a)(5) of Annex I, Incineration, requires that the introduction of PCB into an incinerator must stop automatically whenever combustion temperatures fall below 1200 degrees C ($\pm$ 100 degree C) when a two-second dwell time is employed.
2. On March 31, 1981, the incinerator at the above-cited facility failed to shut off automatically when the combustion temperature consistently fell below 1200 degrees C, in violation of Section 6 of TSCA and regulations promulgated thereunder. 15 U.S.C. §2605, 40 C.F.R. §761.40(a)(5).

Count 3

1. 40 C.F.R. §761.40(a)(3) of Annex I, Incineration, requires that, for every incinerator used to dispose of liquid PCB, the rate and quantity of PCB fed to the combustion system must be measured, and recorded regularly at intervals of no more than 15 minutes.
2. 40 C.F.R. §761.45(c)(1)(A) also requires that the owner or operator of PCB incinerators compile records on the rate and quantity of PCB supplied to the combustion system, under the terms specified at 40 C.F.R. §761.40(a)(3).
3. On March 31, 1981, records maintained at the above-captioned facility noting the rates and quantities of PCB introduced into the combustion system reflected a recording at irregular intervals (varying in length from ten to 28 minutes) of the rates and quantities of PCB introduced into the combustion system, in violation of Section 6 of TSCA and regulations promulgated thereunder. 15 U.S.C. §2605; 40 C.F.R. §§761.40(a)(3), 761.45(c)(1)(A).

II

PROPOSED CIVIL PENALTY

Section 16 of TSCA, 15 U.S.C. §2615 and the regulations promulgated thereunder, 40 C.F.R. §§ [for the Section 16 civil penalty regulations when promulgated] authorize a civil penalty of up to \$25,000 per day for each violation of the Act. Based on the facts given in I above, and on the nature, circumstances, extent and gravity of the above-cited violations, as well as the Respondent's ability to pay, effect on ability to continue to do business, history of prior violations and degree of culpability, the following proposed penalties are hereby proposed for the subject violations:

Count 1

15 U.S.C. §2614(1)
40 C.F.R. §761.40(a)(1)
Failure to maintain proper
incineration temperature \$15,000

Count 2

15 U.S.C. §2614(1)
40 C.F.R. §761.45(a)(5).
Failure to automatically
cease operation \$15,000

Count 3

15 U.S.C. §§2614(1), (3)
40 C.F.R. §§761.40(a)(3)
761.45(c)(1)(A)
Failure to record regularly
rate and quantity of PCB \$15,000
\$45,000 TOTAL

Payment of this penalty may be made by certified or cashier's check,
payable to the United States of America, and remitted to:

Regional Hearing Clerk
Region etc.

III

OPPORTUNITY TO REQUEST A HEARING

As provided at TSCA Section 16(a), and in accordance with Section 554 of Title 5, United States Code, you have the right to request a hearing regarding the proposed Order to contest any material fact contained in this Complaint, or to contest the appropriateness of the amount of the proposed penalty. If you wish to avoid being found in default, you must request a hearing of the Region Hearing Clerk, EPA Region , etc., within fifteen (15) days of this Complaint. A receipt of written answer must be made, which answer shall clearly and directly admit, deny or explain each of the factual allegations contained in the Complaint with respect to which Respondent has any knowledge; or which shall clearly state that respondent has no knowledge as to particular factual allegations in the Complaint. The answer shall also state:

ACM CC6778

1. The circumstances or arguments which are alleged to constitute the grounds of defense;
 2. The facts which Respondent intends to place at issue.
- The denial of any material fact or the raising of any affirmative defense shall be construed as a request for a hearing. Failure to deny any of the factual allegations in this Complaint constitutes admission of the undenied allegations.

Any hearing that you request will be held in the county, parish, or incorporated city of your residence. Hearings held in the assessment of these civil penalties will be conducted in accordance with the provisions of the Administrative Procedure Act (5 U.S.C. 552 et seq.) and the "Consolidated Rules of Practice Governing Administrative Assessment of Civil Penalties or the Revocation or Suspension of Permits" (40 C.F.R. §), a copy of which accompanies this complaint.

If you fail to file a written answer and request for a hearing within fifteen (15) days of service of this Complaint, such failure constitutes a binding admission of all allegations made in the Complaint and a waiver of your right to a hearing under TSCA. A Default Order may thereafter be issued by the Regional Administrator [Administrator], and the civil penalty proposed herein shall become due and payable without further proceedings. Such Default Order is not subject to review in any court.

V

SETTLEMENT CONFERENCE

Whether or not you request a hearing, an informal conference may be requested in order to discuss the facts of this case and to arrive at settlement. To request a settlement conference, please write to Mr. Attorney, Region __, etc., or telephone him at _____.

Please note that a request for an informal settlement conference does not extend the fifteen (15) day period during which a written answer and request for a hearing must be submitted. The informal conference procedure may be pursued as an alternative to and simultaneously with the adjudicatory hearing procedure.

U.S. EPA encourages all parties against whom a civil penalty is proposed to pursue the possibilities of settlement as a result of informal conference. However, no penalty reduction will be made simply because such a conference is held. Any settlement which may be reached as a result of such conference shall be embodied in a written Consent Agreement and Final Order by the Regional Administrator [Administrator], U.S. EPA Region __. The issuance of such Consent Agreement shall constitute a waiver of your right to request a hearing on any matter stipulated to therein.

ACM GC8779

If you have neither effected a settlement by informal conference nor requested a hearing within the 15-day time period allowed by this Notice, the above penalties will be assessed without further proceedings, and you will be notified that the penalties have become due and payable.

To explore the possibility of settlement in this matter by informal conference, contact Mr. _____, at
telephone _____

Sincerely yours,

Enforcement Division Director

ADM CCE70C

2. Failure to request a hearing shall result in issuance of a default order by the Regional Administrator (depending on the final form of the Consolidated Rules of Procedure). A sample Default Order follows.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION

IN THE MATTER OF

B. G. POWER INDUSTRIES, INC.,

Respondent.

TSCA-V-001

DEFAULT ORDER

PRELIMINARY STATEMENT

1. This civil proceeding for the assessment of a penalty was initiated pursuant to Section 16(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq. The action was instituted by the issuance of a Complaint and Notice of Opportunity for Hearing to the Respondent, charging violations of 15 U.S.C. 2605 and 2614. It is hereby determined that an appropriate Default Order shall be issued based on the Finding of Fact and Conclusions of Law as set out below.

FINDINGS OF FACT

1. B. G. Power Industries, Inc., is a corporation organized pursuant to the laws of the State of Michigan.

2. Respondent operates a facility at Alton, Michigan, which houses 86 large high-voltage capacitors, each containing PCB dielectric fluid.

3. On or about March 31, 1981, Respondent was unable to produce the records of monitoring data required under Section 6 of TSCA, 15 U.S.C. 2605, and 40 CFR 761.45, or produce the identity of the central records location.

4. On or about March 31, 1981, there were stored in Respondent's above cited facility PCB's that were clearly marked for disposal.

5. On or about March 31, 1981, Respondent failed to provide the flooring required by TSCA and regulations promulgated thereunder in that no curbing has been installed in the area of the above-referenced facility wherein PCB's marked for disposal were stored.

6. On or about March 31, 1981, Respondent failed to provide the flooring required by TSCA and regulations promulgated thereunder in that the floor installed in the above-referenced facility wherein PCB's marked for disposal were stored consisted of linoleum tiles.

7. On June 1, 1981, the Enforcement Division, EPA, Region ("the Complainant") issued a Complaint and Notice of Opportunity to Respondent pursuant to 15 U.S.C. 2615(a) and the then applicable

ACM 006782

Rules of Practice, alleging that Respondent has violated TSCA by failing to maintain records on the disposition of PCB's and by failing to comply with certain construction specifications for a facility that stores PCBs designated for disposal by not installing a curb of a minimum height of six inches and by not installing a floor composed of smooth and impervious materials.

8. In the instant Complaint, a civil penalty of \$24,500.00 was proposed against the Respondent. Said penalty was proposed based on the nature, circumstances, extent and gravity of the violations, and, with respect to the Respondent, ability to pay, effect on Respondent's ability to continue to do business, Respondent's history of prior such violations, and the Respondent's degree of culpability. For purposes of assessing the said penalty, Respondent's gross annual revenues were determined to be in excess of \$5,000,000.00 during the previous year. Based on a comparison of Respondent's gross annual revenues with the amount of the proposed penalty, it was determined that said penalty would have no substantial effect on Respondent's ability to continue in business.

9. The Complaint in the instant case set forth Respondent's right to request a hearing within fifteen (15) days of receipt of the Complaint, the requirement of a written Answer to the Complaint within fifteen (15) days of receipt of the Complaint if said hearing was desired, and the consequences of failure to do either. Furthermore, a copy of the Interim Rules of Practice was enclosed with the Complaint.

10. Said Complaint was mailed to Respondent on June 1, 1981, by certified mail. Receipt No. 202684 was returned to Complainant stamped June 5, 1981, and bearing the signature "Betty Wilson" as signor for the addressee. (A copy of certified mail receipt No. 202684 is attached to and made a part of this Order.)

11. As of this date Respondent has failed to either request a formal hearing, or file an Answer to the Complaint pursuant to the Rules of Practice.

CONCLUSIONS OF LAW

1. By reason of the facts as set out in the Findings of Fact, Respondent has violated TSCA by failing to develop and maintain records on the disposition of PCB's in violation of 15 U.S.C. 2614(3) and 40 CFR 761.45 and by failing to comply with certain construction specifications in violation of 15 U.S.C. 2614(1)(c) and 40 CFR 761.42(b).

2. By failing to file a timely Answer to the Complaint and/or to request a formal hearing, Respondent has admitted the facts alleged in the Complaint and has waived its right to a hearing. Accordingly, Respondent is in default and the proposed civil penalty is therefore due and payable.

3. It is further concluded that by reason of the facts set out in (Finding 8) the Findings of Fact the amount of the proposed penalty is appropriate pursuant to 15 U.S.C. 2615(c)(2)(B).

ORDER

Respondent shall immediately upon receipt of this Order pay by cashier's or certified check a civil penalty in the amount of Twenty-Four Thousand Five Hundred Dollars (\$24,500.00) payable to the Treasurer of the United States of America. Such remittance shall be delivered to the Regional Hearing Clerk, United States Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Ill. 60604. In the event of failure of Respondent to make such payment the matter shall be referred to the Attorney General pursuant to 15 U.S.C. 2615(a)(4) for collection of said amount by an appropriate action in United States District Court.

AND NOW, THIS DAY OF July 10, 1981, the foregoing Order is hereby issued under the authority of the Toxic Substances Control Act and the Rules of Practice adopted pursuant thereto, 15 U.S.C. 2601 et seq.

Regional Administrator
United States Environmental
Protection Agency, Region V
230 South Dearborn Street
Chicago, Illinois 60604

Date: _____

3. Settlement will often be reached prior to hearing on a civil penalty assessment. A sample Consent Agreement and Final Order follows (it is not necessary for the Director of the Enforcement Division to sign the agreement, as long as one of his attorneys signs).

ADM 006785

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION V

IN THE MATTER OF

B. G. DISPOSERS, INC.,

Respondent.

TSCA-V-002

CONSENT AGREEMENT
AND
FINAL ORDER

PRELIMINARY STATEMENT

1. This civil proceeding for the assessment of a civil penalty was initiated pursuant to Section 16(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2615. The action was instituted by the issuance of a Complaint and Notice of Opportunity for Hearing served upon the Respondent, charging violations of 15 U.S.C. 2605 and 2614.

2. Respondent admits the factual allegations contained in the Complaint.

3. Respondent has agreed to cooperate fully with the Environmental Protection Agency to conciliate this matter without the necessity of a formal hearing and, therefore, consents to the issuance of the Order hereinafter recited with the Findings of Fact and Conclusions of Law. Respondent consents to the payment of the penalty in the amount hereinafter stipulated as full settlement of any and all civil penalties or liabilities which might have attached as a result of this proceeding.

4. Respondent waives its right to request a hearing on any issue consented to herein.

STIPULATIONS OF FACTS

1. B. G. Disposers, Inc. is a corporation organized pursuant to the laws of the State of Michigan.

2. Respondent operates an incinerator for the purposes of destroying and disposing of liquid PCB mixtures at its facility located in Alton, Michigan.

3. On or about March 31, 1981, Respondent incinerated liquid PCB mixtures at its above-referenced facility with an incinerator temperature of 950 degrees C.

4. On or about March 31, 1981, the above referenced incinerator failed to shut off automatically when the combustion temperature dropped below 1200 degrees C during the incineration of PCB's.

5. On or about March 31, 1981, Respondent maintained records, noting the rate and quantities of liquid PCB mixtures introduced into the combustion system recorded at irregular intervals varying in length from ten to twenty-eight minutes.

ACM 006786

CONCLUSIONS OF LAW

1. By reason of the facts set out in the stipulations of Fact, above, it is concluded that Respondent has violated 15 U.S.C. 2614 (1), and 40 CFR 761.40(a)(1) by failing to maintain an incinerator temperature of 1200 degrees C. with a two-second dwell time at three percent excess oxygen in the stack gas during the incineration and destruction of liquid PCB mixtures.

2. By reason of the facts set out in the stipulations of Fact, above, it is concluded that Respondent has violated 15 U.S.C. 2614(1), and 40 CFR 761.40(a)(5) by operating an incinerator for the incineration and destruction of liquid PCB mixtures where the incinerator does not shut off automatically when the combustion temperature drops below 1200 degrees C.

3. By reason of the facts set out in the Findings of Fact, above, it is concluded that Respondent has violated 15 U.S.C. 2614(1)(3), and 40 CFR 761.40(a)(3), 761.45(c)(1)(A), by failing to maintain records that measure and record the rate and quantity of PCB's which are fed into the incinerator combustion system at intervals of no more than fifteen minutes.

ORDER

Respondent shall within twenty days of receipt of this Consent Agreement and Final Order pay by cashier's check or certified check the amount of Thirty-Five Thousand Dollars (\$35,000.00) payable to the United States of America. Such remittance shall be delivered to the United States Environmental Protection Agency, Regional Hearing Clerk, 230 South Dearborn Street, Chicago, Illinois 60604.

Respondent:

Date: _____

James O. McDonald
Director, Enforcement Division
United States Environmental
Protection Agency, Region V
230 South Dearborn Street
Chicago, Illinois 60604

Date: _____

ACM GC6767

It is so ordered. This Order shall become effective immediately.

Regional Administrator
United States Environmental
Protection Agency, Region V
230 South Dearborn Street
Chicago, Illinois 60604

Date: _____

ADM. CC8786

4. The following is a model pleading in rem for seizure and condemnation of PCBs stored or disposed in violation of the PCB Marking and Disposal Regulation. Following the pleadings are the Verification and Warrant for Arrest of Property.

ACM 008769

United States Attorney

Attorney for the Plaintiff

IN THE UNITED STATES DISTRICT COURT

FOR THE _____

UNITED STATES OF AMERICA,

Plaintiff,

vs.

Defendant.

CIVIL NO. _____

COMPLAINT IN REM

The United States of America alleges that:

I

This is an action in rem instituted pursuant to Section 17(b) of the Toxic Substances Control Act (15 U.S.C. 2616(b)), for the seizure and condemnation of chemical substances or mixtures manufactured, processed, or distributed in commerce which are _____ and in violation of Section _____ of the Toxic Substances Control Act, 15 U.S.C. _____. Authority to bring this action is vested in the United States Attorney by 28 U.S.C. §547(a).

II

This Court has jurisdiction of the subject matter of this action pursuant to 15 U.S.C. 2616(b).

III

The property to be seized is located at _____, which is within this District, and is on land. The location is _____.

IV

is a chemical substance or mixture manufactured, processed, or distributed in commerce by _____

V

WHEREFORE, plaintiff, United States of America, prays:

(1) That the chemical substance or mixture be seized and condemned, and that they be disposed of as the court may direct in accordance with the provisions of Section 17(b) of the Toxic Substances Control Act (15 U.S.C. 2616(b)) and in conformity with the practice of this Court.

(2) That the party specified in Paragraph _____ of this Complaint and any and all other persons having, or pretending to have, any right, title or interest in and to the chemical substances or mixtures be notified to appear in order that they may answer the allegations set forth in this Complaint.

(3) That the Court enter all such orders, decrees, and judgments as may be necessary in order to grant further relief to the plaintiff for the costs of this proceeding.

(4) For such other and further relief as the Court may deem just and proper.

Dated:

United States Attorney

Attorney for the Plaintiff

ACM 008791

United States Attorney

Attorney for the Plaintiff

IN THE UNITED STATES DISTRICT COURT

FOR THE

UNITED STATES OF AMERICA,

Plaintiff,

vs.

Defendant.

CIVIL NO.

VERIFICATION

I, _____, being first duly sworn,
state that:

1. I am _____

2. I am reliably informed of the facts set forth in the foregoing Complaint in Rem which I have prepared accordingly; and

3. All of the facts set forth in the foregoing Complaint in Rem are true to the best of my knowledge, information and belief.

SUBSCRIBED AND SWORN TO BEFORE ME
THIS _____ DAY OF _____

Notary Public

ADP CCE792

1 Melvin D. Close
Nevada Bar #1694
2 JONES, JONES, CLOSE
& BROWN, CHARTERED
3 700 Valley Bank Plaza
300 South Fourth Street
4 Las Vegas, NV 89101-6026
Telephone: (702) 385-4202

5 ATTORNEYS FOR JUI FA LIN, DEBTOR
6

7 UNITED STATES BANKRUPTCY COURT

8 DISTRICT OF NEVADA

9 In re:

10 JUI FA LIN,

11 Debtor.
12
13

BK-S-86-634-LBR
Chapter 11 Proceedings

ORDER DISMISSING CHAPTER 11
CASE AND DISMISSING FEDERAL
DISTRICT COURT CASE

DATE: September 10, 1992
TIME: 10:00 a.m.

14
15 Debtor's Motion to Dismiss Chapter 11 Case and to Dismiss
16 Federal District Court Case having come on regularly for hearing this
17 10th day of September, 1992, the debtor appearing by and through his
18 attorney, Melvin D. Close, Esq., of Jones, Jones, Close & Brown; no
19 opposition having been filed, and good cause appearing therefore, it
20 is hereby

21 . . .

22 . . .

23 . . .

24 . . .

25 . . .

26 . . .

27 . . .

28 . . .

United States Attorney

Attorney for the Plaintiff

IN THE UNITED STATES DISTRICT COURT

FOR THE _____

UNITED STATES OF AMERICA,

Plaintiff,

vs.

Defendant.

CIVIL NO. _____

WARRANT FOR ARREST
OR PROPERTY

TO: UNITED STATES MARSHAL

YOU ARE HEREBY COMMANDED to arrest and take into custody under further order of the Court the following described property:

Claims or persons entitled to possession of the foregoing property shall be filed with the Clerk of the Court and a copy served upon the United States Attorney, _____, within ten (10) days after date of publication or notice of arrest of the foregoing property, or within such additional time as may be allowed by the

Court, and answers to the complaint shall be filed and served within twenty (20) days after date of publication of notice of arrest.

Dated: _____

ADM 008793

5. The following is a model Complaint for Injunction, followed by a Motion for Temporary Restraining Order and a Proposed Preliminary Injunction.

ACH CC8794

UNITED STATES DISTRICT COURT FOR THE
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA —

Plaintiff,

V.

BAD POLLUTER, TSCA,

Defendant

No. _____

COMPLAINT FOR INJUNCTION
Section 17(a) of the Toxic
Substances Control Act,
15 USC 2617

The United States of America, by its undersigned attorneys, by authority of the Attorney General of the United States, and acting on the request of the United States Environmental Protection Agency, alleges that:

I

1. This is a civil injunction to enjoin the above named defendants from the continued storage of transformers containing the chemical substance polychlorinated biphenyls (PCB's) in violation of regulations promulgated by the Administrator of the Environmental Protection Agency (EPA), at Title 40 Parts 761.10, 761.42, Vol. 43, 34 FR 7150 et seq on February 17, 1978, as provided by Section 6(e)(1) of the Toxic Substances Control Act, 15 USC 2605.

2. This Court has jurisdiction of the subject matter of this action pursuant to 15 USC 2616.

3. Defendant is a corporation doing business in Los Angeles, California and such act has occurred and is continuing to occur at its facility located at _____ Street, Los Angeles, California, within the Central District of California.

4. The continued storage of such transformers contrary to the above cited regulations threatens to cause an immediate and irreparable injury to the employees working at said facility and the general public living nearby unless defendants are immediately restrained as prayed, as more fully appears in the affidavits submitted with plaintiff's motion for Preliminary Injunction filed herewith. Plaintiff has attempted to give oral notice of this motion to defendants attorney.

Defendants will not be unduly prejudiced by issuance of a temporary restraining order pending hearing and determination of plaintiff's motion for Preliminary Injunction.

There is a substantial likelihood that plaintiff will succeed on the merits of this case.

ACM CC6755

Wherefore, plaintiff prays:

1. That the defendants, their officers, directors, agents, servants, employees, successors and assigns and each of them cease the storage of transformers containing PCB's contrary to the requirements of Title 40 Part 761.10 CFR, and be immediately required to comply with such regulations.
2. That costs and disbursements of this action be awarded to the plaintiff.
3. That this court grant such other and further relief as it may deem just and proper.

ADM GCE796

UNITED STATES DISTRICT COURT, FOR THE
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA

Plaintiff,

v.

BAD POLLUTER, TSCA

Defendant.

No. _____

MOTION FOR TEMPORARY
RESTRAINING ORDER AND
ORDER TO SHOW CAUSE

Upon the Complaint herein and upon the papers submitted in support of this motion, plaintiff, by its attorneys, respectfully moves the Court for a temporary restraining order restraining defendants as set forth below, and for an order that defendants appear and show cause, as follows:

1. That defendants their officer, agents, servants, employees, and all persons in active concert with them or any of them be restrained and enjoined from the continued storage of transformers containing the chemical substance polychlorinated biphenyls (PCB's) in violation of regulations promulgated by the Administration of the Environmental Protection Agency (EPA) at Title 40, Part 761.10, 761.42 CFR, Vol. 43, 34 FR 7150 et. seq. on February 17, 1978.

2. Immediate and irreparable injury to the employees working at said facility and to the general public will occur unless defendants are immediately restrained as prayed, as more fully appears in the complaint herein and the affidavits submitted with plaintiff's Motion for Preliminary Injunction filed herewith. Plaintiff has attempted to give oral notice of this motion to defendants' attorneys. Notice should not be required herein as a temporary restraining order is necessary to preserve the status quo in this action, pending the determination of plaintiff's motion for a preliminary injunction. Plaintiff's remedies at law are inadequate. Defendants will not be unduly prejudiced by issuance of a temporary restraining order pending hearing and determination of plaintiff's Motion for Preliminary Injunction.

There is a substantial likelihood that plaintiff will succeed on the merits of this case.

WHEREFORE: Plaintiff asks that this Court issue a Temporary Restraining Order and Order to Show Cause, as prayed.

Dated:

Respectfully Submitted,

ACM CC6757

UNITED STATES DISTRICT COURT FOR THE
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA

Plaintiff,

V.

BAD POLLUTER, TSCA,

Defendant.

No. _____

PRELIMINARY INJUNCTION

This matter came on to be heard on the _____ day of _____ 1978, for preliminary injunction. Upon consideration of the evidence adduced at the hearing, the pleadings and papers on file herein, and the arguments of counsel:

It appears to the court that the defendants, personally or through their agents, are engaged in the continued storage of transformers containing the chemical substances polychlorinated biphenyls (PCB's) in violation of regulations promulgated by the Administrator of the Environmental Protection Agency (EPA), at Title 40, Part 761.10, 761.42 CFR, Vol. 43, 34 FR 7150 et. seq. on February 17, 1978, as provided by Section 6(e)(1) of the Toxic Substances Control Act, 15 USC 2605.

It further appears to the Court that the defendants will, if not enjoined by order of this Court, continue to store such transformers contrary to the above cited regulations, and thereby cause an immediate and irreparable injury to the employees working at said facility and the general public and that plaintiff's remedies at law are inadequate.

It further appears that defendants will not be unduly prejudiced by issuance of a preliminary injunction pending hearing and determination of the merits.

It further appears to the Court that there exists a substantial likelihood that plaintiff will succeed on the merits of its case.

NOW THEREFORE, IT IS ORDERED, ADJUDGED AND DECREED that defendants, their officers, agents, servants, employers, and all persons in active concert with them, or any of them, be enjoined from:

The continued storage of transformers containing the chemical substance polychlorinated biphenyls (PCB's) in violation of regulations promulgated by the Administrator of the Environmental Protection Agency (EPA) at Title 40 CFR Parts 761.10, 761.42.

ACM CG8758

IT IS FURTHER ORDERED that this injunction shall remain in effect until final determination of the merits, or until further order of this Court.

Dated:

Judge, United States District Court
Central District of California

ACM 008799

CORRECTIONS TO - EPA's FINAL PCB BAN RULE:

OVER 100 QUESTIONS AND ANSWERS

TO HELP YOU MEET THESE REQUIREMENTS

Page 4, Question 9: Line 22 should read "...July 2, 1979."

Page 7, Question 18: Line 22 should read "Use in Pigments...". Line 26 should read "Use in Small Quantities for Research and Development (Sec. 761.31 (j));". Line 28 should read "Use as a Microscopy Mounting Medium...".

Page 10, Question 25: Line 7, the last sentence in this paragraph should read "Special restrictions are dependent upon the concentration of PCBs in the transformer and whether PCBs are sold during the servicing activities."

Page 11/12, Question 28: Line 19, the last sentence in this paragraph should read "If they sold only uncontaminated mineral oil (less than 50 ppm PCB), then no exemption would be needed."

Page 15, Question 40: Line 5 add the sentence "No exemption from EPA is required for such sales."

Page 16, Question 45: Line 3, add to the end of the sentence "...and again between 12 and 24 months after such servicing."

Page 18, Question 57: Line 2, disregard the current answer and substitute the following response "Repair restrictions apply only to the PCB motors, not the rest of the machine. While the machines are in use in mines or mining areas, PCBs can be added to these motors until January 1, 1982."

When PCB motors in loader-type equipment are returned to a service shop for servicing they must be rebuilt as air-cooled or other non-PCB containing motors or be replaced with non-PCB motors. Because PCB motors in continuous miner equipment cannot be successfully converted to non-PCB motors, these motors are allowed to be rebuilt as PCB motors until January 1, 1980 in order to ease the impacts of phasing out this equipment. Any servicing or repair that involves the sale of PCBs can be performed only by persons who are granted an exemption by EPA."



ALM CC66CC



INDUSTRY ASSISTANCE OFFICE

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ASSISTANT ADMINISTRATOR
FOR TOXIC SUBSTANCES (TS-733)
WASHINGTON, D.C. 20460

TOLLFREE: (800) 424-9069

WASHINGTON, D.C.: 554-1404

Errata:

On page 35 of the Q & A's on PCB's
the answer to question 120 should read:

"Yes, there are OSHA regulations
governing PCB's in the workplace".

Toxic Substances



EPA's Final PCB Ban Rule:

Over 100 Questions & Answers To Help You Meet These Requirements

ADM C088C3

EPA's Final PCB Ban Rule:

Over 100

Questions & Answers
To Help You Meet
These Requirements

Prepared by:
Industry Assistance Office
Office of Toxic Substances
U.S. Environmental Protection Agency

INTRODUCTION

On May 31, 1979 in the Federal Register (44 FR 31514) the U.S. Environmental Protection Agency published the Final Rule for Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions. This Booklet* in a non-technical manner, deals with the Rule's coverage and requirements. Its question-and-answer format is categorized into the following 18 areas.

<u>Q&A Category</u>	<u>Questions</u>
Introductory Information	1-8
General Rule Provisions.	9-21
Import/Export	22-23
Transformers	24-40
Railroad Transformers	41-49
Capacitors	50-54
Mining Equipment	55-60
Hydraulic Systems	61-65
Heat Transfer Systems	66-67
Other PCB Uses	68-75
Labeling	76-83
Testing	84-86
Storage	87-95
Spills	96-99
Recordkeeping	100-104
Disposal	105-119
PCBs in the Workplace	120-125
Contacts for Information	126-127

*This Booklet has been prepared by the Industry Assistance Office within EPA's Office of Toxic Substances. It is an informal document, and persons are directed to the PCB Final Rule for specific legal requirements.

INTRODUCTORY INFORMATION

(1) WHAT ARE PCBs?

The term PCBs is short for polychlorinated biphenyls. PCBs belong to a broad family of organic chemicals known as chlorinated hydrocarbons. PCBs are produced by attaching chlorine molecules to a biphenyl molecule. Although PCBs may be produced naturally in the environment, almost all PCBs in existence today have been synthetically manufactured.

(2) WHO MANUFACTURED PCBs?

Monsanto Corporation was the principal manufacturer of PCBs in the United States. They began production of PCBs in 1929; in 1977 they voluntarily terminated production because of the widespread environmental concerns about PCBs.

(3) WHAT TRADE NAMES WERE PCBs SOLD UNDER?

The tradename Monsanto Corporation sold PCBs under was "Askarel". However, companies who used PCBs in the manufacture of transformers and capacitors, and for other uses, often used other tradenames. The following list is representative of PCB Tradenames: Aroclor, Pydraul, Therminol, Pyroclor, Santotherm, Pyralene, Pyranol, Inerteen, Asbestol, Chlorextol, Diachlor, Dykanol, Elemex, Hyvol, No-Flamol, Saf-T-Kuhl, Aroclor B, Clorinol, Clorphen, Eucarel.

(4) WHAT ARE THE PHYSICAL AND CHEMICAL PROPERTIES OF PCBs?

PCBs have a heavy liquid, oil-like consistency, and weigh 10-12 pounds per gallon. The properties which made them commercially attractive include: a high degree of chemical stability, low solubility in water, low vapor pressure, low flammability, high heat capacity, low electrical conductivity, and a favorable dielectric constant.

(5) HOW ARE PCBs USED?

The primary use of PCBs has been in "closed" or "semi-closed" systems in electrical transformers, capacitors, heat transfer systems, and hydraulic systems. PCBs have also been used in paints, adhesives, caulking compounds, plasticizers,

inks, lubricants, carbonless copy paper, and sealants, coatings, and dust control agents.

Most of the PCBs marketed in the United States are still in service, primarily in electrical equipment.

(6) WHY ARE PCBs HARMFUL TO HUMAN HEALTH AND THE ENVIRONMENT?

PCBs are harmful because once released into the environment they do not break apart into new chemical arrangements, instead they bioaccumulate in organisms throughout the environment. In addition, PCBs biomagnify in the food chain -- that is, they accumulate in the tissues of living organisms and as they move up the food chain towards man their concentration increases. These facts are significant because PCBs have been shown to cause chronic (long-term) toxic effects in many species even when the exposed to very low concentrations.

(7) WHAT ARE THE KNOWN HEALTH EFFECTS OF PCBs?

There are well documented tests which show PCBs cause, among other things, reproductive failures, gastric disorders, skin lesions, and tumors in laboratory animals.

Studies of workers exposed to PCBs have shown a number of symptoms and adverse effects including, but not limited to, chloracne and other epidermal disorders, digestive disturbances, jaundice, impotence, throat and respiratory irritations, and severe headaches.

(8) WHAT ACTION HAS EPA TAKEN AGAINST PCBs?

In 1976, Congress enacted the Toxic Substances Control Act (TSCA). Section 6(e) of this law requires EPA to establish rules to: (1) govern the disposal and marking of PCBs; and (2) prohibit, with certain exceptions, the manufacture, processing, distribution in commerce, and non-totally enclosed use of PCBs.

Final Marking and Disposal Rules appeared in the Federal Register on February 17, 1978 (clarifying amendments to this Rule appeared in the August 2, 1978 Federal Register).

On June 7, 1978, the Proposed PCB Ban Rule was published in the Federal Register. The Final PCB Ban Rule appeared in the Federal Register on May 31, 1979; this Rule supersedes the February 17, 1978 PCB regulation and takes effect on July 2, 1979.

GENERAL RULE PROVISIONS

(9) WHAT DOES THE MAY 31, 1979 PCB BAN RULE DO?

Specifically, the rule:

- (1) prohibits the manufacturing, processing, distribution in commerce, and the use of PCBs except in a totally enclosed manner after July 2, 1979;
- (2) provides authorizations for certain processing, distribution in commerce, and use of PCBs in a non-totally enclosed manner;
- (3) prohibits, unless exempted by EPA, all manufacturing of PCBs after July 2, 1979;
- (4) prohibits, unless exempted by EPA, all processing and distribution in commerce of PCBs after July 1, 1979.

Also, the February 17, 1978 PCB Disposal and Marking Rule requirements are integrated into this PCB Ban Rule. Therefore, with the total scope of the PCB regulation -- from labeling to production ban to disposal -- now appearing in the May 31, 1979 Federal Register, this publication supersedes all earlier PCB regulations upon its July 2, 1979 effective date.

EPA has also published in the May 31, 1979 Federal Register a notice which explains how to file for an exemption from the July 1, 1979 bans on processing and distribution in commerce of PCBs. Petitions for exemptions must be filed by July 1, 1979. EPA earlier published procedures for filing petitions for exemption from the January 1, 1979 prohibition on manufacturing of PCBs. These procedures can be found in the November 1, 1978 Federal Register (43 FR 50905).

(10) DOES THIS RULE APPLY TO ALL PCBs OR IS THERE A CUT-OFF POINT BASED ON THE CONCENTRATION OF PCBs?

In order to practically implement this rule (i.e., exceptions, disposal and marking requirements), EPA had to adopt a PCB concentration cut-off point for regulation. Therefore, the final rule applies to any substance, mixture, or item with 50 ppm or greater PCB; wherever the term "PCB" or "PCBs" is used in the rule, it means PCBs at a concentration of 50 ppm or greater, unless otherwise specified.

This 50 ppm is a change from the February 17, 1978 Disposal and Marking Rule which set a 500 ppm cut-off. By lowering the PCB cut-off point from 500 ppm to 50 ppm, it will substantially increase health and environmental protection --- approximately,

one million additional pounds of existing PCBs will be controlled, as well as 100,000 to 500,000 pounds per year of new PCBs.

- (11) IS THERE ANYTHING WHICH CONTAINS LESS THAN 50 PPM PCBs WHICH IS BANNED FROM BEING USED UNDER THIS RULE?

Yes, waste oil containing any detectable concentration of PCBs is forbidden from being used as a sealant, coating, or dust control agent. To permit the use of waste oil with any PCB-contamination to be used in road oiling, pipe coating, or vegetation spraying would cause PCBs to directly enter the air and waterways, which could introduce them into the food chain.

- (12) WHAT IS THE DIFFERENCE BETWEEN "MANUFACTURING OF PCBs" AND "PROCESSING OF PCBs"?

The actual creation of the chemical substance PCB, or a substance contaminated with PCBs (e.g., PCBs as an impurity), is the "manufacturing of PCBs".

The production of PCB Articles and PCB Equipment is considered "processing of PCBs", and involves the use of existing PCBs. Processing PCBs includes such activities as placing manufactured PCBs into capacitors or transformers.

- (13) WHAT IS CONSIDERED A PCB ARTICLE? PCB EQUIPMENT? PCB ITEM?

An article whose surface is directly contacted by PCBs is considered a "PCB Article". Examples include capacitors, transformers, electric motors, pumps, and pipes.

Equipment whose surface is not directly contacted by PCBs, but contains a PCB article, is considered "PCB Equipment". Examples include televisions, air conditioners, microwave ovens, electronic equipment, and fluorescent light ballasts and fixtures.

"PCB Item" is a collective term used throughout the Rule to refer to PCB Equipment/Articles/Containers/Article Containers.

- (14) WHAT EFFECT DOES THE PCB BAN RULE HAVE ON PCB ARTICLES? PCB EQUIPMENT?

After July 2, 1979, PCB Articles can no longer be produced because the production is not totally enclosed. However, since

the production of PCB Equipment is considered totally enclosed processing, this can continue until July 1, 1979 under the Rule; in order to continue PCB Equipment production after that date, an exemption must be obtained from EPA.

- (15) THE FINAL RULE SAYS THAT EPA CAN GRANT EXEMPTIONS FROM THE PCB MANUFACTURING/IMPORTATION BAN EFFECTIVE JULY 2, 1979 -- OR FROM THE PCB PROCESSING/DISTRIBUTION IN COMMERCE PROHIBITION EFFECTIVE JULY 1, 1979. HOW CAN I GET AN EXEMPTION? HAS EPA ALREADY GRANTED SOME?

In general, anyone wanting an exemption must petition EPA for it. An exemption, valid for only one year, must be granted annually through a formal rulemaking. In some instances, individuals may not have to seek separate exemptions when the Agency grants "class" exemptions for some processing and distribution in commerce bans.

In the November 1, 1978 Federal Register, EPA published interim rules for submitting exemption petitions from the July 2, 1979 PCB manufacturing/importation prohibition; over 70 petitions have been received. EPA announced, in the January 2, 1978 Federal Register, that it would not enforce the ban against those who had submitted petitions until action had been taken on them. Subsequently, in the May 31, 1979 Federal Register notice, EPA published a Notice of Proposed Rulemaking which identifies each exemption petition received, and the action EPA proposed to take on most of them.

Also, in the May 31, 1979 Federal Register, EPA has published procedure rules for submitting exemption petitions from the July 1, 1979 processing/distribution in commerce prohibitions. These procedures include the categories eligible for class exemptions.

- (16) WHERE CAN I DETERMINE WHAT CATEGORIES ARE ELIGIBLE FOR CLASS EXEMPTIONS?

You should make a careful review of Section 750.31(a) of the Interim Procedural Rules for the processing and distribution in commerce exemptions. These rules are published in the May 31, 1979 Federal Register. Section 750.31(a) lists and describes the categories that may file class exemption petitions. If your activity is not listed in Section 750.31(a), you must file a petition on an individual basis.

- (17) THE BAN RULE PROHIBITS THE USE OF PCBs EXCEPT IN A "TOTALLY ENCLOSED MANNER". WHAT IS MEANT BY "TOTALLY ENCLOSED MANNER"?

"Totally enclosed manner" is a term which Congress wrote into TSCA's Section 6(e) and refers to PCBs contained in a way that does not permit any detectable exposure to PCBs.

Examples of totally enclosed PCB uses, allowed to continue after July 2, 1979, are found in television sets, air conditioners, and microwave ovens. These items contain PCB components (such as PCB capacitors) but their normal continued use will not result in any exposure to human beings or their surroundings.

- (18) THE BAN RULE SAYS THAT EPA CAN GRANT EXCEPTIONS, KNOWN AS AUTHORIZATIONS, TO ENABLE THE CONTINUED MANUFACTURING, PROCESSING, DISTRIBUTION IN COMMERCE, OR USE OF PCBs IN A NON-TOTALLY ENCLOSED MANNER AFTER JULY 2, 1979. HOW CAN I GET AN AUTHORIZATION? HAS EPA ALREADY GRANTED SOME?

EPA may propose and grant an authorization without a specific request from those who will benefit from the authorization. Also, the authorization can be valid for any time period that EPA finds appropriate.

The following non-totally enclosed PCB activities have already been authorized by EPA (beside each is the Rule section to refer to for details):

- o servicing PCB Transformers and PCB-Contaminated Transformers (Sec. 761.31(a));
- o use in and servicing of Railroad Transformers (Sec. 761.31(b));
- o use in and servicing of Mining Equipment (Sec. 761.31(c));
- o use in Heat Transfer Systems (Sec. 761.31(d));
- o use in Hydraulic Systems (Sec. 761.31(e));
- o use in Carbonless Copy Paper (Sec. 761.31(f));
- o Pigments (Sec. 761.31(g));
- o servicing Electromagnets (Sec. 761.31(h));
- o use in Natural Gas Pipeline Compressors (Sec. 761.31(i));

o Small Quantities for Research & Development
Sec. 761.31(j));

o Microscopy Mounting Medium. (Sec. 761.31(k)).

EPA authorized the above PCB activities in a non-totally enclosed manner after evaluating: the likelihood, magnitude, and nature of exposure to human beings or the environment; the availability and characteristics of substitutes; and the economic significance of the activity, including its importance to the national economy, small business, technological innovation, the environment, and public health.

(19) WHAT IS THE DIFFERENCE BETWEEN A PCB AUTHORIZATION AND A PCB EXEMPTION?

Authorizations are for certain uses of PCBs to extend beyond July 2, 1979. However, exemptions for manufacturing are needed in order to manufacture PCB-contaminated substances after January 1, 1979. Also, exemptions for processing and distribution in commerce of PCBs are needed in order to continue these activities after July 1, 1979.

Exemptions are only valid for a maximum of one year, while authorizations may be granted for longer periods of time. Other differences between authorizations and exemptions are described in detail in the Preamble to the Final Rule.

(20) WHAT DOES THE RULE PROVIDE FOR LEASED PCB EQUIPMENT?

PCB Equipment can be leased for any period of time as long as the lease begins before July 1, 1979; if you want to lease equipment after this date you will have to first get an exemption from EPA. To import or export leased PCB equipment after July 1, 1979 will also require an exemption from EPA.

(21) IS THERE AN ECONOMIC IMPACT STATEMENT AVAILABLE?

Yes, there is an economic impact statement available on the PCB Ban Rule. It is called "PCB Manufacturing, Processing, Distribution in Commerce and Use Ban Regulation: Economic Impact Analysis", also commonly referred to as the "Versar Report". For a copy of this document call the Industry Assistance Office (see the "Contacts for Information" section of this Booklet).

IMPORT/EXPORT

- (22) CAN PCBs (THE CHEMICAL ITSELF) BE IMPORTED OR EXPORTED AFTER THE BAN RULE'S JULY 2, 1979 EFFECTIVE DATE? WHAT ABOUT PCB EQUIPMENT (TELEVISION SETS, MICROWAVE OVENS, ETC.) WHICH CAN CONTINUE TO BE DOMESTICALLY PRODUCED UNTIL JULY 1, 1979, HOW LONG CAN THEY CONTINUE TO BE IMPORTED AND EXPORTED?

Because TSCA considers the term "import" to be synonymous with "manufacture", no PCBs (except waste) can be imported or exported after July 2, 1979, unless an exemption is obtained from EPA.

Furthermore, it was the intent of Congress to have this Rule treat domestic and foreign PCB production equally. Therefore, PCB Equipment can be imported and exported until July 1, 1979. After July 1, 1979, an exemption must be obtained from EPA in order to continue this activity.

- (23) EPA HAS DECIDED TO ADOPT AN OPEN BORDER POLICY WITH RESPECT TO THE DISPOSAL OF PCBs. WHAT DOES THAT MEAN?

The PCB Ban Rule allows for PCB wastes to be either imported or exported for disposal for one year -- until May 1, 1980. All imported PCB wastes must be disposed of in accordance with Subpart B of the Final Rule. Persons exporting PCB wastes for disposal are to notify EPA at least 30 days before the first export shipment; quarterly reports of actual shipments are also required.

EPA believes that the adoption of this open border policy for PCB waste disposal will be advantageous to both the U.S. and foreign countries, especially Canada. Generators of PCB wastes will be able to select the PCB disposal site that offers the most reasonable transportation and disposal costs. The open border policy will be in effect for almost one year, at which time EPA will examine the progress made by other nations in establishing and operating safe PCB disposal sites. The Agency will also at this time determine if extension of the open border policy is appropriate.

TRANSFORMERS

- (24) UNDER THE FINAL BAN RULE, THE USE OF PCBs IN TRANSFORMERS IS CONSIDERED USE IN A TOTALLY ENCLOSED MANNER. DOES THIS MEAN I CAN CONTINUE TO USE MY TRANSFORMERS CONTAINING PCBs? IF SO, FOR HOW LONG?

Transformers containing PCBs can be used as long as they perform their intended function and do not leak PCBs into the environment.

- (25) IN ORDER TO GET THE FULL USEFUL LIFE OUT OF LIQUID FILLED TRANSFORMERS, THEY MUST BE SERVICED OR REPAIRED PERIODICALLY. ARE THESE ACTIVITIES PERMITTED UNDER THE RULE? ARE THERE ANY RESTRICTIONS?

Servicing of these transformers is authorized until July 1, 1984. EPA will consider the necessity of extending the authorized period prior to the 1984 termination date. Special restrictions are related to the extent of the repairs or servicing activities, and whether PCBs are sold during the servicing activities.

There are four categories of transformers considered in this regulation and the restrictions and special conditions are easier to understand in the context of these categories.

- (26) WHAT ARE THE 4 TRANSFORMER CATEGORIES? WHAT IS THE SIGNIFICANCE OF EACH?

The four categories of transformers established by the PCB Rule are:

- (1) PCB Transformers containing PCBs at a concentration of 500 ppm or greater;
- (2) PCB-Contaminated Transformers containing between 50 ppm and 500 ppm PCB;
- (3) Non-PCB Transformers containing less than 50 ppm PCB;
- (4) Railroad Transformers used in electric railroad locomotives and self-powered cars that contain PCB fluid.

The transformer categories are significant, because under the Rule each is subject to different disposal, servicing (including rebuilding), and storage requirements. (Note: The Rule, as do these Q & A's, address Railroad Transformer

requirements separately; the other 3 categories are discussed simultaneously.)

(27) HOW DO I DETERMINE WHICH OF THE FOUR TRANSFORMER CATEGORIES I HAVE?

A transformer must be assumed to be a PCB Transformer if: (1) the nameplate indicates that the transformer contains PCB dielectric fluid; (2) the owner or operator has any reason to believe that the transformer contains PCB dielectric fluid; or (3) the transformer's dielectric fluid has been tested and found to contain 500 ppm or greater PCB. If a transformer does not have a nameplate or there isn't any information to indicate the type of dielectric fluid in it, the transformer must be assumed to be a PCB Transformer.

If a transformer is tested and found to contain less than 500 ppm PCB, it will then fall into one of the other appropriate categories.

A transformer can be reclassified as a Non-PCB Transformer if its dielectric fluid has been tested or otherwise verified to contain less than 50 ppm PCB. Testing Transformers in order to classify them as Non-PCB Transformers does not significantly change the actions required by the Rule. If your transformers are proven Non-PCB Transformers you should take precautions to see that they aren't later contaminated during servicing with PCB fluid over 50 ppm.

(28) WHY SHOULD I ASSUME THAT MY MINERAL OIL TRANSFORMER IS A PCB-CONTAMINATED TRANSFORMER? IF I GO TO THE EXTRA TROUBLE AND EXPENSE TO TEST MY TRANSFORMER IN ORDER TO CLASSIFY IT AS A NON-PCB TRANSFORMER, WHY WON'T MY REQUIREMENTS UNDER THE RULE BECOME SIGNIFICANTLY SIMPLER?

Current data shows that 25-40% of the existing mineral oil transformers are contaminated with 50 ppm or more of PCBs.

No clear pattern exists to explain why one transformer is contaminated and another one is significantly less contaminated. This means that testing all transformers would be necessary in order to be certain about the appropriate category. This would be extremely expensive. Therefore, the requirements in the Rule for servicing, disposal, labeling, and use have been designed to make this testing step largely unnecessary.

The only servicing restriction on PCB-Contaminated Transformers is that companies servicing transformers owned by others and who sell PCB-contaminated mineral oil to their customers must

receive an exemption from EPA. If they sold only uncontaminated mineral oil (less than 50 ppm PCBs), then an exemption would be needed.

The disposal requirements for PCB-contaminated fluids are specific (high efficiency boilers, incineration or chemical waste landfills). However, the disposal options for fluids from Non-PCB Transformers are not much greater, because of the broad prohibition on using waste containing PCBs for dust control, sealant or coating purposes.

There are no labeling requirements for either transformer categories (PCB-Contaminated or Non-PCB Transformers), and no use restriction differences.

(29) HOW WOULD TRANSFORMERS WHICH USE PCB-FREE MINERAL OIL DIELECTRIC FLUID BE CATEGORIZED?

Because of the widespread contamination of mineral oil dielectric fluid transformers, they must be assumed to be PCB-Contaminated Transformers. Even if PCB-free dielectric fluid was added to an existing transformer, you couldn't be certain that PCB contamination in the transformer would not contaminate the new fluid to a level above 50 ppm PCB.

You, of course, have the option of testing the new aggregate dielectric fluid in the transformer to determine if the PCB concentration is below 50 ppm, in which case it could be considered a Non-PCB Transformer.

(30) CAN I RECLASSIFY MY PCB TRANSFORMER IF I REDUCE ITS PCB CONCENTRATION?

PCB Transformers can be reclassified to PCB-Contaminated Transformers by draining and refilling them with non-PCB dielectric fluid. Before they can be reclassified the transformers must be tested and found to contain less than 500 ppm PCB after at least 3 months of in-service use.

If the PCB concentration was successfully reduced below 50 ppm, then the transformer can be reclassified to a Non-PCB Transformer.

(31) WHAT TYPE OF SERVICING CAN I DO ON MY TRANSFORMER?

Routine servicing of transformers (i.e., testing the dielectric fluid, filtering the fluid, removal of some fluid and then returning or replacing it, replacing gaskets) in any of the categories will result in minimal exposures to PCBs and allow the

use of most existing transformers throughout their lifetime. EPA has decided that this activity doesn't present an unreasonable risk to human health and the environment.

However, any servicing (including rebuilding) of PCB Transformers that involves removing the coils from the casing is prohibited by the Ban Rule. Removing the coils substantially increases PCB exposure, therefore, EPA concludes this servicing to be an unreasonable risk. EPA believes the cost of this prohibition (about \$14 million the first year and steadily less each year after) is justified by the increased risks which would otherwise occur to human health and the environment.

(32) CAN I REBUILD MY TRANSFORMERS?

Rebuilding a transformer would involve one or more of the following: draining the transformer, removing and disassembling the core, reworking the coil or rewinding a new coil, reassembling the core, and refilling the transformer with new fluid.

EPA permits the rebuilding only of PCB-Contaminated Transformers (containing between 50 ppm and 500 ppm PCB), and, of course, Non-PCB Transformers. If your transformer is classified as a PCB Transformer (containing 500 ppm or greater PCB), it cannot be rebuilt unless it is first reclassified to a PCB-Contaminated Transformer.

EPA decided to permit rebuilding of PCB-Contaminated Transformers, because the exposure to PCB is relatively low and the economic impact of not permitting this activity would be very high.

(33) CAN I SERVICE MY OWN TRANSFORMERS?

EPA has decided to authorize this activity, which is considered use, for persons who service their own transformers until July 1, 1984.

(34) CAN I HAVE A SERVICE SHOP WORK ON MY TRANSFORMER?

Yes, you can have work done on your transformer without receiving an exemption from EPA provided the shop does not add any PCB fluid. If PCB fluid (50 ppm PCB or greater) needs to be added, the shop can add your fluid without obtaining an exemption. However, if the service shop adds their PCB fluid to your transformer, they must get an exemption to do so after July 1, 1979.

(35) CAN I REUSE MY DIELECTRIC FLUID?

Dielectric fluid can be reused as long as it is used in either the transformer that it came from or in a transformer which had a higher concentration of PCBs than the replacement fluid.

(36) WHAT FLUIDS CAN I USE WHEN I RETROFILL MY TRANSFORMER?

Dielectric fluids containing less than 500 ppm PCBs can be used to refill transformers. However, dielectric fluids containing less than 500 ppm PCB under no circumstances can be mixed with fluids containing 500 ppm or greater PCBs. In other words, the deliberate dilution of PCB Transformers is prohibited. A PCB Transformer must be drained, refilled, and tested after it was retrofilled before it can be reclassified as a PCB-Contaminated Transformer. It should be noted that PCB Transformers are usually retrofilled with fluids that have fire resistant properties similar to PCBs.

(37) ARE THERE ANY RESTRICTIONS ON WHO CAN SELL ME DIELECTRIC FLUID?

After July 1, 1979, only those persons who have obtained exemptions from EPA can distribute (and sell) PCB dielectric fluid.

(38) CAN I SELL MY DIELECTRIC FLUID TO A WASTE OIL DEALER?

Dielectric fluid containing greater than 50 ppm PCB cannot be sold to a waste oil dealer unless the dealer is to dispose of it in accordance with the regulation. Dielectric fluid with concentrations of less than 50 ppm can be sold to a waste oil dealer as long as it will not be used as a sealant, coating, or dust control agent.

(39) CAN I SCRAP MY TRANSFORMER OR SELL IT TO SOMEONE TO SCRAP?

If your transformer is a PCB Transformer, you cannot scrap or sell your transformer to someone else to scrap. You must dispose of it in an approved chemical waste landfill. On the other hand, if the transformer is a PCB-Contaminated or Non-PCB Transformer, once the fluid is drained, the transformer can be scrapped or sold for scrap.

(40) CAN USABLE TRANSFORMERS BE SOLD BY PRESENT OWNERS?

Yes, provided the seller had originally obtained the transformer for use and not resale --- and the buyer does not purchase the usable PCB transformers for resale, but rather uses them himself.

RAILROAD TRANSFORMERS

(41) HOW DO I KNOW IF MY RAILROAD TRANSFORMERS ARE COVERED BY THE REGULATION?

Unless a nameplate (or a test) indicates that the transformer on an electric locomotive contains dielectric fluid having either no PCBs or a concentration of less than 50 ppm PCBs, your railroad transformer is covered by the PCB regulation.

(42) WHY ARE RAILROAD TRANSFORMERS DIFFERENT FROM OTHER TRANSFORMERS? ARE THEY SUBJECT TO DIFFERENT REQUIREMENTS UNDER THE REGULATION?

Railroad transformers are the transformers used on electric locomotives and some commuter cars. These transformers are subject to occasional leakage due to damage caused by objects thrown up from the tracks and by damage caused from overloads these heavy service units are subjected to. Because of the greater environmental and health risks from these transformers, the PCB Ban Rule requires that the PCBs be removed from these transformers on a phased reduction schedule.

(43) WHAT IS THE SCHEDULE FOR REDUCTION OF PCBs IN RAILROAD TRANSFORMERS?

By January 1, 1982 all Railroad Transformers must contain PCB concentrations of 60,000 ppm (6%) or less. The next deadline is January 1, 1984, at which time all Railroad Transformers must have a PCB concentration of no more than 1,000 ppm.

(44) HOW LONG CAN I USE MY PCB RAILROAD TRANSFORMERS?

You can use your Railroad Transformer until January 1, 1982 if the PCB concentration exceeds 60,000 ppm, after that date it is possible to use the Transformer until January 1, 1984 if the PCB concentration does not exceed 60,000 ppm. You will not be

able to use a Railroad Transformer containing greater than 1,000 ppm PCB after July 1, 1984.

(45) DO I HAVE TO TEST MY RAILROAD TRANSFORMER?

You will have to test your Railroad Transformers immediately after any PCB concentration reduction related servicing.

(46) HOW OFTEN DO I HAVE TO TEST MY RAILROAD TRANSFORMER?

It is necessary to test your Railroad Transformer immediately after it has been serviced to reduce the PCB concentrations in order to verify the new PCB concentration. In addition, between 12 and 24 months after such servicing the transformer is to be tested again to gauge the PCB concentration level.

(47) ARE THERE RESTRICTIONS ON WHAT I PUT IN MY RAILROAD TRANSFORMER?

Yes, there are restrictions. If you rebuild (remove the coil) the Transformer after January 1, 1982 it cannot be refilled with dielectric fluid containing a PCB concentration greater than 50 ppm. After January 1, 1982, Railroad Transformers may only be serviced with dielectric fluid containing less than 60,000 ppm PCB. Finally, after January 1, 1984, Railroad Transformers may only be serviced with dielectric fluid containing less than 1000 ppm.

(48) WHAT KIND OF SERVICING CAN BE DONE ON RAILROAD TRANSFORMERS?

Any kind of servicing can be done on Railroad Transformers until January 1, 1982. After that time, the transformer can be rebuilt only if it is to be refilled with dielectric fluid containing less than 50 ppm PCB. Starting on January 1, 1982 transformers may only be serviced with dielectric fluid containing less than 60,000 ppm PCB (except when it has been rebuilt). After January 1, 1984, Railroad Transformers may only be serviced with dielectric fluid containing less than 1000 ppm PCB (except when it has been rebuilt).

After July 1, 1979, processing and distribution in commerce of PCBs in order to service Railroad Transformers can be conducted only by those persons granted an exemption.

(49) CAN I REBUILD MY RAILROAD TRANSFORMER?

Before January 1, 1982 you can rebuild your Railroad Transformer with PCB dielectric fluid. After January 1, 1982, any rebuilt Railroad Transformers must not contain dielectric fluid with a PCB concentration greater than 50 ppm.

CAPACITORS

(50) HOW DO THESE RULES AFFECT CAPACITORS? CAN I CONTINUE TO USE MY PCB CAPACITORS?

Yes, you can continue to use your PCB capacitors for their useful life. The primary effect of the new prohibition rules is to terminate the manufacture of any new PCB capacitors.

(51) WHAT ABOUT THE DISPOSAL OF PCB CAPACITORS?

These rules continue the provisions of the PCB Disposal and Marking Rule published in the February 17, 1978 Federal Register. Large PCB capacitors must be disposed of in an EPA approved chemical waste landfill or incinerator. After January 1, 1980 all large PCB capacitors will have to be incinerated in special EPA approved incinerators.

Special disposal is not required for small capacitors --- except those waste capacitors owned by PCB capacitor or PCB equipment producers.

(52) WHAT IS THE DIFFERENCE BETWEEN LARGE AND SMALL CAPACITORS?

Small capacitors have less than 3 pounds of contained dielectric fluid; large capacitors have 3 pounds or more of dielectric fluid.

(53) I HAVE PCB CAPACITORS THAT ARE TEMPORARILY OUT OF SERVICE; CAN THEY BE PUT BACK INTO SERVICE?

Yes, but they will be subject to disposal requirements at a later date.

- (54) I NEED SPECIAL PCB CAPACITORS TO SERVICE MY PCB EQUIPMENT. WILL I BE ABLE TO BUY REPLACEMENT PCB CAPACITORS?

If suppliers receive an exemption from EPA, they can sell existing stocks of PCB capacitors to service existing PCB equipment.

MINING EQUIPMENT

- (55) WHAT TYPE OF MINING MACHINES ARE LIKELY TO HAVE PCBs?

PCBs are found in the electric motors in continuous miners and loader-type equipment that were manufactured up through the early 1970's.

- (56) CAN I CONTINUE TO USE THESE MACHINES?

In general, these machines can be used until January 1, 1982. The new rules set up a schedule whereby the motors in the equipment can be converted to non-PCB types. It appears that the continuous miner motors cannot be converted, which means the older models with PCB motors will probably have to be scrapped.

- (57) CAN I REPAIR THESE MACHINES?

Servicing or repair of PCB mining equipment is permitted only for persons who are granted an exemption by EPA. PCB motors in continuous miner-type equipment may be rebuilt until December 31, 1979. PCB motors in loader-type equipment must be rebuilt as air-cooled or other non-PCB containing motors whenever they are returned to a service shop for servicing. After January 1, 1982 PCBs may not be added to mining equipment.

- (58) CAN I REBUILD THESE MACHINES?

Yes you can. In fact, when you have the loader serviced the motor must be rebuilt as a non-PCB motor. Rebuilding of the PCB motors in continuous miners is permitted only until December 31, 1979.

(59) CAN I SCRAP THESE MACHINES?

Yes, but first the PCB motors must be removed and properly disposed. PCB motors can either be incinerated or, after draining the PCBs, placed in a chemical waste landfill.

(60) HOW LONG CAN I USE THESE MACHINES?

PCBs cannot be used in mining equipment after January 1, 1982.

HYDRAULIC SYSTEMS

(61) DO ALL HYDRAULIC SYSTEMS HAVE PCBs IN THEM?

Probably not. PCB hydraulic fluid was developed for use in machines that were subject to high temperatures, such as aluminum die casting machines and hydraulic machines in steel mills. Because of their low flammability, PCBs provide an extra measure of fire protection. The use of these high concentration fluids was discontinued several years ago by most users, because of serious water pollution problems. However, residues of the original fluid remain in sufficient quantities to be of continuing environmental concern.

In addition, it is possible that hydraulic systems on other machines that did not pose any special fire risk also had these PCB fluids added to them. These may be sufficiently contaminated to require action under these regulations.

(62) CAN THESE PCB CONTAMINATED HYDRAULIC SYSTEMS CONTINUE TO BE USED? IS ANY CORRECTIVE ACTION NECESSARY?

These PCB contaminated systems can be used until July 1, 1984, provided that a corrective program of testing, draining, refilling, and/or topping-off is undertaken.

(63) HOW OFTEN MUST I TEST MY HYDRAULIC SYSTEM?

Any hydraulic system that ever contained PCB hydraulic fluid must be tested by November 1, 1979, and, at least annually thereafter, until the system reaches 50 ppm PCB.

- (64) DO I HAVE TO DRAIN AND THEN REPLACE ALL OF THE HYDRAULIC FLUID IN MY MACHINES WHENEVER THEY EXCEED 50 PPM PCBs?

The regulations provide a flexible approach for reducing PCB concentrations. Highly contaminated systems will have to be drained and probably flushed and wiped clean in order to effectively reduce the PCB levels. Other systems may be effectively decontaminated by a drain and refill approach. Systems with low level contamination or borderline levels may be effectively controlled by simply topping-off with non-PCB fluid.

- (65) ARE THERE ANY RESTRICTIONS ON THE FLUIDS THAT CAN BE ADDED TO THESE SYSTEMS?

No fluids containing more than 50 ppm PCBs can be added. This means that fluids collected from leaking seals, fittings, etc. cannot be returned to the systems if the fluid exceeds 50 ppm PCBs.

HEAT TRANSFER SYSTEMS

- (66) DO HEAT TRANSFER SYSTEMS CONTAIN PCBs? WHAT ARE THE REQUIREMENTS FOR USE/OR REMOVAL?

PCBs have been used in heat transfer systems because of their high heat retention capacity. These systems do leak at times, and, therefore, are controlled by this rule. The requirements for testing, refilling, and topping-off are very similar to hydraulic systems.

- (67) ARE THERE DIFFERENT REQUIREMENTS FOR HEAT TRANSFER SYSTEMS USED IN THE MANUFACTURE OF FOODS, DRUGS, AND COSMETICS?

Yes, after November 1, 1979 all heat transfer systems must contain fluid with 50 ppm PCB or less if they are to be used in the manufacture or production of foods, drugs, and cosmetics.

OTHER PCB USES

- (68) CAN PCBs BE USED AS A MOUNTING MEDIUM FOR MICROSCOPIC SLIDES?

Yes, until July 1, 1984. EPA will decide later whether to extend the authorized time for this PCB use.

- (69) CAN PCBs CONTINUE TO BE USED IN SMALL QUANTITIES FOR RESEARCH AND DEVELOPMENT?

Yes, until July 1, 1984. As with microscopic slides, EPA will decide later whether to extend the authorized time for use.

- (70) IN THE EARLY 1970's CARBONLESS COPY PAPER WAS MADE WITH INK CONTAINING PCBs. WHAT PROVISIONS DOES THE PCB BAN RULE MAKE FOR THIS PAPER?

Although carbonless copy paper is no longer made with PCBs, supplies of this paperstock still exists; most are in files. Because the amount of PCB on each sheet is extremely small and no inexpensive method of separating PCB from non-PCB carbonless paper has been developed, EPA has authorized the use of existing PCB carbonless copy paper indefinitely.

- (71) SOME PIGMENTS CONTAIN PCBs, CAN THEY CONTINUE TO BE USED?

EPA's PCB Ban Rule authorizes the use of diarylide and phthalocyanine pigments, containing PCBs as an impurity in concentrations ranging from several thousand parts per million to 50 ppm, until January 1, 1982. However, after July 2, 1979, these pigments, containing greater than 50 ppm PCB, cannot be manufactured, and they cannot be processed or distributed in commerce after July 1, 1979, unless EPA grants exemptions for these activities.

- (72) OTHER CHEMICALS ALSO CONTAIN PCBs IN LOW CONCENTRATIONS, CAN THEY CONTINUE TO BE USED?

At this time, EPA's Ban Rule does not authorize the use of any other chemicals containing PCBs. Several manufacturers have requested exemptions to manufacture chemicals with low concentrations of PCBs, and, if these exemptions are granted, EPA will consider appropriate authorizations to permit the use of the chemicals.

- (73) IF SOMEONE MANUFACTURES PCB CONTAMINATED CHEMICALS BUT DID NOT APPLY TO EPA FOR AN EXEMPTION CAN THEY STILL REQUEST ONE?

Anyone in that situation should apply to EPA for an exemption using the procedures EPA published in the Federal Register on November 1, 1978. (See the "Contacts for Infor-

mation" Section of this Booklet to find out how to obtain a copy of this Federal Register Notice.)

(74) CAN ELECTROMAGNETS CONTAINING PCBs STILL BE USED?

EPA considers the use of electromagnets (similar to transformers in construction) containing PCBs to be used in a totally enclosed manner, therefore, these PCB electromagnets may continue to be used and serviced.

Persons may service their own PCB electromagnets. However, if someone else adds PCBs, not owned by the electromagnet owner, during the servicing, they must obtain an exemption from EPA after July 1, 1979.

(75) CAN PCBs CONTINUE TO BE USED IN NATURAL GAS PIPELINE COMPRESSORS?

Yes, until May 1, 1980. In general, these systems were drained of high concentration PCB fluid several years ago, thus removing most of the PCBs. EPA has authorized these compressors to be used until May 1, 1980 -- so that they can be drained and refilled with non-PCB fluid to further reduce the PCB concentration until it is below 50 ppm.

LABELING

(76) WHAT NEEDS A LABEL?

Most PCB Items (including PCB Containers, PCB Article Containers, PCB Articles, PCB Equipment, and PCB Transport Vehicles) that contain 50 ppm or greater PCBs must be labeled. This labeling requirement is a modification from the February 17, 1978 Disposal and Marking Regulation which applied to PCB Items that contain 500 ppm or greater PCBs. To provide sufficient time to identify and mark these additional items containing between 50 and 500 ppm PCB, the final May 1979 Rule allows until October 1, 1979 for labeling requirements to be met.

(77) DO ALL TRANSFORMERS CONTAINING PCBs HAVE TO BE LABELED?

PCB Transformers, containing 500 ppm or greater PCB, are required to be labeled. PCB-Contaminated Transformers, containing between 50 and 500 ppm PCB, are not required to be labeled. The cost of marking a very large number of PCB-Contaminated Transformers while they are in service would be

extremely high (approximately \$10 for each of the 35 million transformers).

An unmarked transformer is automatically assumed to be a PCB-Contaminated Transformer. However, if a transformer has no nameplate information but there is a reasonable suspicion that PCBs may be present above 500 ppm --- the transformer should be labeled as a PCB Transformer until the PCB content can be verified.

(78) WHERE DO I HAVE TO PUT THE LABELS?

All labels (or marks) are to be put on the exterior of PCB Items and transport vehicles in a place that they can be easily seen and read by anyone inspecting or servicing them.

(79) THERE ARE A LOT OF PCB CAPACITORS AND EQUIPMENT CONTAINING THESE CAPACITORS IN USE. DO THEY ALL HAVE TO BE LABELED?

The requirements for labeling capacitors are primarily related to disposal; the labels serve as a positive reminder regarding disposal. All large, high voltage PCB capacitors have to be labeled, including those in service. Large, low voltage capacitors have to be labeled when they are taken out of service for disposal.

Small capacitors do not have to be labeled. Equipment containing PCB capacitors does not have to be labeled unless the capacitor is a large, high voltage type or if the equipment was produced after January 1, 1979 and contains a small PCB capacitor.

(80) DO I HAVE TO LABEL A PCB CAPACITOR THAT IS ON A POLE OR IN A SIMILAR INACCESSIBLE LOCATION?

If a PCB capacitor is installed in a "protected" area (e.g., on a power pole, or structure, or behind a fence) the pole, structure, or fence is to be labeled in a place easily seen by interested persons, such as servicemen.

(81) I SUBMITTED A PETITION TO EPA TO BE GRANTED AN EXEMPTION FROM THE JULY 2, 1979 MANUFACTURING BAN. IF I AM GRANTED AN EXEMPTION, WHAT WILL THE LABELING REQUIREMENTS BE FOR THE PCBs I MANUFACTURE?

Any labeling requirements for chemical substances or mixtures containing 50 to 500 ppm PCBs manufactured after July 2,

1979, including PCBs that are byproducts or impurities, will be included in the exemption response EPA might grant to permit such manufacture.

If you have already submitted a petition to EPA for a manufacturing exemption and your chemical contains less than 500 ppm PCBs, you do not have to apply a label until EPA acts on your petition. However, any container or any products that contain 500 ppm or greater PCB must be labeled -- even before EPA acts on the petition for your chemical.

(82) IF RENTED OR LEASED EQUIPMENT CONTAINS PCBs, WHO IS RESPONSIBLE FOR LABELING?

Both the owner and the operator could be held responsible for the labeling of rented PCB equipment. #

(83) DOES EPA SUPPLY LABELS FOR PCB CONTAINERS OR PCB ARTICLES AND EQUIPMENT? DOES EPA PROVIDE NAMES OF SOURCES FOR SUCH PCB LABELS?

EPA does not supply any PCB labels. However, the Agency knows of two sources from which you can obtain the required labels: LABELMASTER, 7525 North Wolcott Ave., Chicago, Illinois 60626, phone: 312-973-5100 -- to place only orders call toll free 800-621-5808 (except in Illinois); W.H. BRADY CO., Facilities, Identification, Products Division, 727 W. Glendale Ave., Milwaukee, Wisconsin, phone: 414-332-8100 (X624).

Printing shops who produce labels would also be potential sources for these labels. The label format and sizes are included in the regulation.

TESTING

(84) IS THERE AN EPA APPROVED TESTING AND SAMPLING PROCEDURE FOR PCB DETECTION?

A variety of procedures exist for determining PCB concentrations in various media such as water, air, soil, mineral oil, pigments, etc. EPA has already made available through its Regional Offices copies of test procedures for PCBs in air, soil, water, and sediments. EPA is also preparing additional information on test procedures for PCBs in oils; this information will also be available from EPA Regional Offices. In addition, copies of these procedures can be obtained from EPA's Office of Industry Assistance. (See the "Contacts for Information" Section of this Booklet on how to obtain this information.)

(85) WHAT EQUIPMENT IS AVAILABLE TO DETECT PCBs?

There is no simple field test for detecting PCBs. It is usually done using gas chromatography/electron capture. The best solution would be to contact an experienced chemical laboratory in your area that could perform such tests.

(86) ARE THERE EPA APPROVED LABS TO ANALYZED SAMPLES OF PCBs?

No, EPA does not have a program for recommending or approving analytical laboratories.

STORAGE

(87) WHAT KINDS OF CONTAINERS ARE APPROPRIATE FOR STORAGE?

The May 31, 1979 Final Rule permits 5 container types (5, 5B, 6D, 17C and 17E) which comply with Department of Transportation (DOT) specifications set out in 49 CFR 173.346, to be used to store liquid PCBs. Most of industry already is using these containers for PCB storage and handling.

(88) CAN LARGE CONTAINERS, SUCH AS STORAGE TANKS, BE USED FOR THE STORAGE OF PCB LIQUIDS?

EPA decided in the Final Rule to permit large containers, such as storage tanks, to be used to store bulk PCB liquids. This is to allow safe transfer and storage of large PCB liquid quantities; in addition, reduce storage costs. In other words, the transfer of stored bulk PCBs from tanks to other tanks or tank trucks will lessen the spill risks as opposed to having to transfer these large quantities from a number of smaller storage drums into transfer tanks.

These storage tanks must meet design and construction standards adopted by OSHA (29 CFR 1910.106). Also the storage facilities must have a spill prevention control and counter measure plan similar to the plans required for oil spill prevention.

Owners and operators of bulk storage facilities will have to keep records of the amounts added to and removed from bulk containers. These records will be important in tracing waste shipments and enforcing the disposal and storage requirements.

- (89) CAN PCB CONTAINERS OF CONTAMINATED SOIL BE TEMPORARILY STORED?

Yes, non-liquid PCB wastes, such as contaminated soil, can be temporarily stored for up to 30 days.

- (90) CAN PCB LIQUIDS OF LOW CONCENTRATION BE TEMPORARILY STORED? OR HIGH CONCENTRATION?

Low concentration PCB liquids (50 to 500 ppm) can be temporarily stored for up to 30 days. All temporary storage areas must have a spill prevention control and counter measure plan. However, the final rule does not allow temporary storage for high concentration PCB liquids (above 500 ppm) because of the potential harm from a spill.

- (91) I HAVE A SMALL QUANTITY OF PCBs (I.E., A FEW SOAKED RAGS AND 1 GALLON OF PCBs IN AN APPROVED CONTAINER), AND I DON'T WANT TO SEND THEM A LONG DISTANCE FOR DISPOSAL. CAN I STORE THEM UNTIL A PCB DISPOSAL SITE CLOSE TO ME IS APPROVED?

The mentioned items may be stored until the last day of 1983.

- (92) ONCE PCB ARTICLES ARE TAKEN OUT OF SERVICE, HOW LONG CAN THEY BE KEPT BEFORE BEING PLACED IN AN APPROPRIATE STORAGE AREA? WHAT ABOUT PCB EQUIPMENT CONTAINING LEAKING PCB ARTICLES?

Non-leaking PCB articles and PCB containers containing leaking articles can be temporarily stored for up to 30 days.

- (93) WHEN PCB CAPACITORS OR CONTAINERS ARE STORED IN AN APPROPRIATE STORAGE AREA, WHAT HAPPENS WHEN ONE OF THESE ITEMS STARTS TO LEAK?

A leaking PCB capacitor should be immediately placed in a non-leaking Department of Transportation approved drum and any spillage cleaned up using sorbent or suitable solvents. It is a good practice to add sorbent material, such as saw dust, to the container to soak up any liquid that continues to leak out of the capacitor.

When a container develops a leak, the contents should immediately be transferred to another, non-leaking container or to special "overpack" containers, such as those used in the chemical industry for leaking containers.

- (94) MUST THE EPA INSPECT A PCB STORAGE AREA ONCE IT IS BUILT BEFORE IT CAN BE USED?

No, it is the responsibility of the organization storing the PCBs to insure that the storage area meets the specifications.

- (95) DO PCB STORAGE AREAS HAVE TO BE PERIODICALLY CHECKED FOR LEAKS OR OTHER PROBLEMS? WHAT ABOUT PCB ARTICLES, SUCH AS TRANSFORMERS, THAT ARE IN SERVICE? 0

PCB storage areas must be checked by the owner or operators at least every 30 days. Articles in service are not required to be checked by the regulations, but periodic checks would be a wise practice.

SPILLS

- (96) DO PCB SPILLS HAVE TO BE REPORTED

Under the authority of TSCA, PCB spills have to be reported whenever the incident poses a substantial risk to human health or the environment. Since "substantial risk" cannot be precisely defined, however, any spill should be reported when people come into direct and uncontrolled contact with PCBs, or the extent of the spill is large enough to expose significant numbers of animals.

In addition, a spill should also be reported when the volume or the extent of the spill is unknown -- such as spills that enter drainage systems. PCB spills into water, onto shorelines, or those that threaten water-courses should always be immediately reported.

EPA is currently completing regulations under the Clean Air Act that will require reporting for water-related hazardous chemical spills (including PCBs). These regulations will have criminal penalties for failing to report such spills.

As a general rule, spills involving a single capacitor do not have to be reported unless PCBs threaten or enter a water-course. Because of the greater threat to health and the environment, transformer spills should be reported -- unless only

minor leaks, such as bushing leaks, are involved. Any spilling or leaking should be stopped and repaired as soon as possible.

(97) HOW DO I REPORT PCB SPILLS?

PCB spills can be reported to the National Response Center operated by the U.S. Coast Guard at 800-424-8802 (in the District of Columbia, call 426-2675).

(98) WHAT HAPPENS WHEN I REPORT A PCB SPILL? CAN I GET INFORMATION OR ADVICE ON WHAT TO DO ABOUT THE SPILL?

The National Response Center will direct the report to the appropriate EPA environmental emergency office, based on the location of the spill. Experts from these offices (or related state and local experts) will contact persons responsible for the spills, in order to evaluate the potential environmental threat and to determine the appropriate spill control and cleanup measures.

(99) IF I HAVE A SPILL, WHAT SHOULD I DO TO CONTROL OR CLEAN UP THE SPILL?

The first priority is to control the spread of the spill by damming or diking the leak. Also, any threats to water should be given top priority.

Once a spill is contained clean up measures can begin. Clean up can be simply the removal of contaminated soil or debris. In some cases, more complex techniques may be required, such as special PCB sorbents or special filtration/carbon absorption removal of PCBs from water.

Large and complicated spills should be cleaned up by trained and experienced personnel. Organizations, who frequently handle PCBs, should develop contingency plans and conduct training for dealing with spills. Commercial firms are also available on a contract basis to clean up spills. Government spill experts can provide information on such firms.

RECORDKEEPING

(100) MUST COMPANIES KEEP RECORDS OF THE DISPOSITION OF PCBs IN SERVICE? IN STORAGE? IF SO, FOR HOW LONG?

If you own or operate a facility which uses PCBs or PCB items, or have either stored, you are to keep records of their

disposition. Specifically, this applies to facilities using or storing at least 99.4 pounds (45 kilograms) of PCBs in PCB Container(s); one or more PCB Transformers; or 50 or more PCB High or Low Voltage Large Capacitors.

These records shall be maintained for at least 5 years after the facility ceases using or storing PCBs or PCB Items in prescribed quantities.

(101) DO PCB INCINERATOR FACILITIES HAVE TO KEEP RECORDS?
CHEMICAL WASTE LANDFILL FACILITIES? HIGH EFFICIENCY BOILER
FACILITIES? IF SO, FOR HOW LONG?

Owners or operators of all three types of PCB Disposal Facilities have to keep records. Incinerator and high efficiency boiler facilities must keep their records for 5 years; chemical waste landfill facilities must keep their records for at least 20 years after PCBs have stopped being disposed there.

(102) WHEN MUST I BEGIN KEEPING RECORDS OF MY PCB FACILITIES?

PCB recordkeeping, if applicable, was to have begun on July 2, 1978. These records form the basis of an annual document prepared for each facility by July 1; the first annual reports should be compiled by July 2, 1979.

(103) MUST COMPANIES SEND THEIR ANNUAL REPORTS CONCERNING PCBs TO
EPA OR KEEP THEM FOR THEIR OWN RECORDS?

Companies should keep their PCB records and annual reports at their facility for inspection by EPA personnel. Do not send the records or reports to EPA unless it is specifically requested by the Agency.

(104) I HAVE PCB FACILITIES IN SEVERAL LOCATIONS. DO RECORDS
HAVE TO BE KEPT AT EACH SITE?

Owners or operators of more than one facility having PCBs may choose to keep all of the records at a single facility, but the identify of that single facility must be available at each location. The record location must be manned at least 8 hours a day.

DISPOSAL

(105) HOW DO I DISPOSE OF TRANSFORMERS CONTAINING PCBs?

There are two ways to dispose of a PCB Transformer, which contains PCB concentrations in excess of 500 ppm. The transformer and the dielectric fluid can be burned together in a high temperature incinerator approved by EPA, or the liquid can be drained out of the transformer first. If the liquid is drained, the transformer must be flushed with solvent for 18 hours; the solvent and the dielectric fluid must then be disposed of in an EPA approved high temperature incinerator. The drained transformer after it is resealed must be disposed of in a chemical landfill which has been approved by EPA.

If the transformer is a PCB-Contaminated Transformer, containing more than 50 ppm PCB and less than 500 ppm PCB, the transformer and the liquid can also be incinerated or the dielectric liquid can first be drained. If the liquid is drained it can be disposed of in a high temperature incinerator, a chemical landfill which has been approved by EPA, or in a high efficiency boiler. The drained transformer can be disposed of as scrap or in a disposal facility equivalent to good municipal solid waste disposal practices.

(106) HOW DO I DISPOSE OF LARGE PCB CAPACITORS?

Until January 1, 1980, large PCB capacitors can be disposed of in EPA approved chemical waste landfills or high temperature incinerators. After January 1, 1980, they must be disposed of by high temperature incinerators. It is expected that hammermill-type crushers will be used at the incinerators to improve the destruction efficiency. These large capacitors account for approximately one-third of the PCBs currently in service.

(107) WHERE CAN PCB ARTICLES (OTHER THAN PCB TRANSFORMERS AND CAPACITORS) BE DISPOSED?

PCB articles can be disposed of in a chemical waste landfill, as well as, in high temperature incinerators, provided they are EPA approved. Examples of these articles, which account for less than 1% of the PCBs currently in use in the U.S., are pipes, hoses, parts of heat transfer systems, electromagnets, and electric motors.

When these articles are disposed of in chemical waste landfills, they must be drained of free flowing liquid, and therefore, will contain only small amounts of PCBs.

(108) ARE THERE SPECIAL DISPOSAL REQUIREMENTS FOR SMALL PCB CAPACITORS CONTAINED PRIMARILY IN SMALL APPLIANCES AND FLUORESCENT LIGHT BALLASTS?

No, small capacitors can be disposed of as municipal waste. EPA has determined that the random disposal of small capacitors in municipal solid waste sites by householders and other infrequent disposers does not present an environmental hazard.

However, the disposal of large quantities of small PCB capacitors by commercial and industrial activities poses a larger environmental risk. Therefore, EPA encourages these persons to establish voluntarily a collection and disposal program that would result in the waste capacitors going to chemical waste landfills or high temperature incinerators.

(109) HOW ARE HYDRAULIC MACHINES CONTAMINATED WITH PCBs TO BE DISPOSED?

In general, only a relatively small portion of these machines are contaminated with PCBs, in particular those used in die-casting and forging operations. Therefore, instead of requiring disposal in a chemical waste landfill, the final rule permits disposal of hydraulic systems as municipal solid waste and salvaging of these machines after draining. First, the machines must be drained of all free-flowing liquid. If the fluid contains more than 1000 ppm PCBs, the machine must be flushed with a solvent and thoroughly drained before disposal. The liquid must be disposed of by high temperature incinerators or, if the PCB concentration is 50 to 500 ppm, by high efficiency boilers or in chemical waste landfills.

(110) HOW CAN I DISPOSE OF THE DIELECTRIC FLUID IN MY TRANSFORMER?

Fluids from PCB Transformers (concentrations of 500 ppm greater) must be disposed of only by high temperature incineration. Fluids from PCB-Contaminated Transformers (with 50 ppm to 500 ppm PCBs) must be disposed of in high efficiency boilers, in approved chemical waste landfills, or in high temperature incinerators. Fluids from Non-PCB Transformers (with less than 50 ppm PCBs) have one disposal restriction: they cannot be used as a sealant, coating, or dust control agent if they contain any detectable PCB.

(111) WHERE CAN OTHER LIQUID WASTES WITH OVER 500 PPM PCB BE DISPOSED? BETWEEN 50 and 500 PPM PCBs? LESS THAN 50 PPM PCBs?

The same disposal options apply as for transformer dielectric fluid. (refer to Question #110).

(112) WHERE CAN NON-LIQUID PCBs BE DISPOSED?

Non-liquid PCBs at any concentration (e.g., contaminated rags and absorbent materials, and contaminated soils and other solids recovered from spills or removed from old disposal sites) can be disposed in Annex II chemical waste landfills.

(113) CAN DECONTAMINATED PCB CONTAINERS BE DISPOSED OF IN AN ORDINARY LANDFILL SITE?

Yes, decontaminated PCB containers may be disposed of in ordinary landfill sites, rather than in EPA approved chemical waste landfills.

(114) CAN DECONTAMINATED PCB CONTAINERS BE REUSED?

Containers decontaminated in accordance with Annex IV can be reused for general use.

(115) HOW CAN PCB CONTAINERS USED ONLY TO HOLD LOW PCB CONCENTRATIONS BE DISPOSED?

PCB Containers used only to contain materials or fluids with PCB concentrations between 50 and 500 ppm can be disposed of as municipal waste.

(116) WHAT ARE THE REQUIREMENTS FOR DISPOSAL SITES?

Incinerators used to dispose PCBs must be approved by the appropriate EPA Regional Administrator. The approved incinerators must meet the requirements set out in Annex I of the May 31, 1979 Rule.

Likewise, the chemical waste landfills used for the disposal of PCBs and PCB Items must be approved by the appropriate EPA Regional Administrator, which must meet the requirements established in Annex II of the Final Rule.

(117) HAVE ANY DISPOSAL SITES BEEN APPROVED FOR PCBs? WHERE ARE THEY?

Yes, eight chemical waste landfill sites have been approved. No incinerator sites have yet been approved, but three sites are currently being considered.

The landfill locations are as follows:

1. Facility: General Electric Co., Silicone Products Division. Facility Address: 260 Hudson River Rd., Waterford, New York 12189. Facility Telephone Number (518) 237-3330. Type of facility Approved: Incinerator. Type of PCB Waste Handled: Approval allows G.E. to incinerate only those PCB wastes which are generated on site, i.e., G. E. can not accept PCBs for incineration from any other company or any other G.E. facility. Expiration Date of Approval: September 1, 1981. EPA Regional Office Contact: Wayne Pierre. EPA Telephone Number: (212) 264-0505.
2. Facility: Newco Chemical Waste Systems, Inc. Facility Address: 4526 Royal Avenue, Niagara Falls, New York 14330. Facility Telephone Number: (716) 285-6944. Type of Facility Approved: Chemical Waste Landfill. Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, and other debris; Dredge spoils; Municipal sludges; and Properly drained containers (drums). Expiration Date of Approval: August 18, 1981. EPA Regional Office Contact: Wayne Pierre. EPA Telephone Number: (212) 264-0505.
3. Facility: SCA Chemical Services, Inc. Facility Address: 1550 Balmer Rd., Model City, New York 14107. Facility Telephone Number: (716) 754-8231. Type of Facility Approved: Chemical Waste Landfill. Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, and other debris; Dredge spoils; Municipal sludges; and Properly drained containers (drums). Expiration Date of Approval: October 2, 1981.
4. Facility: Waste Management of Alabama, Inc. Facility Address: P.O. Box 1200 Livingston, Alabama 35470. Facility Telephone Number: (205) 652-9529. Type of Facility Approved: Chemical Waste Landfill. Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soils, dirt, rags, and other debris; Dredge spoils; Municipal sludges; and Properly drained containers (drums). Expiration Date of Approval: Open-ended. EPA Regional Office Contact: Mr. James Scarbrough. EPA Telephone Number (404) 881-3016.
5. Facility: Casmalia Disposal. Facility Address: 539 Ysidro Rd., P.O. Box 5275, Santa Barbara, California 93108-main office (site located near Casmalia in Santa Barbara County). Facility Telephone Number: (805) 969-4703. Type of Facility Approved:

Chemical Waste Landfill. Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags and other debris; Dredge spoils; Municipal sludges; and Properly drained containers (drums). Expiration Date of Approval: Open-ended. EPA Regional Office Contact: Raymond Seid, EPA Telephone Number: (414) 556-3450.

6. Facility: Nuclear Engineering Co., Inc. Facility Address: 9200 Shelbyville Rd., Suite 526, P.O. Box 7246, Louisville, Kentucky 40207, main office (site located near Beatty, Nev. in Nye County). Facility Telephone Number: (502) 426-7160. Type of Facility Approved: Chemical Waste Landfill. Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags and other debris; Dredge spoils; Municipal sludges; and Properly drained containers (drums). Expiration Date of Approval: Open-ended. EPA Regional Office Contact: Raymond Seid. EPA Telephone Number: (415) 556-3450.

7. Facility: Chem-Nuclear Systems, Inc. Facility Address: P.O. Box 1269, Portland, Oregon 97205 main office (Site located in Arlington, Oregon). Facility Telephone Number: (503) 223-1912. Type of facility Approved: Chemical Waste Landfill. Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, asphalt, and other debris; and Properly drained containers (drums). Expiration Date of Approval: January 1, 1980. EPA Regional Office Contact: Mr. Roger Fuentes. EPA Telephone Number: (206) 442-1260.

8. Facility: Wes-Con., Inc. Facility Address: P. O. Box 564. Twin Falls, Idaho 83301. main office (Site located in Grand View, Idaho). Facility Telephone Number: (208) 734-7711. Type of Facility Approved: Disposal in Missile Silos. Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, asphalt, and other debris; and Properly drained containers (drums). Expiration Date of Approval: January 1, 1980. EPA Regional Office Contact: Mr. Rogers Fuentes. EPA Telephone Number: (206) 442-1260.

(118) CAN A COMMON CARRIER (E.G., TRUCK LINE) TRANSPORT PCBs FOR A COMPANY TO A DISPOSAL FACILITY IF THE TRANSPORT IS NOT WITHIN THE INDUSTRY?

If the common carrier complies with the Hazardous Materials requirements set by the Department of Transportation, and the vehicle is properly and visibly labeled on its exterior with a PCB label it can be used to transport PCBs to a disposal site.

(119) CAN PCBs OR PCB ITEMS BE EXPORTED FOR DISPOSAL? BE IMPORTED FOR DISPOSAL?

Yes, refer to Question #23 in the "Import/Export" section of this Booklet.

PCBs IN THE WORKPLACE

(120) ARE THERE ANY OSHA RULES GOVERNING PCBs IN THE WORKPLACE?

No, not at the present time; however, in 1977 the National Institute of Occupational Safety and Health (NIOSH) -- the HEW organization responsible for researching workplace safety -- published "Criteria for a Recommended Standard ... Occupational Exposure to Polychlorinated Biphenyls (PCBs)". OSHA, associated with the Department of Labor, will use this document to develop mandatory standards regarding PCBs.

(121) WHAT IS A RECOMMENDED STANDARD FOR OCCUPATIONAL EXPOSURE? WHAT IS THE STANDARD RECOMMENDED BY NIOSH FOR OCCUPATIONAL EXPOSURE TO PCBs?

A recommended standard is a determination of the level of exposure that will substantially reduce any risks of reproductive or tumorigenic effects of PCBs and prevent other adverse effects of exposure in the workplace. It is based on a 10-hour workday, 40-hour workweek, over a normal working lifetime.

NIOSH has recommended in their Criteria Document for PCBs that occupational exposure to PCBs be controlled so that no worker is exposed at a concentration greater than 1.0 microgram total PCBs per cubic meter of air (1.0 Mg/cu m), determination as time-weighted average (TWA) concentration, for up to a 10-hour workday, 40 hour workweek. This is only a recommended standard and it has not been adopted to date, by either OSHA or EPA. At the present time, however, OSHA is reviewing this recommended standard.

(122) DID NIOSH RECOMMEND ANYTHING ELSE TO REDUCE EXPOSURE TO PCBs IN THE WORKPLACE?

Yes, NIOSH made recommendations about work practices, personal protective equipment and clothing, medical surveillance, personal clean up and sanitation practices, and employee information programs.

(123) HOW DO OSHA STANDARDS AND NIOSH RECOMMENDATIONS RELATE TO EPA'S PCB REGULATION?

EPA's PCB Rules do not directly regulate workers, but the Rules do restrict or prohibit certain PCB activities which reduce the number of workers exposed. The EPA Rules prohibit PCB transformer and capacitor manufacture, as well as PCB transformer rebuilding (except for railroad transformers); these activities were the major long-term occupational exposures to high concentration PCBs. The rebuilding of PCB railroad transformers and mining machine PCB motors will result in long-term worker exposure that will warrant special worker protection, but these activities will be phased out over the next several years.

Worker exposure can also occur as a result of PCB spills and authorized servicing operations for PCB transformers.

§9

(124) WHAT KIND OF PROTECTIVE CLOTHING SHOULD BE WORN WHEN WORKING WITH PCBs?

The type of protective clothing which should be worn when working with PCBs is dependent on the individual circumstances. Worker protective clothing and equipment is intended to prevent skin and eye contact, and control respiratory exposure.

Respiratory exposure control (whether individual protection or workplace control) is most relevant for long-term production operations or major spills. PCB Transformer spills pose respiratory problems because of solvents, such as trichlorobenzene, that are mixed with the PCBs. Small spills, such as capacitor failures, seldom pose respiratory problems, but protection should be provided for incidents in confined areas.

Skin protection can usually be achieved by wearing non-porous gloves and boots and heavy overalls. For major spill clean up activities, a full suit of non-porous clothing may be appropriate. Also, non-porous aprons can be effective in reducing contamination of worker clothing. Non-porous protective gear can usually be decontaminated with solvents. Work clothing can usually be laundered and reused, unless the garment is heavily contaminated. It is wise to launder work clothes separately from other garments.

Eye protection should be worn when it is possible for PCBs to be splashed in the eyes. Removing contaminated soil does not usually pose such a threat.

(125) IF I GET PCB LIQUID ON MY SKIN, HOW CAN I REMOVE IT?

If liquid or solid PCBs are splashed or spilled on an employee, contaminated clothing should be removed promptly and the skin washed thoroughly with soap and water for at least 15 minutes.

Eyes should be irrigated for at least 15 minutes if liquid or solid PCBs get into them. A drop of vegetable oil may be put into the eye to relieve the irritating effect of PCBs.

CONTACTS FOR INFORMATION

(126) IF I HAVE OTHER QUESTIONS ABOUT THE PCB BAN RULE'S PROVISIONS, IS THERE SOMEONE I CAN CONTACT?

If you have more questions call the Industry Assistance Office on their nationwide toll free number: 800-424-9065; persons in the Washington, D.C. area can reach this Office by calling 554-1404.

(127) HOW DO I GET A COPY OF THE RULE? SUPPORT DOCUMENT/ VOLUNTARY ENVIRONMENTAL IMPACT STATEMENT (REFERRED TO IN THE RULES AS THE VERSAR REPORT)?

Copies of both can be obtained by calling the phone numbers mentioned in the answer to Question 126, or by writing to:

John B. Ritch, Jr., Director
Industry Assistance Office
Office of Toxic Substances (TS-799)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

United States
Environmental Protection
Agency
Washington DC 20460

75-799

Official Business
Penalty for Private Use \$300

THIS CASE

ADM 006842

RICHARD B. OGILVIE
Governor

WILLIAM L. BLASER
Director

STATE OF ILLINOIS
ENVIRONMENTAL PROTECTION AGENCY

November 9, 1971

Re: Your letter of September 24, 1971

Monsanto Company
Sauget, Illinois 62201

Attention : Mr. M. R. Foresman

Dear Sir:

In reply to your request to discontinue perpetual monitoring of HCL and free chlorine gas, emitted from the chemical waste incinerator, the Agency feels, that before a decision can be made to discontinue the monitoring, a representative of the Agency must inspect the monitoring of HCL and chlorine during actual operation of the incinerator.

Based on the submitted waste analysis, incineration of di-chloroaniline waste, may be permitted under the following conditions:

Condition 1: Di-chloroaniline waste should be burned in the thermal oxidizer at rates not greater than 800 pounds per hour

Condition 2: The operator has the responsibility to dispose of any air contaminants removed or collected by the control equipment in such a manner as to not cause air, water, or land pollution.

Condition 3: Stack effluent should not contain more than 5.0 pounds per hour of hydrogen chloride, .05 grain of particulates per standard cubic foot of air, 50 parts per million of free chlorine and contain no chlorinated derivatives of aniline. The actual concentrations of these materials shall be continuously determined and recorded according to such procedures as are acceptable to this Agency.

Very truly yours,

Keith J. Conklin
Keith J. Conklin, Manager
Permit Section

Division of Air Pollution Control

In the New Illinois, we accommodate!

1001 SPRINGFIELD ROAD
AT 2ND WEST JEFFERSON
SPRINGFIELD, ILLINOIS 62760
AREA CODE 217-525-1100

HD:lp



ACM 008843

Corrected entry received 7/21/76 from EPA in Chicago

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: PCB Inspection, Monsanto Krummrich Plant Correction to Calculated Storage Tank Emissions. DATE: MAY 20 1976

FROM: Chief, Air Surveillance Branch

TO: Karl Bremer, Member, Lake Michigan Toxic Substances Committee

An error was discovered in the calculation of storage tank emissions at the Krummrich Plant. The vapor pressure of Aroclor 1242 at 100° C is 0.3 mm Hg instead of 3 mm as used in the calculations (see figure 2.2 from the Draft Mitre - copy attached).

A corrected report cover sheet and the section of the report showing the calculations is attached.

Please provide the corrections to all the parties that received the original report.

Gerald F. Regan
Gerald F. Regan



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Calculation of PCB Air Emissions from Storage and
Dispensing Operations at the Krumrich Plant of
Monsanto.

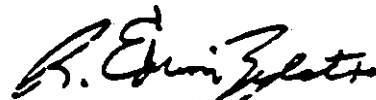
DATE: MAY 20 1976

FROM: Technical Advisor, Special Projects Section
Air Surveillance Branch

TO: Gerald F. Regan, Chief, Air Surveillance Branch

Potential air emissions from the storage and dispensing of PCB were
calculated based on information supplied by Monsanto. The results
of these calculations are:

Storage tanks for virgin products	- 59.7 kg/year
Product loading	- 0.0184 kg/year
Storage and handling waste aroclors	- 0.00066 kg/year


R. Edwin Zylstra

Attachment (Calculations)

CORRECTED COPY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: PCB Inspection, Monsanto Krummrich Plant,
Sauget, Illinois

DATE: MAY 20 1976

FROM: Chief, Air Surveillance Branch, Surveillance and Analysis Division

TO: Karl Bremer, Member, Lake Michigan Toxic Substances Committee

A preliminary survey was made of the above installation to identify and sample point sources of potential PCB emissions to the atmosphere. The sampling and analysis were carried out at this source to furnish information to arrive at a further decision that may require and intensive testing program to quantify the PCB emissions. The sample analysis revealed the following:

SAMPLING LOCATION	NO. OF SAMPLES	PCB CONCENTRATION ug/M ³
Steam Ejector - Ground Level, Site #1	2	* 3A - 27.5 3B - 33.9
Steam Ejector - Top Level, Site #2	2	3A - N.A. 3B - N.A.
Calculated Storage Tank Emissions		
Virgin Product		59.7 kg/year
Product Loading and Waste Storage		0.02 kg/year

Monsanto has performed a stack test at the Sauget location quantifying the PCB emissions to the atmosphere. Stack-sampling and other reports describing process and sampling methodology used at this site are attached.

* 3A - Right Side of sampling train - 3B - Left Side

CORRECTED COPY



Emissions:

$$\text{Kg/yr.} = 460,000 \times .0283 \times 1.41 \times \frac{1 \text{ kg}}{10^6 \text{ mg}}$$

$$\text{Kg/yr.} = 0.0184$$

Emissions from handling of waste aerosols:

Total waste material received into plant as reported by Monsanto for 9 mos. of 1975 = 1,431,000 lbs. Assume that all this material is received and stored at 70°F and that it displaced an equal volume of tank headspace gas at 70°F.

$$\text{Volume of product} = 1,431,000 \text{ lbs.} \times \frac{1 \text{ gal.}}{11.5 \text{ lbs.}} \times 3.785 \frac{\text{liter}}{\text{gal.}}$$

$$\frac{1}{10^3} \frac{\text{liters}}{\text{M}^3} = 471 \text{ M}^3$$

The concentration would be the same as in the loading operation that is 1.41 mg/M³.

Emissions:

$$\text{Kg/yr.} = 471 \text{ M}^3 \times 1.4 \text{ mg/M}^3 \times \frac{1 \text{ kg}}{10^6 \text{ mg}}$$

$$\text{Kg/yr.} = .00066$$

Clarence Buckley of Monsanto estimated that storage and loading operations at the plant would displace the following volume of

1. Storage tanks 635,000 ft³
2. Loading 460,000 ft³

Calculation of emissions:

From Fig. 2.2 from the Draft Mitre report the vapor pressure of Aroclor 1242 is 0.3 mm Hg at 100°C and 10⁻⁴ at 21°C. The aroclors are stored at 100°C. It may be assumed that the temp. in the tanks being loaded would be approximately 70°F (21°C).

From Dalton's law of partial pressure:

$$B_x = \frac{P_x}{P_{\text{mix.}}} \text{ where } B_x = \text{proportion by volume of a gas component}$$

P_x = partial pressure of gas component and
 $P_{\text{mix.}}$ = absolute pressure of gas mixture.

$$B_x = \frac{0.3}{760} = \frac{.039}{1} \text{ or } 390 \text{ ppm}$$

To change ppm to mg/M³ use the following formula:

$$\text{mg/M}^3 = \text{ppm} \times \frac{\text{mol. wt.}}{\text{molecular volume}}$$

molecular volume = 30.62 liters/mol. at 100°C

$$\text{mg/M}^3 = 390 \times \frac{261}{30.62} = 3324$$

Emissions from storage tanks:

Emissions kg/year = Vol. of gas displaced/year x concentration of PCB

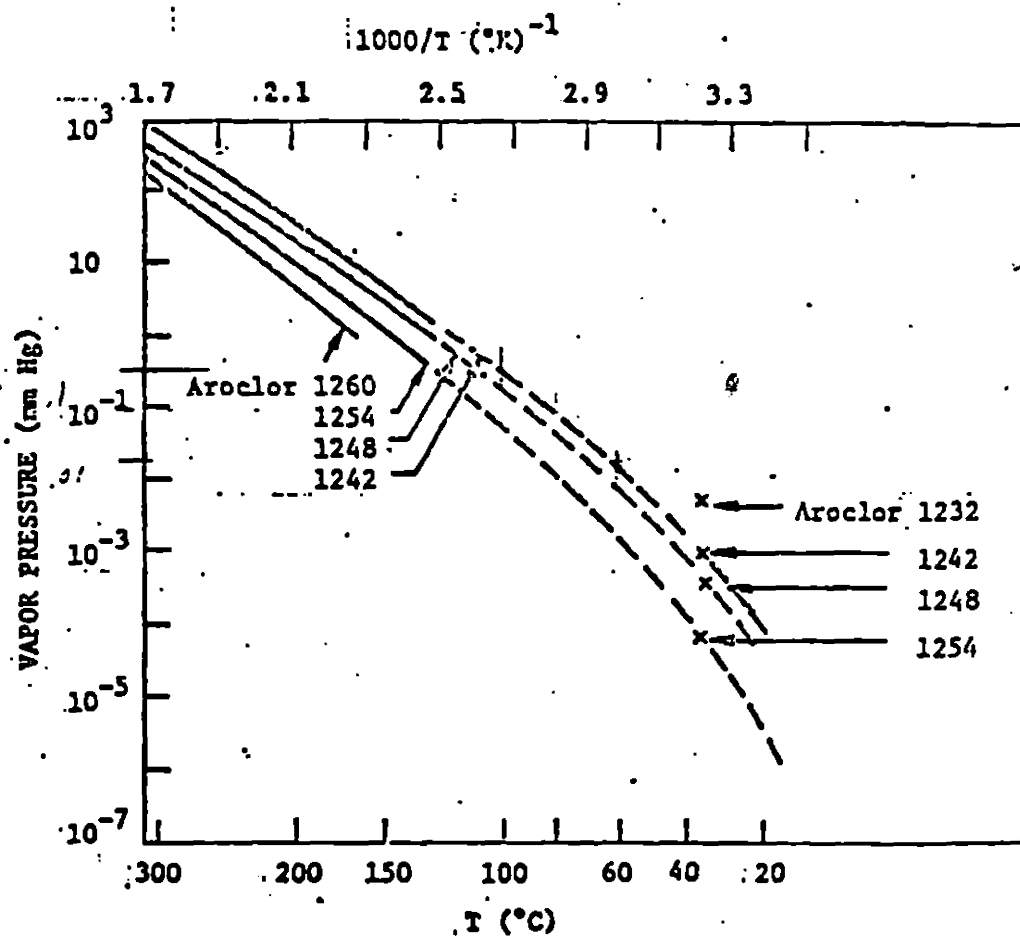
$$\text{Kg/yr} = 635000 \text{ ft}^3 \times .0283 \frac{\text{M}^3}{\text{ft}^3} \times 3324 \times \frac{1 \text{ kg}}{10^6 \text{ mg}}$$

$$\text{Kg/year} = 59.7$$

Emissions from loading operations:

$$B_x = \frac{P_x}{P_{\text{mix.}}} = \frac{10^{-4}}{760} = 1.3 \times 10^{-7} \text{ or } .13 \text{ ppm}$$

$$\text{mg/M}^3 = .13 \times \frac{261}{24.04} = 1.41 \text{ mg/M}^3$$



Source: Hutzinger, O., S. Safe, and V. Zitko, "The Chemistry of PCBs," CRC Press, Cleveland, Ohio, 1974.

FIGURE 2.2
VAPOR PRESSURES OF DIFFERENT AROCLOR PREPARATIONS



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DEC 31 1981

MEMORANDUM

SUBJECT: Review of Studies on the Health Effects of PCB

FROM: Irwin Baumel *IB/CC Lee*
Director
Health and Environmental Review
Division (TS-796)

TO: Margaret J. Stasikowski
Acting Director
Chemical Control Division (TS-794)

As per your request, HERD staff have reviewed the documents on the various health effects of PCB toxicity. Our review is based on the six review documents and the Summary of the Health Effects of PCB (summary of the findings reported in the above six review documents) submitted by CMA. The original articles cited in these documents were not secured and evaluated. Thus, the validity of the conclusions as to the original experimentation and findings cannot be assessed without substantial efforts. Our comments are summarized in the attached paper. Contributors for the review are C. C. Lee, J. Springer, C. Jason, J. Toth, C. Nadolney, P. Hurley and D. Kram..

Attachment



ACM CC6650

General Comments

These documents are somewhat unobjectively written with unscientific discussions such as:

On page 3-23 the author states: "However, the overzealous use of mathematical models and the assumptions made by the EPA without comparing these results to reality are easily demonstrated."

The report by the New England Gas Association begins "The discovery of small amounts of PCBs, the use of which has been banned by the EPA, in natural gas transmission lines is neither unexpected nor cause for public alarm."

Later in discussing acute PCB toxicity the report states: "Short term effects of moderate doses in animals are minimal. The toxicity is comparable to that expected from such substances considered relatively safe such as table salt, alcohol or caffeine."

In discussing chronic effects the report states: "...PCBs produce minimal changes in new borns. In fact they are no more toxic to the fetus than most chemicals, and less toxic with regard to birth defects than some common vitamins and hormones."

Summary of the Health Effects of PCBs

The "Summary of the Health Effects of PCBs" tends to misguide the reader as to what the actual articles present. The overall tone of the Summary is a refutation of the technical presentation or an exaggeration of the "negative" arguments presented in the six review articles.

On pp. 1, 2-1, and 2-2 of the Summary, the authors cite and discuss Weisburger's and William's concept of promoters and initiators, and epigenetic and genotoxic mechanisms. However, they do not point out that the concept and the classification of carcinogens by Weisburger and William are not shared by many.

On pp. 1, 2, and 1-5 the authors discuss the large number of negative carcinogenicity studies for PCBs and present the inadequacies of the positive studies. They do not mention the inadequacies of the negative studies. For example, the reference papers show that only a few of the negative studies are of sufficient duration to adequately characterize them as negative studies. Most of the studies quoted in the six articles are of one year or less duration (e.g., see article by Crump, p. 24). For the positive studies, they criticize that the length of exposure was too short for an adequate study design (p. 2-3). This is not a relevant concern for a positive study.

"genetic," and yet neither the sequence of bases nor the number of chromosomes is affected. Because of such difficulties it is better, perhaps, not to stereotype chemicals.

Even if we accept the contractors reasoning, it is important to note that not all mutagenicity tests on PCBs were negative. In the Monsanto document entitled "A review and evaluation of carcinogenicity in mice and rats and mutagenicity studies with PCB" several positive mutagenicity tests were cited along with the negative results: Aroclor 1221 and 4-chlorobiphenyl were positive in the Ames test. TCB and the 3, 4 epoxide of TCB induced single strand breaks in DNA of L-929 cells. Kanechlor 300 was found to induce chromosomal aberrations in vitro while Kanechlor 500 was positive in vivo. Continuous exposure of C3H 10T $\frac{1}{2}$ cells to Aroclor 1254 caused cell transformation to type III foci. These cells formed a sarcoma when implanted into irradiated mice. Aroclor 1260 and 2,4,5,2',4',5' hexachlorobiphenyl also caused morphological transformation of C3H 10T $\frac{1}{2}$ cells. 4-Chlorobiphenyl caused an increase in unscheduled DNA synthesis in CHO cells while Aroclor 1254 induced chromosome damage in ring doves fed a 10 ppm diet. Clearly, based on these data one can argue that PCBs may have initiator activity.

Finally, in calculating the risk estimate for increased human cancer cases caused by exposure to PCBs, the contractor made (but did not state) an enormous assumption. It was assumed that because hepatomas were induced in rodents, this was the only tumor type for which humans were at risk. Although the correlation between carcinogenicity in animals and man is good, the issue of site concordance is not clear. Therefore, humans may be at risk for other types of tumors as well. Since the incidence of hepatomas in the human population is low, the risk estimate produces a very low number of PCB induced cancer. However, if these chemicals were also associated with lung carcinoma, for example, risk estimates would be much higher.

The latter part of the Summary consists mostly of a complete refutation of the risk assessment done by Crump and Masterman, the last document on the "Assessment of Carcinogenic Risks from PCBs in Food," with very little documentation of the reasons for not accepting Dr. Crump's assessment. In his assessment, certain models are used to derive virtually safe doses of PCBs at specified risks. He includes the probit model, the one-hit model, and the multi-stage model. He also uses the one-hit and multi-hit models to derive estimates of life time extra risks to humans for certain subpopulations at risk. Although the "Summary" is interesting reading, in most cases it is not of sufficient scientific validity to warrant a response. In any case, the Summary conclusions for risk assessment are not supported by the technical review documents. In fact, unlike the other section such as epidemiology, the risk assessment section

5) The authors of the summary document makes no attempt to estimate any risks according to their proposed model of cancer. This may be because the probit model, also used by Crump, gives the lowest risks of almost any model available at low levels. The safe levels shown on page 34 of Crump's report using this model are below the exposure of average capacitor workers, even for risks as high as 10^{-3} .

The Epidemiology of PCBs

The Epidemiology of PCBs by Gaffey was reviewed in great detail. Our comments are directed to answer the question of whether his conclusions and generalizations are justified based on our cursory review of the cited studies. We chose to begin with the review of the carcinogenicity section since this is of most concern.

Carcinogenicity: In general, Gaffey's conclusions concerning the strength of epidemiologic evidence necessary to support a causal association between PCB exposure and carcinogenicity are reasonable in light of the criteria established in Richard Doll's paper. However, several of the studies reviewed by Gaffey (Bertazzi et al, Zack and Musch) suggest an overall increase in risk from death due to cancer and all studies reviewed by Gaffey do in fact reveal excesses for specific sites; although most of these excesses were not statistically significant or site concordant with one another. It should be stated at the outset, that the presence of consistency strongly supports causality, but its absence does not rule it out.

Gaffey deliberately omitted the preliminary mortality findings of the Yusho incident from this section because this study was not an epidemiologic analysis directed at cancer. Urabe et al reported 11 deaths from malignant neoplasms among 35 confirmed deaths of Yusho victims. The authors state that "this rate (11/35) is substantially higher than the 21.1% that is the mortality rate from neoplasms in the same prefecture" for that year (1977) but the authors also state that "it would be premature to conclude that this high mortality bears association with PCB poisoning." Nevertheless, three of these deaths were due to liver cancer and two from lung cancer, which suggests some concordance with reports from previous studies (Zack and Musch, Brown and Jones).

Several of the studies reviewed by Gaffey (Bahn et al, Zack and Musch) are based on so few deaths, especially among those workers with ten or more years of exposure or 15 years since first exposure, that it would be premature to conclude that PCBs are definitely non-carcinogenic. For instance, in the one study (Brown and Jones) with the greatest number of person-years observed, there were 163 deaths and it is not clear how many of these deaths were among workers with five or more years of exposure or 15 years latency since first exposure to PCBs.

Accidental Heavy Exposure: Gaffey reviews two incidents in this section (Meigs et al, Yusho reports), but Meigs is more appropriately reviewed in the next section.

The numerous studies which have been published in conjunction with the Yusho incident represent a sizeable fraction of the total health effect literature concerning PCBs. Gaffey, and the authors of the General Electric health effect report, attempt to minimize the relevance of these findings for two main reasons: (1) samples of the Kamani Rice Oil were found to be contaminated with dibenzofurans, and (2) victims of this incident ingested large doses of PCBs which are irrelevant to assessing the health effects from lower occupational exposures found in the United States. Proper evaluation and interpretation of these objections are crucial to the assessment of health effects related to PCB exposure.

Yusho disease is a Japanese term which refers specifically to acute and sub-acute poisoning due to ingestion of Kamani Rice Oil which was contaminated with PCBs. There seems to be a general consensus that the average amount of Kanechlor ingested was estimated to be about 2 gm while the minimum amount ingested by a patient was about 0.5 gm. As of 1977, there were 1,665 victims of Yusho, who exhibited a variety of acute symptoms ranging from severe chloracne and hyperpigmentation to less specific effects such as vomiting and diarrhea.

The most notable finding from this incident seems to be that patients seen three and six years after first coming down with Yusho disease still exhibited symptoms of Yusho, biochemical abnormalities and persistent blood levels of PCBs. Unless these effects can all reasonably be attributable to the dibenzofuran contamination, then I would say that the severity, incidence and persistence of these effects all warrant serious concern for PCB exposure. Both the specific toxic effects (as determined from animal and human studies) of PCDFs and PCBs must be compared, as well as the quantitative evidence supporting the extent of PCDF contamination.

With respect to the preliminary mortality reports, Gaffey justifiably calls attention to the problem that the population-at-risk, or denominator of the relative risk rates, cannot be determined, and therefore presents a problem for determining the actual "attack rate" as well as the relevance of elevated cancer deaths among Yusho victims. This problem is mitigated somewhat by the finding that among a group of 146 known users of oil, 80 consumed less than 720 ml, and 88 percent of these users were affected. Among those who used more than 720 ml, 100 percent were affected. This would suggest that Yusho victims, as defined by various clinical criteria, do in fact represent the total number of people exposed to contaminated oil. This, of course, is conjecture and is subject to much criticism. But until this problem is resolved, epidemiologic analyses utilizing the cohort approach may be inappropriate and unacceptable.

"Most studies, including one non-occupational study have associated increased triacylglycerides with PCB exposure. The data on cholesterol are not consistent; an increase, a decrease and no change were found (one study each). HDL cholesterol either decreased or was unchanged (one study each). Even if PCB exposure has some effect on fat metabolism, it appears to be without any apparent clinical significance."

Symptoms, Illness and Other Conditions: All of the studies reviewed in this section should be more thoroughly evaluated. Gaffey quotes Smith et al. as saying "that no studies to date have shown that occupational exposure to PCBs is associated with any adverse health outcome, to be distinguished from demonstrable subclinical biochemical alterations." It is possible that these biochemical abnormalities have not yet revealed any clinical manifestations, and it is not clear whether the subclinical alterations present serious health effect concerns.

In general, most of these studies are cross-sectional, and therefore make no effort to ascertain the true population-at-risk. In other words, the investigators did not identify their study populations from historical employment records - thereby ensuring that all workers had some minimal duration of exposure - and furthermore, these studies made no effort to identify workers who may have left employment for occupational health reasons. In most cases, the study population represented those workers currently employed and healthy.

Adverse Reproductive Outcome Discussion
(Health Effects of Electrical Grade PCBs)

I. General problems with document

A. It is impossible to discuss PCB related problems in isolation. Various amounts of PCDF are always found with PCBs.

B. Many isomers of PCB are found in any mixture of PCBs, some of which are extremely toxic.

C. The fate of PCB in nature beside bioaccumulation is not clear. For example, photooxidation of PCB to PCDF does occur (Nutzinger 1974), but the probability of such occurrence in nature is not known.

D. Heating of PCBs as would occur with PCB use in heat exchangers results in increased conversion to PCDF. It is not clear how they address this issue and its inherent risk. How hot do capacitors and "closed" systems get in their life time. What conversion occurs?

E. Given the limits of our attempts to eliminate the remaining PCBs in the environment, its transport through the food chain, uncertain chemical transformations, and worrisome persistence in the animal world as the type of chlorination changes and the degree increases, it appears extremely unwise to change any position without much further work at the health and basic chemical level.

II. Deficiencies in consideration of reproductive effects

A. Increased estrogen effect may be seen via two different mechanisms.

1. Estrogen like activity which would add to or compete with endogenous estrogens (uterotrophic activity in rats, Gellett 1978).

2. Increased metabolism of endogenous estrogens through PCB effect on hepatic MFO system. These types of effects could easily account for menstrual irregularities seen as well as impair the ability to maintain the fetus.

B. Animal studies Ringer 1972, Linder 1974, Villeneuve 1971 show pronounced fertility problems depending upon PCB type and animal species at less than 50 ppm PCB.

August 10, 1973

Dr. Barbara C. Levin
National Institute of Health
Room 3C25, Building 36
Bethesda, Maryland 20014

Dear Dr. Levin:

In response to your request for samples of Aroclor 1016, Aroclor 1242 and Aroclor 1254 I have enclosed a Request for Sample Quantity of Product Containing PCBs. If you will return the completed form to me I will make arrangements to have these samples forwarded to you.

Kaneclor 400, of which you also requested a sample, is a PCB mixture that at one time was manufactured in Japan but is no longer available.

If I can be of further service, please let me know.

W. B. Papageorge
Manager
Product Acceptability

WBP/bt

Enclosure



ACM CC8862



PCB-

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

CENTER FOR DISEASE CONTROL

August 30, 1976

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

ROBERT A. TAFT LABORATORIES

4676 COLUMBIA PARKWAY, CINCINNATI, OHIO 45226

cc Bruce Ely
Mike Pienke

Paul E. Heisler
Monsanto
Route 3
Sauget, Illinois 62201

~~Thompson, Thomas, et al.~~

H.I. Horner
F.J. R...
T. J. ...

Dear Mr. Heisler:

Enclosed is a paper describing the method NIOSH is using to analyze the samples collected at your facility on July 21 and 22, 1976. I apologize for the delay in sending you the information but the paper is currently under review and hopefully will be published in the future.

I will forward the results of the sample analysis to you as soon as I receive them.

Thank you for your cooperation and if you have any questions, call me at (513) 684-3255.

Sincerely yours,

Mark W. Jones

Mark W. Jones
Industrial Hygienist
Industrial Hygiene Section

enclosures
cc: B. Hill

Mike/Bruce
I don't know if
you have any
interest in this-but
here's a copy
Paul



ADM CC6863

Polychlorinated Biphenyls (PCB) in Air

Measurements Research Branch
Analytical Method

DRAFT

Analyte:	Polychlorinated biphenyls (PCB)	Method No.: P&CAM 244
Matrix:	Air	Range: 0.001 to 1.5 mg/m ³
Procedure:	Adsorption on Florisil ^R , desorption with hexane, gas chromatography with electron capture detection	Precision: 4.4% Relative Standard Deviation
Date Issued:	7/1/76	
Date Revised:	8/20/76	Classification: D (Operational)

1. Principle of the Method

A known volume of air is drawn through a small sorbent tube containing Florisil^R which adsorbs the PCB's present in the air sample. The collected PCB's are desorbed with hexane, and the resulting solutions are analyzed using a gas chromatograph with an electron capture detector. The concentration of PCB's relative to the standard (Aroclor^R) most resembling the sample is read from a standard curve.

2. Range and Sensitivity

The minimum detectable amount of PCB (Aroclor 1016) was found to be 32 picograms per injection (4 µl injection). If the total desorption volume were 5 ml, this would represent a total sample of 40 ng. The recommended sample volume is 50 liters and thus the lower range of the method is approximately 0.001 mg/m³. The upper range is apparently limitless depending only upon the degree of dilution needed to maintain the concentration of the sample within the linear range of the electron capture detector (33 picograms up to 3 nanograms per injection). Field samples have been found to range as high as 1.5 mg/m³.

3. Interferences

3.1 Strict measures to avoid contamination are required with the electron capture detector. Foremost the syringe must be thoroughly cleaned after each injection. Hexane to be used for desorption and back flush should be injected periodically for a purity check. It should show no peaks later than forty-five seconds providing that not more than 5 µl have been injected.

PLAINTIFF'S
EXHIBIT

964

244-1

ACM CC6664

- 3.2 Any compound which has nearly the same retention time on the GC column as one of the PCB's is an interferent. This type of interference can often be overcome by changing the GC operating conditions or by selecting another column. Retention time data on a single column, or even on a number of columns, cannot be considered as conclusive proof of chemical identity. It is important, therefore, that a sample of the bulk mixture of PCB's be submitted at the same time as the sample tubes so that chemical identification of possible interferents can be made. (The bulk sample must not be shipped in the same shipping container as the sample tubes.)

4. Accuracy and Precision

- 4.1 The volume of air sample can be measured to within $\pm 1\%$ if a pump with a calibrated volume indicator is used. Volumes calculated from initially set flow rates may be less accurate ($\pm 5\%$) because of changes in flow rates during sampling.
- 4.2 The collection efficiency for PCB's is essentially 100% as demonstrated by the negligible amount of PCB's collected in the backup section of the sorbent tube.
- 4.3 No loss of PCB has been observed in sealed tubes or desorbed samples stored for two months.
- 4.4 The precision of the analysis is dependent upon the precision and sensitivity of the technique used to quantitate the gas chromatograph peaks of samples and standards.
- 4.5 Known concentrations of PCB's which were spiked on Florisil^R and allowed to sit overnight were quantitatively (100%) recovered. The precision of twenty-seven spiked samples was reflected by a relative standard deviation of 4.4%.

5. Advantages and Disadvantages of the Method

- 5.1 The sampling device is small, portable, and involves no liquids. Interferences are minimal, and most of those which do occur can be eliminated by alternating chromatographic conditions. The tubes are analyzed by means of a quick instrumental method.
- 5.2 One disadvantage of the method is that the amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the Florisil^R trap exceeds 25% of that found on the front section, the possibility of sample loss exists. During sample storage the more volatile compounds may migrate throughout the tube until equilibrium is reached (33% of the sample on the backup section).

- 5.3 The precision of the method is limited by the reproducibility of the pressure drop across the tubes. This drop will affect the flow rate and cause the volume to be imprecise because the pump is usually calibrated for one tube only.
- 5.4 A substantial difference in air sample composition and the commercial PCB mixture being used may result in a large error in accuracy since the standardization of this method is based on comparison with the PCB mixture being used. If this is the case an alternate method of standardization (Ref. 4) or determination (Ref. 2) may be used.

6. Apparatus

- 6.1 An approved and calibrated personal-sampling pump with a flow volume meter which operates in the range of 50-200 cc/min is preferred. These pumps should be calibrated with a representative sorbent tube in the sampling line. A wet or dry test meter or a glass rotameter capable of measuring a flow rate of 200 cc/min within $\pm 5\%$ may be used in the calibration.
- 6.2 Sorbent Tubes. Each glass tube is at least 7 cm long with 4 mm i.d. Each contains two sections of 30-48 mesh deactivated Florisil^R, the front, which is preceded by glass wool, contains 100 mg and the backup section contains 50 mg. Urethane foam is placed between the sections and after the backup section. The ends of the tube are flame sealed to prevent contamination before use.
- 6.3 Gas chromatograph equipped with an electron capture detector (⁶³Ni foil).
- 6.4 Glass column (6 ft x 2 mm i.d.) packed with 1.5% OV-17/1.95% QF-1 on 80/100 mesh Supelcoport.
- 6.5 Vials (20 ml) with aluminum lined caps.
- 6.6 Microliter syringe (10 μ l).
- 6.7 Volumetric flasks (10 ml for standards) with glass stoppers.
- 6.8 A mechanical or electronic integrator or a recorder and some method for determining peak area.

7. Reagents

7.1 Hexane, Pesticide Quality

- 7.2 Florisil^R, (Registered Trademark of the Floridin Co.) 30-48 mesh chromatographic adsorbent, deactivated. Florisil^R 30-60 mesh is sieved to the proper mesh size.

Deactivation of Florisil^R Prior to packing tubes, dry a weighted amount of Florisil^R at 105°C for 45 minutes. After cooling to room temperature, the Florisil^R is added to a round bottom flask which can be attached to a rotary evaporator. Three mls of water per 100 gms of Florisil^R (i.e., 3% W/W water) are added and the mixture is turned in the rotary evaporator for one hour or until it is uniformly mixed (free flowing).

7.3 Nitrogen, prepurified

- 7.4 Aroclor^R 1016 or a sample of the specific PCB compound under study. This procedure has been field tested only for Aroclor^R 1016 (Registered Trademark of the Monsanto Co.) Aroclor 1016 is a PCB mixture whose chlorine content is approximately 42%.

8. Procedure

- 8.1 Cleaning of Equipment. All glassware used for the laboratory analysis should be detergent washed and thoroughly rinsed with tap water and distilled water and dried.

8.2 Collection and Shipping of Samples

8.2.1 Immediately before sampling, break each end of the sorbent tube so as to provide an opening at least one-half the internal diameter of the tube (2 mm).

8.2.2 The smaller section of Florisil^R is used as a back-up and should be positioned nearest the sampling pump.

8.2.3 The sorbent tube should be vertical during sampling.

8.2.4 Air being sampled should not be passed through any hose or tubing before entering the sorbent tube.

8.2.5 The flow, time, and/or volume must be measured as accurately as possible. The sample should be taken at a flow rate of 200 cc/min or less to attain the total sample volume required. The recommended sample volume is 50 liters.

- 8.2.6 The sorbent tubes should be capped with the supplied plastic caps immediately after sampling. Under no circumstances should rubber caps be used.
- 8.2.7 One tube should be handled in the same manner as the sample tubes (break, seal, and ship) except that no air is pumped through it. Label this tube as a blank.
- 8.2.8 Pack the tubes tightly before shipping to minimize breakage in transit.
- 8.2.9 After the sample is collected, the tubes should not be subjected to extremes of high temperature or low pressure.
- 8.2.10 Samples of the PCB whose presence in the environment is suspected should be submitted to the laboratory performing the analyses. These bulk materials should not be transported in the same container as the samples or blank tubes. If possible, a bulk air sample should be shipped for qualitative identification purposes.

8.4 Analysis of Samples

- 8.4.1 Preparation of Samples. Each tube is scored with a file and the glass wool and front section are placed in a clean, dry vial. The separating urethane foam plug, the back section of the sorbent, and the retaining urethane foam plug are placed in a second clean dry vial.
- 8.4.2 Desorption of samples. Prior to analysis, 5.0 ml of hexane is pipetted into each vial. Florisil^R particles should not be allowed to cling to the glass above the solvent. A minimum of 10 minutes desorption time is required before analysis. Further dilutions may be necessary to bring the concentration of the sample solution into the linear range of the electron capture detector.
- 8.4.3 Gas Chromatographic conditions:
 - 1. Nitrogen carrier gas flow, 60 mls/min
 - 2. Injector temperature, 300°C
 - 3. Interface and detector temperatures both 325°C
 - 4. Column temperature, 180°C

8.4.4 Injection. The solvent flush injection technique is recommended. The volume of back flush plus the volume of standard or sample solution should equal 5 μ l, since larger volumes may give a solvent peak which interferes with sample components. For example, in order to inject 2 μ l of sample, the following procedure would be followed. Three μ l of solvent (hexane) would be drawn into the syringe, followed by 1 μ l of air, followed by 2 μ l of sample solution. (The plunger now rests at the 6 μ l mark). After the needle is removed from the sample solution one additional μ l of air is drawn into the solution to minimize evaporation at the tip of the needle. Not less than 1 μ l of back flush should be used. The syringe must be cleaned with hexane after each injection.

8.4.5 Interpretation of the Chromatogram. The peak heights or areas of the prominent peaks in the sample chromatogram are selected and compared with those of the standard which most nearly resemble the sample composition.

8.5 Determination of Desorption Efficiency. Experiments have demonstrated quantitative (100%) recovery of PCB's spiked on Florisil^R. Thus results need not be corrected by desorption efficiencies.

9. Calibration and Standards

The particular PCB mixture being used in the work area in which air samples were taken is used as the standard. If, however, the air sample composition is different from that of the PCB mixture, then a different method determination (Ref. 2) or standardization (Ref. 4) must be used. Standards are prepared in hexane at concentrations ranging from 8 to 500 pg/ μ l (within the linear range of the electron capture detection -- upper limit is approximately 2 ng per injection). Calibration curves should be established daily since the sensitivity of the electron capture detector may change from day to day.

10. Calculation

- 10.1 The height or area of several selected prominent peaks in the chromatogram are added and compared to the total height or area of those same peaks in the standard and the weight, in pg, of sample is calculated.
- 10.2 The weight found is divided by the number of microliters injected and this concentration is multiplied by the total volume, in μ l, of solution in sample to obtain the weight of PCB in the sample in pg.

DRAFT

$$PG_s = \frac{PG_i}{\mu l_i} \times \mu l_{ts}$$

μl_i = μ l of sample injected into GC

μl_{ts} = total sample volume in μ l

PG_i = weight of PCB injected

PG_s = weight of PCB in sample

10.3 Corrections for the blank should be made, if necessary, and the weight of PCB in the front and backup sections is added to obtain the total weight of PCB in the air sample. This weight is conveniently expressed in ng.

$$ng_{ts} = \frac{[PG_s - PG_b]_{front} + [PG_s - PG_b]_{backup}}{1000 \text{ pg/ng}}$$

ng_{ts} = total sample weight in ng

pg_b = PCB weight in pg found in blank

10.4 The concentration of PCB in the air sampled in $\mu\text{g}/\text{m}^3$, which is numerically equal to ng/l, is calculated by dividing ng_{ts} by the volume, V, of air sampled in liters.

$$\mu\text{g}/\text{m}^3 = \frac{ng_{ts}}{V}$$

11. References

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

JAN 21 1977

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ROBERT A. TAIT LABORATORIES
4676 COLUMBIA PARKWAY, CINCINNATI, OHIO 45226

January 17, 1977

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JCB
PC

JAN 24 1977

W.B. Papageorge, Manager
Product Acceptability
Monsanto Chemical Intermediates Company
800 N. Lindberg Boulevard
St. Louis, Missouri 63166

Dear Mr. Papageorge:

Thank you for your letter of December 20, 1976 in which you question the role of PCB's as human carcinogens.

I assure you that NIOSH is carefully studying all the PCB data in our possession. Conclusions drawn from that data and recommendations based thereon will be made after we have consulted with representatives of both the public and private sectors. However, conclusions and recommendations made in the criteria document will be those of NIOSH and will not necessarily be those of any of the reviewers.

Sincerely yours,

Jerry M. Johnson, Ph.D.
Chief, Criteria Documentation
Section 1

cc: Dr. J. May



ACM CC6871

FILED
DEC 21 1976

December 20, 1976

Dr. Jerry M. Johnson
Acting Chief,
Criteria Documentation, Section 1
NIOSH, DCDSO, RM 142
4676 Columbia Parkway
Cincinnati, Ohio 45226

Dear Dr. Johnson:

At the review meeting held on November 30 on the draft criteria document for polychlorinated biphenyls I was left with the impression that future drafts of the document would continue to contain allegations that PCBs are human carcinogens and that they should be labeled as "cancer suspect agents".

In previous opportunities to comment I have emphasized the lack of persuasive evidence to provide a sound basis for designating PCBs as carcinogens. At the review meeting Dr. Paul E. Brubaker reported that the cohort in the ongoing Mobil Epidemiological Study has been reidentified and changed and that the results are now expected to differ from those initially reported. The reports, from Industrial Biostat Laboratories and the Eppley Institute, which I gave to Mr. John Fajen, contain conclusions which differ from those reached by Dr. Renate Kimbrough in her studies with female rats.

It is our considered opinion that this information further emphasizes the uncertainty of some of the available data and we strongly recommend that your office reconsider its decision to continue to designate PCBs as cancer suspect agents.

Sincerely,

ORIGINAL SIGNED BY
W. B. PAPAGEORGE

W. B. Papageorge
Manager,
Product Acceptability

ja

cc: Mr. John Fajen - NIOSH

bcc: R. A. Stohr/J. C. Weber

PLAINTIFF'S
EXHIBIT

966

ADP CC0074

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63168
Phone: (314) 694-1000

November 29, 1976

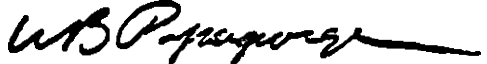
Dr. Jerry M. Johnson
Acting Chief, Criteria Documentation, Section 1
NIOSH, DCSD, CDB, RM 142
4676 Columbia Parkway
Cincinnati, Ohio 45226

Dear Dr. Johnson:

Attached are answers to the questions on the draft criteria document concerning occupational exposure to polychlorinated biphenyls.

We hope our comments are helpful and appreciate the opportunity to participate in the preparation of a responsible criteria document.

Sincerely,


W. B. Papageorge
Mgr., Product Acceptability

WBP/ken

attachment



ACM CC8873

POLYCHLORINATED BIPHENYL EXTERNAL REVIEW QUESTIONS

1. The document inadequately documents industrial exposure related effects of PCB. It also inadequately defines clinical tests which could be used to monitor for potential adverse effects of PCB exposure among the industrial population. The document dwells at great length upon the effects observed in a population of Japanese citizens who were accidentally exposed to an acute dose of PCB in a cooking oil. No relation is established between this accidental acute oral exposure to a relatively high concentration of PCB and industrial type exposures. No relationship is established defining relative body burdens resulting from acute oral exposure versus other routes of exposure, dermal absorption and respiratory, that are more likely to occur in an industrial environment. Another study given seemingly unwarranted consideration, involved an unpublished report of an epidemiological study conducted among a group of research workers with some unknown previous exposure to PCB. No sound basis has been established to support the contention that PCBs are human carcinogens. It is suggested that efforts be extended to accurately assess the clinical health of U.S. workers exposed to PCB.
2. In studies with rodents and subhuman primates the most sensitive target organ was usually found to be the liver. In these studies the dietary level which did not produce an effect on the liver was between 1 and 10 ppm. Based upon these studies the most probable toxic effect of excessive PCB exposure would be chronic hepatic injury.
3. From the manner in which the document is put together it is impossible to tell if the recommended standard is based upon a logical scientific extrapolation of the information cited. Specifically, no attempt is made to relate the body burdens which would result from an industrial inhalation or dermal exposure to those obtained from animal experimentation or the usual data following oral administration.

Chapter V consists of a series of data relating the toxic effects observed after many different types or routes of exposure. It then states that on the basis of all this data the environmental limit should be 0.05 mg/M³ of PCBs in air. There is no logical support for the stated limit as based on the industrial usage this document is intended to relate. There has been no evidence shown to indicate that, as inferred on lines 4071-4072, "teratogenicity, fetotoxicity or carcinogenicity has occurred to man and to laboratory animals when they have been subjected to air-borne PCB levels below the current standard of 1.0 mg/M³ (42% chlorine)."

- 4a. To be supportable a standard must be based on the application of a safety factor to experimental animal data and/or upon the utilization of previous work history exposure concentration and clinical worker monitoring data. Which of these was used in establishing this standard is not clear. Specifically, the limit of 0.05 mg/M³ has not been supported by any data relating industrial worker exposure to clinical effects. In fact, the arrival of 0.05 mg/M³ as a "safe" level has not been explained at all.
- b. The document on line 3929 states that the current PCB standard is based on an 8-hour dermal exposure. This is not entirely correct.

The current standard does include a "skin notation" which refers to the potential contribution to the overall exposure by cutaneous route or particularly by direct skin contact. An environmental limit for air-borne material cannot totally prevent direct skin contact with material and the resulting dermal exposure. This concern has been aptly addressed by the ACGIH TLV committee on line 3925 by their reference to the fact that the current standard may not guarantee protection against dermal effects. The recommended environmental limit cannot guarantee such also since workers can still put unprotected hands in the material if they wish.

- c. Inadequate information exists to properly evaluate the need for and type of protection for the pregnant worker.
 - d. Until better scientific evidence is brought forth supporting a necessary change in the current OSHA standard on PCBs, no justification exists for modifying the existing environment limit.
5. We recommend that the current users of PCBs, capacitor and transformer manufacturers, be consulted regarding feasibility of compliance.
 6. To exclude biological monitoring in a standard for a material known to accumulate in fatty tissues would not appear advisable.

Biologic testing is an acceptable monitoring device if it is shown that a reasonable correlation exists between body burden, detrimental health effects, and degree of worker exposure. Biological monitoring may well give an indication of dermal exposure and degree of skin absorption that might not be evident through the use of air monitoring.

7. We assume that if the composition of PCBs is unknown, the sample chromatogram does not match the chromatogram of any commercial PCB standard mixture. In this case, measurement by electron capture gas chromatography is inadequate for two reasons. First, interferences may be present which may account for the differences in the chromatograms. Secondly, as pointed out in Table I of the draft, electron capture detector response varies by orders of magnitude for different PCB isomers. Hence, the analyst would not know what response factor to apply, even using the weight factor technique of Webb & McCall (see attached comments for line 5354).

Therefore, when the PCB composition is unknown, a more specific and accurate technique must be used. We recommend using GC/MS in the selected ion monitoring mode as the detector device. The parent ion and a characteristic fragment ion are monitored for each PCB homolog. This technique is much less subject to interferences and is more accurate because MS response factors are nearly constant. GC/MS detection can be used with samples collected on Florisil if sensitivity is adequate. If sensitivity is inadequate, samples should be collected on a porous polymer sorbent such as Tenax GC. Collected components are then thermally desorbed directly into the GC/MS for analysis.

8. In those cases where the sample chromatogram matches a standard PCB chromatogram, the sampling procedure is adequate. However, as mentioned in 7., we recommend sampling with Tenax GC as a more general method. Collected components can be thermally or solvent desorbed from Tenax GC. For further details, see pp 147-160 of the transcript of the Second NIOSH Solid Sorbents Roundtable in December, 1973.

9. No, several deficiencies should be corrected. See attached comments relative to lines 5252, 5253, 5258, 5273, 5291, 5292, 5303, 5310, and 5320 of the draft.
- 10a. We recommend collection on Tenax GC adsorbent, thermal desorption and measurement by GC/MS. See 7., 8., and attached notes.
- b. See attached comments, especially the notes relevant to lines 5354, 5381, 5396, 5410, 5460, 5533, and 5590 of the draft.
- 11a. Annual comprehensive medical examinations are considered appropriate.
- b. The medical requirements listed in the document under Section 2 are patterned after the criteria document on Tetrachloroethylene. It would seem that the medical tests for PCB exposed workers could be more specific for that particular material. Pulmonary function tests should be included as a check on capability of wearing respiratory protective devices.

Contrary to lines 202-203, medical surveillance should be made available to all workers occupationally "exposed" to PCBs who contact the material and yet not be "exposed" on the basis of the NIOSH definition given on lines 176-177.

12. There is no persuasive evidence supporting the "cancer suspect agent" labelling all PCBs, therefore such labelling is inappropriate. Warning signs should be posted in those areas in which workers are exposed above some specified limit or where potential skin contact is possible. To be functional a warning sign must inform the reader of specific effects of a material. PCBs have relatively mild irritant properties and has not been associated with acutely toxic effects. However, tissue accumulation and target organ effects may occur following prolonged exposures above the established permissible limits. A meaningful sign would warn of potential tissue PCB accumulation and indicate avoidance of skin and eye contact.
13. Considering that the concentration limits as listed in Table I-1 represent the protection factors as shown below, the limits are considered to be appropriate and consistent with the respirator decision logic used in the Standards Completion Project.

Along with the protection factor limits are listed various additional respirator types which should provide adequate protection when used in areas of respective air contaminant concentrations.

Concentrations of
Polychlorinated Biphenyls
0.5 mg/M³ or Less (10x)

Respirator Type
(Modifications to Table)

3. Chemical cartridge respirator with replaceable cartridges approved for organic vapors and mists and half-mask facepiece.
4. Gas mask, chin-style or front or back mounted organic vapor and mist canister.

Concentrations of Poly-chlorinated Biphenyls cont'd.Respirator Type (Modifications to Table) cont'd.2.5 mg/M³ or Less (50x)

3. A gas mask with a full facepiece and front or back mounted vapor cannister with high efficiency filter.

5.0 mg/M³ or Less (100x)

(No modification)

Greater than 5.0 mg/M³ (100x)

(No modification)

14. Line 292: Detectable level is mentioned. Since the detectable limit of PCBs has not been addressed, this level is meaningless. It would make more sense to reduce air-borne concentration of PCBs to below the (TWA) environmental limit or permissible exposure limit.

Lines 379 through 382 should be deleted since it seems unnecessary to have escape type devices available in all areas of "potential" exposure where the exposures might be brief at low or moderate levels. Escape type devices are generally made available in defined high risk areas containing potentially hazardous operations involving extremely toxic substances. The document does not provide data which supports PCBs as being considered extremely toxic.

Earlier comments addressed the modifications in Table I-1 on respirator types vs. concentration limits.

15. Line 405: Do hazards imply only health related hazards or environmental hazards also?

In general, Section 5 provides adequate avenues for communicating work hazards to workers.

16. The work practices and control procedures are considered adequate for the protection of workers.
17. The recommended record retention period appears to be appropriate.
18. Additional research is needed in the following areas:
- Comparative data on the PCB body burden resulting from oral, dermal and inhalation exposures.
 - Comparative metabolism studies of an homologous series in humans, non-human primates and rodents. These studies should include both a characterization of the metabolites formed and kinetic studies to determine the rates of mobilization and excretion.
 - Clinical evaluation including liver function tests on industrial populations with previously documented PCB exposure.
 - Epidemiological studies on major populations of PCB-exposed workers.
19. Attached is a report compiled by Monsanto and distributed in November 1975 to representatives of concerned governmental agencies, (NIOSH, OSHA, EPA, FDA, NCI, NIH) relating to histopathological evaluation of livers from rats treated with PCBs.

COMMENTS ON SAMPLING AND ANALYTICAL METHODS

Minor comments are on the original NIOSH draft.

General comments: In using trade names, the document should be consistent. Any shorthand such as dropping registration notation should be documented at the earliest opportunity and then a standard format adopted thereafter e.g. Aroclor ^R

Florisil ^R

Environmental Sampling and Analytical Methods

3714evaluated under laboratory conditions using aerosol generation techniques. Field studies were also performed in a PCB environment containing aerosol and vapor components.

The statement as it stands leaves open the question of aerosol or vapor studies. The document should be completed by inclusion of this information in a manner similar to the above amended statement, and expressing the true nature of the exercise. Both aerosol and vapor concentrations must be included.

3724 Earlier in the text, 2 solvents are mentioned along with the use of
-3726 single and multiple impingers.

Which solvent was used should be clarified (toluene or ethylene glycol) and the number of impingers.

The conclusions reached imply a study using an aerosol of PCBs or an equilibrated vapor environment. Is this true?

3737 to use when personal sampling for PCBs.

This circumvents other techniques such as area monitoring for calculating effective exposures.

3738 NIOSH has not tested all available solid sorbents (e.g. porous polymers).
Hence, this line should be reworded to reflect only those methods tested.

3752 Electron capture gas chromatography is the most widely used method, but
not necessarily the "preferred" method. For example, the wide variance
in response factors referred to in Table I is a distinct disadvantage.

3801 In this day, it is not possible to eliminate a method based on the lack
-3803 or expense of a computer. In many small companies, the OSHA requirements
will rapidly force the purchase of such a unit for many applications.

3809 One might prefer NBS as a repository for "standard" samples.
-3810

3824 Perchlorination should definitely not be used to quantitate PCBs. We
have confirmed that not only biphenyl, but also substituted biphenyls,
cause large positive errors. At least one of the replacement fluids
for PCBs in capacitors is a substituted biphenyl (Chemical and Engineering
News, p. 25, Nov. 15, 1976). Hence this interference is already present

3834 See comments on alternate standardization procedure, line 5354.
-3835

3843 See above comments on perchlorination.
-3845

APPENDIX I

5248 Samples collected must be representative of the personal exposure of individual workers.

5252 Records should include: Pump model & Serial no.
-5253 Sampling Tube type and no.
i.e. sampling equipment details

5258 Calibration data should also be recorded.
-5260

5266 The aim of sampling is to permit determination of the personal
-5268 exposure level primarily. This leads to a decision on compliance/
non-compliance situations. It cannot lead to the "lowest feasible
level" without other major input beyond the scope of sampling and analysis.

5273 Airflow through the pump shall be controllable within $\pm 5\%$ of the desired rate during the entire sample period.

5291 A more frequent requirement for pump calibration is required. At least monthly and preferably in the method for a daily setup calibration.

5292 Spot-checked is an open statement and means nothing.
-5293 For digital readout pumps specify parity check between expected stroke count versus actual.
For pump with rotameters specify before and after readings. We would prefer a calibration after flow stabilization and again before pump is turned off, for each sample.

5303 The sorbent tube should not be vertical.
Pointing down - loses glass wool and Florisil
Pointing up - dust from overhead, hard hat, etc. enters.
Suggest a close to horizontal location, attached to the collar of the worker.

5304 Air being sampled should pass directly into the open inlet of the sorbent tube.
This precludes filters.

5308 The recommended sample volume for this method is 50 liters (U.S. spelling)

5310 The sorbent tubes should be labelled. At this point it should reiterate checking label and I.D. Number.

5320 A bulk air sample is of no value unless the restraints required to obtain a good and recoverable sample are fully documented.

- 5324 Throughout Appendix II nomenclature for PCB and PCBs is confused. In general, PCBs should be used as a noun describing a PCB mixture, while PCB is an adjective.
- 5346 This reads more smoothly if written, "This would correspond to a detection limit of 40 ng of 5 ml of desorbent".
- 5354 This alternate standardization procedure is of highly questionable utility. As pointed out in line 5358, it has not been evaluated in NIOSH laboratories. As correctly stated in the draft, the reason an alternate procedure is needed are two-fold. First, most of the GC peaks in a chromatogram of a PCB product contain more than one component. Secondly, electron capture detector response differs significantly for different PCB isomers (See Table I of the draft). These two factors indicate that the absolute quantity of PCB represented by a given peak containing unresolved components varies depending on the relative amounts of the components.

The relative composition of a given peak can vary for the following reasons:

1. PCBs with a given degree of chlorination (i.e. 42%) from different manufacturers contain different isomer ratios.
2. Component ratios vary for products with different degrees of chlorination. For example, from Table XII - 6, the ratio of dichloro- to trichlorobiphenyls for the peak with RRT 28 in Aroclor 1221 is 85:15. From Table XII - 8, the same peak in Aroclor 1242 has a ratio of 25:75. Similarly, for peak RRT 70 in Aroclor 1242 and 1254, the tetrachloro-to pentachlorobiphenyl ratios are 90:10 and 25:75.
3. Vapor pressure differences alter the composition of vaporized PCBs relative to the liquid. (See attached figure showing chromatograms of liquid and vapors from Aroclor 1016).
4. Interfering components may be present which distort the sample chromatogram. This is likely to be a major problem in capacitor and transformer manufacturing facilities because several of the PCB replacement products (i.e. phthalate esters and chlorobutyl-diphenyl ether) have similar GC retention times to PCBs and give an electron capture response.

The weight factor technique of Webb and McCall does not adequately account for these difficulties.

For those situations where the sample chromatogram closely matches the chromatogram of a reference PCB mixture, the Standard Analysis described in 5554 ff should be followed. However, if the chromatograms do not match, we believe the only satisfactory analytical method which will yield accurate results is gas chromatography/mass spectrometry (GC/MS) using selected ion monitoring (SIM). The detection limit of this technique for Aroclor 1016 is about one nanogram of PCB injected into the instrument. Considering the environmental limit of 0.05 mg/m³ recommended in this document, it might be possible to reach this lower detection limit for the total procedure by sampling as outlined in the draft. evaporating the hexane desorbent and analyzing

Alternatively, thermal desorption from a suitable solid sorbent directly into the GC/MS can be used. This well documented technique analyses the entire collected sample at once, rather than only an aliquot at a time. Response factors vary only slightly for different PCB isomers and most interferences are eliminated.

- 5381 The bulk sample must not be shipped in the same container as the sample tubes.
- 5396 The volume of air sampled can be measured to within at least $\pm 5\%$.
Delete next sentence.
- 5410 Delete 100% and conclude sentence with "... recovered with a relative standard deviation of 4.4% for 27 spiked samples". Delete next sentence.
- 5460 Type of electron capture detector is not important.
- 5515 rinsing with pesticide grade acetone and hexane should follow the water rinses.
- 5533 Argon/methane is also a suitable GC carrier gas. The flow rate for either carrier gas should be only about 30 ml/min for a 2 mm id column.
- 5590 Actual retention times should be used in calculations if available. If not available, then the measurements described here can be used.
- 6118 The vapor pressures in Table XIII - 5 appear to be too high. What is the source of these data, and has their accuracy been verified?



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

NOV 4 - 1974

NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH
U.S. POST OFFICE AND COURTHOUSE
CINCINNATI, OHIO 45202

October 30, 1974

Dr. Emmett Kelly
Medical Director
Monsanto Chemical Corp.
800 N. Lindberg
St. Louis, Mo. 63166

Dear Dr. Kelly:

This letter will serve to introduce to you the personnel from the National Institute for Occupational Safety and Health (NIOSH) who will be attending the meeting concerning polychlorinated biphenyls we have tentatively scheduled for Friday, November 22, 1974. From this office in addition to myself the following persons will attend:

Mr. Richard Lemen, Chief, Biometry Branch, Division of Field Studies and Clinical Investigations;
Mr. Jay Jones, Industrial Hygienist, Environmental Investigations Branch, DFSCI;
Mr. Benjamin Braucker, Regional Program Director, NIOSH, Region VI.

The following individuals possibly may attend:

Dr. Joseph Wagoner, Director, Division of Field Studies and Clinical Investigations;
Dr. Clark Heath, Director of Cancer and Birth Defects Division, CDC.

Mr. Richard Lemen, Dr. Joseph Wagoner, Dr. Clark Heath and myself are epidemiologists.

Mr. Jay Jones indicated a desire to do a quick "walk-through" survey of the facility where the PCB's are manufactured. Could this be arranged?

Sincerely yours,

David L. Bayliss
David L. Bayliss

Assistant Chief, Biometry Branch
Division of Field Studies and
Clinical Investigations

PLAINTIFF'S
EXHIBIT

968

ADM CG59C1

Circle

October 22, 1974

Dr. Joseph K. Wagoner
Director, Division of Field Studies
and Clinical Investigations
Dept. of Health, Education & Welfare
Public Health Service
National Institute for Occupational
Safety & Health
U. S. Post Office & Courthouse
Cincinnati, Ohio 45202

Dear Dr. Wagoner:

With reference to my letter to you yesterday, regarding a meeting with members of Monsanto and NIOSH to discuss effects of PCB on humans, I was in error in giving you the name of Dr. Oliver DeGarmo. The man you should contact if you want a meeting before I return from my trip is Mr. William B. Papageorge, who can be reached at the above address.

Sincerely,

R. Emmet Kelly, M. D.
Medical Director

REK/ln

cc: Mr. W. B. Papageorge
Dr. Oliver De Garmo

- Ollie, will you please send the correspondence I sent you on this on to Bill Papageorge.



ACM CC8902

File	1	✓
Director		
CDJ		
ENE		
ETG		
EPK		✓
ESJ		✓
GR		
EPW		✓
PLW		
FEJ		

October 21, 1974

Dr. Joseph K. Wagoner
 Director, Division of Field Studies
 and Clinical Investigations
 Dept. of Health, Education & Welfare
 Public Health Service
 National Institute for Occupational
 Safety & Health
 U. S. Post Office & Courthouse
 Cincinnati, Ohio 45202

Dear Dr. Wagoner:

Monsanto will be happy to attend a meeting similar to the one you proposed in your letter of October 15 concerning whether any of our workers would constitute a suitable occupational group for the study of the effects of PCB on humans.

We have a slight logistic problem. I leave St. Louis on October 26 for a tour of our far eastern plants and will return the early part of the week of November 17. Dr. Roush, our Associate Medical Director will be here but I don't think he is as familiar with the PCB situation as I am. If you want a meeting before then, I would suggest you contact Dr. Oliver DeGarmo, of our Monsanto Industrial Chemicals Company at this same address. Dr. DeGarmo is in charge of environmental matters for the MIOC group.

Mr. Elmer Wheeler, of our own department, who is in charge of our environmental health services, is also familiar with the PCB matter. Neither of these are medical individuals and it may be that you will want to wait until I return. Please let me know before the 25th if I can be of any help.

Sincerely,

R. Emmet Kelly, M. D.
 Medical Director

REK/ln

cc: Dr. Oliver DeGarmo
 Mr. Elmer P. Wheeler
 Mr. Gerry Bratsch



ADM 006903

OCT 17 1974



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH
U.S. POST OFFICE AND COURTHOUSE
CINCINNATI, OHIO 45202

Room 523
October 15, 1974

Emmett Kelly, M.D.
Medical Director
Monsanto Chemical Corp.
800 N. Lindberg
St. Louis, Missouri 63166

Dear Dr. Kelly:

As you are aware, the Occupational Safety and Health Act gives the National Institute for Occupational Safety and Health (NIOSH) legislated authority and responsibility for the conduct of industry-wide studies of the effect of long-term, low-level exposure to industrial materials, processes, and stresses on the potential for illness, disease or loss of functional capacity in occupationally exposed adults. This epidemiological research is aimed at defining the relationship of disease incidence to possible causative factors in the work environment. The primary responsibility for conducting such research in NIOSH belongs to the Division of Field Studies and Clinical Investigations (DFSCI).

A tremendous quantity of research has demonstrated that environmental exposure to polychlorinated-biphenyls (PCB's) causes serious impairment of the functions of the liver. This impairment subsequently affects a variety of enzyme systems as is indicated in several articles in the literature. A recent article by Nobuyuki, Nagoeki, et al. entitled "Histopathologic Studies on Liver Tumorigenesis Induced in Mice by Technical Polychlorinated Biphenyls and Its Promoting Effect on Liver Tumors Induced by Benzene Hexachloride" suggests PCB's are carcinogenic in animals. However, results that evaluate long-term health effects in humans from either acute or chronic exposure to PCB's are not available.



ADM CCE9C4

Dr. Emmett Kelly

Page 2

For the purpose of assessing the potential for chronic effects, DFSCI is attempting to identify a suitable occupational group for study. To this end, I would like to arrange a meeting with representatives of Monsanto Chemical and NIOSH to discuss the inclusion of PCB-exposed active and inactive workers at Monsanto in a planned retrospective cohort study. The possibility of including other manufacturers and users of PCB's in this study is being considered.

I may be contacted by writing to the address above or calling 513-684-3255. Your cooperation in this matter is appreciated.

Sincerely yours,

Joseph K. Wagoner *by JAL*
Joseph K. Wagoner, S.D. Hyg.
Director, Division of Field Studies
and Clinical Investigations

Encl:
OSH Act of 1970

ADM C089C5



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

Handwritten:
DMEH
on 8/25

August 20, 1976

NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH
3600 FISHERS LANE
ROCKVILLE, MARYLAND 20852

Dear Colleague:

In a June 24, 1976 letter, Mobil Oil Corporation advised the National Institute for Occupational Safety and Health (NIOSH) of a possible association between occupational exposure to polychlorinated biphenyls (PCBs) and cancer in humans. Mobil Oil reported preliminary results of an epidemiologic analysis based on medical records of employees exposed to PCBs at their Paulsboro, New Jersey plant. This study was conducted by Professor Anita K. Bahn (School of Medicine, University of Pennsylvania) and is being reported by Dr. Bahn in a letter to the editor of the New England Journal of Medicine, August 19, 1976.

The study included two cohorts of Mobil employees who were reported to have had varying exposure to Aroclor 1254 (a mixture of PCBs). The cohort of research and development employees was exposed to PCBs between 1949 and 1957 and the cohort of refinery plant employees between 1953 and 1958. The extent of exposure of these workers to other chemicals is not known. The cancer incidence among these workers for the period 1957 through 1975 was determined using Mobil medical records. Because medical records for 37 employees were incomplete, these workers were excluded from this analysis.

Among the 92 workers in these two cohorts for whom adequate medical records were available, eight cancers (in seven workers) were observed between 1957 and 1975. Of these eight cancers, three were malignant melanoma and two were cancer of the pancreas. This is significantly more skin cancer (melanoma) and pancreatic cancer than would be expected in a population of this size (based on the Third National Cancer Survey). The remaining cancers were found at three other sites in two employees; sarcoma of the right thigh and multiple myeloma in one employee, and recto-sigmoid cancer in the other.



ACM CC89C6

Page 2 - Dear Colleague

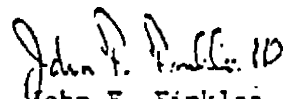
NIOSH is unaware of any other published animal or human data which suggest a correlation between exposure to PCBs and skin (melanoma) or pancreatic cancer. However, hepatomas (mice, Aroclor 1254) and hepatocellular carcinomas (mice, Kanechlor 500; rats, Aroclor 1260) have been reported in PCB feeding studies of laboratory animals.

Background information on PCBs has been summarized in the NIOSH Current Intelligence Bulletin on Polychlorinated Biphenyls issued to the occupational health community on November 3, 1975, and subsequently published in the Journal of Occupational Medicine, Volume 18, pages 109-113, February 1976. Since the NIOSH Bulletin was first issued, a number of large firms have introduced products (e.g., butylated monochlorodiphenyl oxide and dimethyl siloxane polymer) claimed to be fire resistant dielectrics which can serve as alternatives to PCBs. In addition, one of the large domestic transformer manufacturers announced that it will cease using PCBs as fire resistant transformer fluids at the end of this year. NIOSH would like to stress that alternatives for PCBs should be thoroughly studied to assess the consequences they may pose to human health.

To aid in evaluating PCBs as a potential occupational health problem, NIOSH would welcome receiving reports of studies regarding the possible association between exposure to PCBs and human cancer.

Your cooperation in this matter is appreciated.

Sincerely yours.


John F. Finklea, M.D.
Director

Draft

MORTALITY AND INDUSTRIAL HYGIENE STUDY OF
WORKERS EXPOSED TO POLYCHLORINATED BIPHENYLS

Bill
W. H. Brown
Gen. Dr. H. H. H.
Bill
File 13

David P. Brown

Mark Jones

U.S. Department of Health, Education and Welfare

Public Health Service

Center for Disease Control

National Institute for Occupational Safety and Health

Division of Surveillance, Hazard Evaluations and Field Studies

Cincinnati, Ohio 45226



ADM CC69CE

ABSTRACT

Due to the demonstrated toxic effects from polychlorinated biphenyls (PCB's) on exposed animals, the National Institute for Occupational Safety and Health (NIOSH) conducted a series of industrywide studies to determine whether or not there are any long term health effects among workers occupationally exposed to PCB's. As part of these industrywide studies, NIOSH conducted a retrospective cohort study of mortality among two worker populations employed in the manufacturing of electrical capacitors. The two study cohorts included 979 workers from plant 1 and 1581 from plant 2 who were employed for at least three months in areas of the plant where PCB's were used. 59
123
250

The vital status of over 97% of the two cohorts was determined as of January 1, 1976 and 45,620 person-years were accumulated. There were 172 death certificates collected and coded by a nosologist. A person-years life table analysis was carried out to obtain the number of cause specific deaths expected for each cohort, adjusted for age, race, sex, and calendar time period. All-cause mortality was lower than expected (172 obs. vs. 190.2 exp.) as well as all cancer mortality (39 obs. vs. 43.6 exp.). Among the specific cancer causes, rectum (4 obs. vs. 1.15 exp.) and liver (3 obs. vs.

0.93 exp.) were elevated. The observed mortality due to cirrhosis of the liver was also in excess. None of these differences were statistically significant at $p < 0.05$.

A summary of the detailed industrial hygiene surveys conducted in each plant to characterize the occupational exposures is presented. The significance of the mortality and industrial hygiene results are discussed.

ACM CG8910

INTRODUCTION

Polychlorinated biphenyls (PCB's) are a class of compounds composed of biphenyl molecules with a varying number of substituted chlorine atoms. In commercially prepared PCB's, the weight-percent of chlorine has varied between 21 and 68%. In some preparations, there has also been some degree of contamination by chlorodibenzofurans.(1)

The primary use of PCB's has been as a liquid insulating material in electrical capacitors and transformers, and the greatest potential for occupational exposure has been in the manufacturing and repair of these components. PCB's have also been used in heat exchange units, hydraulic systems, vacuum pumps, gas transmission turbines, plasticizers, adhesives, pesticide extenders, paints, and carbonless copying papers.

As of 1971, PCB's were sold only for use in closed systems. According to the Toxic Substances Control Act of 1976, specific rules and regulations were promulgated to limit the manufacture and use of PCB's. This Act stipulated that all U.S. production of PCB's end January 1, 1979 and that all U.S. sale and distribution of PCB's end July 1, 1979. However, continual exposure to PCB's will occur among workers who

maintain transformers and capacitors, and among the general population mainly through contaminated food.

During the past few years, there has been a great deal of interest in studying the health effects among individuals exposed to PCB's. This interest has been stimulated by: (1) the tendency for PCB's to accumulate in tissues and in certain organs, (2, 3) (2) the stability of PCB's and their persistence in the environment, (4, 5) and (3) the demonstrated long term effects in exposed laboratory animals (6-13) - including liver tumors and other liver diseases. Much of this interest was expressed at the National Conference on Polychlorinated Biphenyls in November, 1975 (14) and the toxicity of PCB's has been extensively reviewed in the NIOSH Criteria Document on PCB's. (15)

In order to determine whether or not past occupational exposure to commercially produced PCB's has caused any long term health effects, NIOSH initiated an epidemiologic study among workers in two capacitor manufacturing plants. In conjunction with this study, detailed industrial hygiene surveys were also conducted by NIOSH.

DESCRIPTION OF FACILITIES

The two facilities chosen for the study were selected after preliminary walk-through surveys were conducted at numerous types of plants where PCB's were used. Both of the plants manufacture electrical capacitors. These plants were selected because of their large workforce, the early dates (1938 & 1946) at which PCB's were first used at these plants, the potential for exposure to PCB's with little potential for exposure to other known toxic contaminants, and the availability of records necessary to identify individuals to be included in the study population. At the time the study was initiated both plants were still using PCB's. Plant 1 is located in New York State and is divided into two manufacturing facilities within close proximity. One facility produced small industrial capacitors using PCB's since 1946 and the other produced large PCB filled power capacitors since 1951. The type of PCB's used has varied over the years from "Aroclor" (Aroclor is a Monsanto tradename) 1254 (54% chlorine) to 1242 (42% chlorine) to 1016 (41% chlorine). Several other kinds of oils were used, but in a small number of capacitors. These oils included castor oil, dibutyl sebacate, diethylthalate and mineral oil.

Plant 2 is located in Massachusetts where the use of PCB's to manufacture capacitors started in 1938. This plant also changed the type of PCB's used from "Aroclor" 1254 to 1242 to 1016. Until 1972, other types of capacitors which did not contain PCB's were made at this plant including mica, electrolytic and tubular. Castor oil was used in lieu of PCB's to produce the large power capacitors at this plant.

Both plants assemble the capacitors using the same general techniques, whether they are the small or large types. The following is a brief description of the assembly process:

- A. Winding and Pre-assembly - The inner components of the capacitor are made of paper, foil and sometimes plastic film, wound together, which are subsequently loaded into metal casings. This job is done in an enclosed dust-free room where there is minimal exposure to PCB's.
- B. Impregnation - The pre-assembled capacitors are filled or impregnated with the PCB's. Within this area there is potential for exposure to PCB's.
- C. Final Assembly - The tops of the capacitors are closed using various techniques - crimping (rubber stoppers) or soldering, which involves some exposure to PCB's. The

capacitors are washed to remove excess PCB's by running them through a detergent wash or a degreaser such as trichloroethylene. Finally, they are sent through the final operations involving drying, testing, and painting.

Other areas of importance where there is potential exposure to PCB's in the plants, include the laboratory and the area where rejected capacitors are rebuilt. Approximately 10% of the two workforces have been employed in jobs where there has been potential exposure to PCB's.

Historically, the workforce at Plant 1 has been approximately 50% white males and 50% white females. Plant 2 has had a less homogeneous workforce with two-thirds being female and reflects the general racial make-up of the area, which is largely Cape Verdean and Portuguese.

METHODS

A retrospective cohort study of mortality was conducted to determine whether or not individuals occupationally exposed to PCB's have experienced any increase in cause-specific mortality. The study cohorts were defined as all workers who accumulated at least three months of employment any time between January 1, 1946 and January 1, 1976 for Plant 1 and

January 1, 1938 and January 1, 1976 for Plant 2, in areas of the plants where there was a potential for exposure to PCB's. These exposed jobs were designated by the companies and verified by the labor unions, and through the industrial hygiene surveys.

An effort was made to determine the vital status (alive or deceased) of each individual in the cohorts as of January 1, 1976. Vital status was determined through records maintained by Federal and State agencies, including the Social Security Administration, state motor vehicle registration, and state vital statistics offices. For those individuals who could not be located through these sources, U.S. Postal Mail Correction Services and other follow-up searches were used. For all those who were known to be deceased, death certificates were requested and causes of death were interpreted by a qualified nosologist according to the International Classification of Diseases (ICDA) in effect at the time of death and then converted to the 7th Revision of the ICDA. Those who had an unknown vital status were assumed to be alive as of January 1, 1976 so that the true risk of mortality was not overestimated. Those who died after January 1, 1976 were considered alive for purposes of analysis.

Person-years were accumulated for each worker starting at the point in time when three months of employment in exposed jobs was completed and ending at the date of death or the study end date (1/1/76), whichever occurred first. Using a modified life table computer program similar to that described by Cutler, (16) the person-years for each cohort were combined into five-year calendar and five-year age time periods and multiplied by the corresponding U.S. white male (for male cohort members) and U.S. white female (for female cohort members) cause-specific mortality rates to yield the expected number of deaths. Person-years were additionally distributed by five-year exposure and five-year latency (number of years from date first employed in exposed jobs to date of death or study end date) categories. Observed and expected cause-specific deaths were compared and differences were tested based on the Poisson distribution.

The detailed industrial hygiene surveys included personal time-weighted air samples of employees from selected job titles, as well as area air samples. In both plants, samples were taken for PCB's (Aroclor 1016), trichloroethylene, lead, tin, and zinc. In addition, samples for toluene, methyl isobutyl ketone (MIBK), aluminum and iron were taken at Plant 1. These surveys were designed to characterize the exposures occurring at the time of the survey and may not represent

exposures of previous years, especially those of Plant 1 where exposures may have been reduced because of new production techniques which had recently been initiated.

RESULTS

There were a total of 2,560 workers who met the definition of the study cohort. Table 1 gives a breakdown of vital status ascertainment and the number of person-years within each sub-cohort. The vital status ascertainment was more than 97% complete and only 3 death certificates could not be located.

Approximately 55% (560 workers) of the cohort members from Plant 1 began employment prior to 1965 whereas, approximately 75% (1,180 workers) of those from Plant 2 began employment prior to 1965.

Approximately 37% of the study cohort from Plant 1 was employed in "PCB exposure" jobs for less than 1 year (but greater than 3 months), 55% were employed in these jobs for 1 to 10 years and 8% for greater than 10 years. In Plant 2, approximately 44% of the study cohort was employed in "PCB exposure" jobs for less than 1 year (but greater than 3

months), 47% for 1 to 10 years, and 9% for greater than 10 years.

Tables 2 and 3 summarize the number of deaths observed from the study cohorts and the number of deaths expected. The all-cause mortality is lower than expected in each cohort, with an SMR (SMR = observed deaths/expected deaths x 100) of 90 (74 obs. vs. 82.3 exp.) for Plant 1 and an SMR of 91 (98 obs. vs. 107.91 exp.) for Plant 2. These low SMR's reflect the "healthy worker effect".(17) There was no increase in observed mortality for the major causes of death listed in Table 2.

Table 3 lists the observed and expected number of deaths by specific cancer cause. When both cohorts were combined, the observed number of deaths were more than those expected for cancer of the rectum (4 obs. vs. 1.2 exp.) and liver cancer.- ICD=155, 156A (3 obs. vs. 0.9 exp.). The only statistically significant difference (at $p < 0.05$) in observed versus expected deaths occurred in females from Plant 2 for cancer of the rectum (3 obs. vs. 0.5 exp.; $p < 0.05$). For both cohorts combined, there were 6 deaths due to cirrhosis of the liver, while 5.9 were expected. Five of these cases were from the Plant 2 cohort while 3.3 were expected. According to hospital reports, at least three of the six persons who died of

cirrhosis of the liver were known to have consumed alcohol on a regular basis.

The relationship between latency and the mortality from all cancer, cancer of the rectum, liver cancer, and cirrhosis of the liver is shown in Table 4. For "all cancer" there is no apparent pattern in either cohort. However, for cancer of the rectum, all four deaths occurred in the greater than 20 years latency period where there were 0.5 deaths expected ($p < 0.05$). There is no clear association between latency and mortality from liver cancer, however, the three liver cancers occurred between the 10-19 years latency period whereas 0.33 deaths were expected ($p < 0.05$). The risk of mortality due to cirrhosis of the liver as observed in plant 2 increases with an increase in the latency periods.

The relationship between these same causes of mortality and length of employment in PCB exposed areas of the plants is given in Table 5. For all-cancer as well as for liver cancer there is no increase in observed mortality with increasing lengths of exposure. For rectal cancer and cirrhosis of the liver, there is an increase in the risk of mortality with an increase in lengths of exposure.

The industrial hygiene survey results of area and personal sampling for PCB's (Aroclor 1016) are summarized in Tables 6 and 7. Due to differences in the production processes, the results by specific jobs or work areas are not comparable between the two plants. However, relative comparisons can be made and the range of concentrations observed in Plant 1 were lower than those in Plant 2. In Plant 1, the time weighted average (TWA) personal air samples ranged from $24 \mu\text{g}/\text{m}^3$ to $393 \mu\text{g}/\text{m}^3$ and the TWA area air samples ranged from $3 \mu\text{g}/\text{m}^3$ to $476 \mu\text{g}/\text{m}^3$. In Plant 2, the TWA personal air samples ranged from $170 \mu\text{g}/\text{m}^3$ to $1260 \mu\text{g}/\text{m}^3$ and the TWA area air samples ranged from $50 \mu\text{g}/\text{m}^3$ to $810 \mu\text{g}/\text{m}^3$. The current OSHA standard and ACGIH TLV for chlorodiphenyl (42% chlorine) is $1000 \mu\text{g}/\text{m}^3$. There is no current OSHA standard or ACGIH TLV for Aroclor 1016.

Trichloroethylene was measured near the degreasers in both plants. Out of eleven area air samples from Plant 1, all were below 35 ppm except for two which measured 195 ppm and 321 ppm. At Plant 2, three area air samples were taken which ranged from 53.4 ppm to 77.5 ppm. The OSHA standard for trichloroethylene is 100 ppm based on a 8 hour time weighted average.

Area air samples were measured for tin, lead and zinc near the soldering operations. There were no detectable levels for tin at either plant. Out of four samples collected for lead and zinc at Plant 1, lead was detected in one sample at a level of $12 \mu\text{g}/\text{m}^3$, zinc was detected on two samples at levels of 8 and $24 \mu\text{g}/\text{m}^3$. At Plant 2, fifteen samples were collected for lead and zinc. All but one of these samples showed no detectable levels for lead, the one detectable sample was $41.2 \mu\text{g}/\text{m}^3$. Six of the fifteen samples found concentrations of zinc ranging from 2.3 to $94.1 \mu\text{g}/\text{m}^3$. The current OSHA standard for lead and zinc oxide (reported as zinc) are $200 \mu\text{g}/\text{m}^3$ and $5 \text{ mg}/\text{m}^3$ respectively.

Both personal and area samples were taken around the welding operations for measuring aluminum and iron at Plant 1. The aluminum samples ranged from non-detectable to $233 \mu\text{g}/\text{m}^3$ and the iron samples from $47 \mu\text{g}/\text{m}^3$ to $123 \mu\text{g}/\text{m}^3$. The ACGIH TLV for aluminum (Al_2O_3) is $10 \text{ mg}/\text{m}^3$ and the current OSHA standard for iron oxide (measured as iron) is $10 \text{ mg}/\text{m}^3$.

Twelve personal samples were collected for toluene and MIBK during painting operations at Plant 1. Toluene concentrations ranged from 0.48 to 22 ppm and MIBK ranged from 2 to 5 ppm. The current OSHA standard for toluene is 200 ppm and 100 ppm for MIBK.

DISCUSSION

There are few previous epidemiologic studies that have examined the long term health effects of humans exposed to PCB's. Individuals poisoned by rice oil heavily contaminated with PCB's (Yusho Disease) have been studied extensively years after the incident took place in Japan in 1968.(18, 19) However, the rice oil contaminant also contained ~~polychlorinated dibenzofurans~~, and quarter phenyls in higher concentrations than that found in commercially prepared PCB's. A high prevalence of skin and eye conditions were noted in the Yusho patients. In addition, there were clinical and laboratory findings that included changes in the microanatomy of liver cells and a decreased concentration of bilirubin in the serum of these individuals.(20, 21)

Early reports regarding the health effects from occupational exposure to PCB's include chloracne (22), digestive disturbances, eye irritation, liver injury and impotence.(23, 24) Most of these findings have been reported as case histories.

In a recent study of volunteers conducted by the Mount Sinai School of Medicine (25), 326 workers who were employed at Plant 1 were examined. The most prevalent symptoms noted were

dermatological, and those of the central nervous system. There was a low prevalence of abnormal liver findings on physical examination. However, a subgroup exposed to PCB's were found to have liver enzyme changes different from that of a normal, non-exposed group. In addition, abnormal SGOT levels were associated with plasma levels of PCB's. There was a relatively high prevalence of decreased lung capacity among a subgroup of 243 workers tested. (26).

*Mobil
Study*

In a preliminary report, Bahn (27) reported an increase in deaths due to malignant melanoma (2 obs. vs. 0.04 exp.) and cancer of the pancreas among 51 research and development employees and 41 refinery plant employees at a New Jersey petrochemical facility. These individuals were considered to have had some exposure to Aroclor 1254 during various periods between 1949 and 1957, along with exposure to other toxic and potentially carcinogenic compounds.

In a summary of case histories (27) among approximately 300 workers employed in the manufacturing of PCB's, no malignant melanomas or pancreatic cancers were observed. However, among the death certificates of 50 former workers at this manufacturing facility, seven cases of lung cancer were observed whereas 2.7 cases were expected. The findings were preliminary and were not adjusted for age or smoking.

(Written communication to NIOSH from Roush, G. September, 1976.)

The previously reported findings of an increased risk for mortality due to malignant melanoma, cancer of the pancreas, and lung cancer among workers exposed to PCB's were not corroborated in the present study. There were no observed deaths due to malignant melanoma and only 1 observed death from pancreatic cancer while 1.86 were expected. There were 7 observed deaths from respiratory system cancer, whereas 8.2 were expected. The only categories of cancer in which the number of observed deaths were greater than expected were for cancer of the rectum and cancer of the liver. When both cohorts and sex groups were combined these excesses were not statistically significant at an alpha level of 0.05. However, the excess in liver cancer is noteworthy because it is consistent with the toxicology data observed in laboratory animals exposed to PCB's, where effects have been noted in the liver(6-13). The increase in deaths due to cirrhosis of the liver in the Plant 2 cohort is also consistent with the notion that PCB's have a toxic effect on the liver.

The exposures to PCB's at the time of the surveys (Plant 1 - April, 1977; Plant 2 - March, 1977), were relatively higher in Plant 2. However, historic levels of exposure may have been

more equivalent and it is these exposures that occurred 20 to 30 years ago that are more relevant when considering the occupational cancer risk among the study cohorts. The PCB mixtures used during these time periods were Aroclor 1254 and 1242, whereas, Aroclor 1016 was first used in 1971. In addition, several different stabilizers have been added to the PCB's (1% or less by weight) used at Plant 1 since the early 1960's. These include potential carcinogens such as diglyceride ether-disphenol-a and more recently, vinyl cyclohexene dioxide. It is not known which stabilizers have been used at Plant 2.

The only significant exposure other than PCB's at either plant was trichloroethylene and these exposures were usually below the TLV. However, due to this potential confounding exposure, workers employed around the trichloroethylene degreasers were not included in the cohorts.

In most occupational health studies where cancer mortality is being assessed, latency is an important variable; the hypothesis being that there is an increased risk of mortality once a certain time period after initial exposure has elapsed. In this study, this hypothesis is difficult to examine due to the small number of deaths among specific cancer causes. For "all cancers" there does not appear to be

a relative increase in risk after any latency time period. All deaths due to cancer of the rectum occurred after at least 20 years and all deaths due to liver cancer occurred after at least 10 years. This same pattern is apparent for deaths due to cirrhosis of the liver that occurred in Plant 2. Even though these are small numbers, the results indicate that there is a potential relationship between these causes of death and occupational exposure to PCB's.

The risk of mortality from rectal cancer and cirrhosis of the liver, at least in Plant 2, also increases as the length of exposure increases. This would be the expected observation for a response that is dependent on the magnitude of exposure.

There are several variables that could potentially bias the results of this study; and should be considered.

First, the possibility of missing records from the personnel files that were used to assemble the Plant 1 cohort was questioned at the initiation of the study. This is currently being investigated by the New York State Department of Health. (Personal communication from Phil Taylor, NYSDH, October, 1979.) In order to check the completeness of the microfilmed personnel files, they are being compared with the Social Security Administration (SSA) quarterly earnings

statements from 1945-1965.(28) At the present time, the personnel records have been checked with the SSA quarterly earnings records from 1945 to 1955, and approximately 179 additional names out of a group numbering around 3,000 have been identified from the SSA records. The vital status of these 179 additional workers was ascertained and 44 were known to be deceased, 35% of which were due to cancer. Therefore, based on this check of the records the Plant 1 study cohort may be missing up to 6% of the actual population at risk. In addition, this missing group has a higher proportion of deaths due to cancer than the study cohort identified only from personnel records (35% for the missing group compared to 18% for the identified Plant 1 study cohort: $\chi^2 = 3.30$; $p < 0.10$). Thus, the Plant 1 cohort could be missing individuals who should have been part of the study, potentially biasing the results of the Plant 1 cohort. Considering these findings, more emphasis should be directed to the mortality results of the Plant 2 cohort, which when examined alone shows an increase in liver and rectal cancer, as well as, cirrhosis of the liver. According to plant officials, there was no reason to believe that the personnel file system at Plant 2 was missing records, and it appeared

from our inspection that the personnel file system had been maintained in tact.

Another potential confounding variable is the possible effect of alcohol ingestion on the observed increase (at Plant 2) in mortality from cirrhosis of the liver. However, this cannot be properly assessed in the present study since not enough is known about the ingestion of alcohol among the entire study cohort.

CONCLUSIONS

Due to a relatively small number of deaths, conclusions drawn from the results of this study are tentative. In addition, up to 6% of the actual population at risk may be missing from the Plant 1 cohort.

Despite these study limitations, the observed excesses in liver cancer and cirrhosis of the liver are consistent with previously reported findings of experimental animals exposed to PCB's, and suggest that there may be an association between these causes of death and occupational exposure to PCB's (Aroclor 1254 and 1242). The observed excess in cancer of the rectum related to PCB exposure was unexpected and needs

further investigation. Additionally, the possible role of alcohol ingestion together with exposure to PCB's is unknown and needs further examination.

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re:

Proposed Toxic Pollutant Effluent
Standards for Polychlorinated
Biphenyls

) FWPCA (307)
) Docket No. 4
)

AFFIDAVIT OF ROSCOE M. MOORE, JR.

Roscoe M. Moore, Jr., being duly sworn, deposes and says:

1. I am currently employed as an epidemiologist by the National Institute for Occupational Safety and Health (NIOSH), at 5600 Fishers Lane, Rockville, Maryland. My biography is attached to this affidavit as exhibit 1.

2. As part of my duties at NIOSH I was involved in the preparation of a "Dear Colleague" letter" which was sent out on August 20, 1976, by Dr. John F. Finklea, Director of NIOSH. A copy of that letter is attached to this affidavit as exhibit 2.

3. In this letter NIOSH reviewed the preliminary results of an epidemiologic analysis based on medical records of Mobil Oil Company employees exposed to PCBs at Mobil's Paulsboro, New Jersey plant.

4. Among the 92 workers studied, for whom adequate medical records were available, eight cancers (in seven workers) were

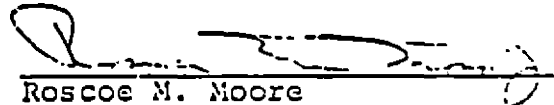


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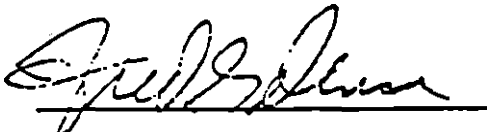
observed between 1957 and 1975. Of these eight cancers, three were malignant melanomas and two were cancers of the pancreas. This is significantly more skin cancer (melanoma) and pancreatic cancer than would be expected in a population of this size (based on the Third National Cancer Survey).

5. Based on these findings and those reported earlier on the carcinogenicity of PCBs in test animals, it is my conclusion that when the results of further studies on occupationally-exposed individuals are completed, there is strong likelihood that PCBs will be shown to be carcinogenic to humans.

6. NIOSH is currently conducting such follow-up studies on workers occupationally exposed to PCBs.


Roscoe M. Moore

Sworn to and subscribed before me
this 2nd day of November, 1976.


Notary Public

My commission expires: 7/1/78

12-1
Moore

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Son: Roscoe Michael Moore, III, born May 16, 1971

Son: John Haywood Moore, born April 6, 1973

EDUCATION

Tuskegee Institute, Tuskegee, Alabama, 1962-1965, B.S. - 1968

Tuskegee Institute, Tuskegee, Alabama, 1965-1969, D.V.M.

Chairman of the Honor Code, School of Veterinary Medicine, 1967-1968

President of Student Chapter of the American Veterinary Medical
Association, Tuskegee Institute, 1968-1969

Congressman to the Student Government Association, Tuskegee
Institute, 1968-1969

Who's Who in American Colleges and Universities, 1968-1969

University of Michigan, Ann Arbor, 1969-1970, M.P.H. in Epidemiology

University of Maryland, College Park, February 1971 - May 1971, evening
course in Spanish

CONTINUING EDUCATION PROGRAMS

Fortran Training Course at the Center for Disease Control, November 8-12, 1971

Pesticides and Public Health Training Course, sponsored by the Environmental
Protection Agency (EPA), February 1-4, 1972, Atlanta, Georgia

Advanced Course - Pesticides and Public Health, sponsored by EPA,
May 16-19, 1972, Atlanta, Georgia

ACM 008936

CONTINUING EDUCATIONS PROGRAMS (CON'T.)

Grid Management Course, sponsored by Scientific Methods, Inc.,
October 21-26, 1973, Morristown, New Jersey

Neurology Course, sponsored by D.C. Academy of Veterinary Medicine,
April 4-5, 1974, Fairfax, Virginia

Pharmacology Course, sponsored by the Food and Drug Administration,
May-June, 1974, Rockville, Maryland

Immunology Course, presented by Johns Hopkins University,
October 25 - December 11, 1974, Rockville, Maryland

Comparative Pathology Course, sponsored by the Department of Defense,
Armed Forces Institute of Pathology, May 10-12, 1976, Washington, D.C.

WORK EXPERIENCE

January 1976 - Present

A Veterinary Medical Officer in the U.S. Public Health Service,
stationed at the National Institute for Occupational Safety and
Health (NIOSH), Rockville, Maryland.

Chief, Technical Evaluation and Review Branch, Office of Extramural
Coordination and Special Projects (OECSP), NIOSH, with primary
responsibility in conducting and coordinating short-term technical
studies including evaluation of toxicologic information transmitted
to the Institute for review. Also, maintaining and supervising
the NIOSH Current Intelligence System. This system prepared back-
ground information on potentially hazardous substances in the
occupational environment including toxicity to man and animals,
production and uses, and the potential population at risk. This
system informs the occupational health community, other government
agencies, management, labor and public interest groups of new
information on potential occupational health hazards.

In addition, as Epidemiologist for the Office of Extramural
Coordination and Special Projects, provides the necessary sta-
tistical and epidemiological information to quantitate the relative
risk of human exposure to chemical substances in the work environment.

WORK EXPERIENCE (CON'T.)

December 1974 - January 1976

A Veterinary Medical Officer in the U.S. Public Health Service, stationed at the National Institute for Occupational Safety and Health (NIOSH), Rockville, Maryland.

Chief, Priorities Evaluation Branch, Office of Occupational Health Surveillance and Biometrics (OOHSB), NIOSH, with primary responsibility in directing the development, implementation, and maintenance of the Priorities Evaluation System which provides guidance to the Institute Director and the NIOSH scientific staff for the allocation of resources to assure maximum effort in combating health hazards in the work environment.

In addition, as Senior Medical Epidemiologist for the OOHSB, provide the necessary statistical and epidemiological information to quantify the relative risk of human exposure to chemical substances in the work environment.

July 1973 - December 1974

A Veterinary Medical Officer in the U.S. Public Health Service, stationed at the Food and Drug Administration (FDA), Rockville, Maryland.

A Surveillance Officer, Bureau of Veterinary Medicine, Food and Drug Administration with major responsibility in evaluating the safety, reliability, and efficacy of veterinary drugs for the target species as well as human safety with respect to tissue residues in food animals. Also, have been active in drug residue monitoring in edible tissue while serving as FDA consultant to the States of Wisconsin and New York. In addition, a member of the Project Advisory Group on FDA contracts for Heavy Metals Research. Primarily functioning as a toxicologic epidemiologist for the Bureau.

July 1971 - June 1973

A Veterinary Medical Officer in the U.S. Public Health Service, stationed at the Center for Disease Control (CDC), Atlanta, Georgia.

An Epidemiologist with the Epidemic Intelligence Service (EIS) with primary responsibility for national psittacosis, listeriosis, viral pox, Venezuelan equine encephalitis, and animal bite surveillance. A consultant to Family Planning Activities at CDC to develop animal models for reproduction and population studies. Also, CDC Liaison, Rabies Control Program, Dade County, Florida. In addition, consultant to the Alabama and Florida State Health Departments on Lead Toxicoses.

WORK EXPERIENCE (CON'T.)

September 1970 - June 1971

Senior Assistant Veterinary Officer in the U.S. Public Health Service, stationed at the National Institutes of Health (NIH), Bethesda, Maryland..

A member of the Animal Disease Investigation Service with major responsibility for prevention and control of diseases within the germ-free and specific pathogen-free animal colonies at NIH. In addition, assisting NIH Investigators with research problems related to animal disease.

Summer 1968

Worked as a Veterinary Trainee with the U.S. Department of Agriculture, Animal Health Division in the State of Georgia.

Summers of 1965 and 1967

A tutor in the Tuskegee Institute summer education program, a poverty program operating in the "Black Belt" counties of Alabama. Taught biology in special science centers to high school aged children in this program.

While in School at Tuskegee

I financed my education through Work Study Program, Federal loans, and scholarships.

PERSONAL

Professional Affiliations

Member:

American Public Health Association

Action Board Member (1974-1976)

Joint Policy Committee Member (1975)

American Association of Food Hygiene Veterinarians

American Association for Laboratory Animal Science

American Society of Laboratory Animal Practitioners

American Veterinary Medical Association

Conference of Public Health Veterinarians

Drug Information Association

Society for Epidemiologic Research

Professional Affiliations (con't.)

Member by Election:

American College of Veterinary Toxicologists (Associate Fellow)
Society for Occupational and Environmental Health
Veterinary Cancer Society

Appointments:

An Advisory Committee member on curriculum for the School of Agriculture and Natural Resources, Washington Technical Institute, Washington, D.C. (1974 - Present)

External Reviewer for the National Cancer Institute's Bioassay Program (Trichloroethylene, Chloroform) (1975 - Present)

NIOSH Occupational Carcinogenesis Task Force - Working Group on Mutagenicity Testing (1975 - Present)

Awards

United States Public Health Service (USPHS) Commendation Medal Award, April 2, 1976, for outstanding performance in the development of a Current Intelligence System for the National Institute for Occupational Safety and Health, and dedicated service to the occupational health mission of the organization.

Licensure

Licensed to practice Veterinary Medicine in Alabama, Georgia, and Virginia.

Non-Professional Affiliations

Alternate delegate representing the Division of Research Services (DRS) at NIH in the Recreation and Welfare Association (1970-1971)

A member of the Director's Advisory Committee of DRS. This committee is concerned with equal employment opportunities with DRS at NIH (1970-1971)

A member of the National Wildlife Federation (1970 - Present)

An Associate Member of the Interreligious Foundation for Community Organizations, Inc. (1974 - Present)

An Associate Member of the American Committee on Africa (1974 - Present)

Hobbies

A philatelist and tennis enthusiast

PUBLICATIONS

- Moore, R. M.; Zehmer, R. B. Listeriosis in the United States. 1971. - J. Infect. Dis., Vol. 127:610-611, 1973.
- Moore, R. M. Human Orf in the United States. 1972. J. Infect. Dis., Vol. 127:731-732, 1973.
- Moore, R. M., Zehmer, R. B., Moulthrop, J. I., Parker, R. L. Surveillance of Animal Bite Cases in the United States. 1971-72. Arch. Environ. Hlth. (In Press)
- Moulthrop, J. I., Moore, R. M., Parker, R. L. Venezuelan Equine Encephalitis Surveillance in the United States. 1972. J. Infect. Dis., Vol. 127:572-573, October 1973.
- Durfee, P. T., Moore, R. M. Human Psittacosis in the United States. 1971-1973. J. Infect. Dis., Vol. 131:193-194, 1975.
- Lloyd, J. W., Decoufle, P., Moore, R. M. Background Information on Chloroprene. J. Occu. Med., Vol. 17:263-265, 1975.
- Lloyd, J. W., Moore, R. M., Ereslin, P. P. Background Information on Trichloroethylene. J. Occu. Med., Vol. 17:603-605, 1975.
- Kaufmann, A. F., Moulthrop, J. I., Moore, R. M. A perspective of Simian Tuberculosis in the United States. 1972. J. Med. Primatology, Vol. 4:278-286, 1975.
- Lloyd, J. W., Moore, R. M., Woolf, E. S., Stein, H. P. Polychlorinated Biphenyls. J. Occu. Med., Vol. 18:109-113, 1976.
- Levine, R. J., Moore, R. M., McLarn, G., Barthel, W. F., Landrigan, P. J. Occupational Poisoning, Animal Deaths, and Environmental Contamination at a Lead Scrap Smelter. June Issue, AJPH, 1976.
- Moore, R. M., Moulthrop, J. I., Sather, G., Holmes, C. L., Parker, R. L. Venezuelan Equine Encephalitis Vaccination Survey in Arizona and New Mexico. 1972. Public Health Reports (Submitted).
- Moore, R. M. The Epidemiology of Animal Bite Cases in the United States. Proceedings of the 11th (1976) Annual Veterinary Symposium, School of Veterinary Medicine, Tuskegee Institute (In Press).

PUBLICATION EXPERIENCE

Prepared monthly surveillance reports for the Center for Disease Control concerning listeriosis, psittacosis, and Venezuelan equine encephalitis from 1971 to 1973.

PUBLIC SPEAKING

Chaired session at the 102nd Annual Meeting of the APHA in New Orleans on October 22, 1974, entitled "Zoonoses and the Non-White and Poor."

"Public Health and Legal Significance of Drug Residues in Food Animals" presented at the Ninth Annual Symposium, School of Veterinary Medicine, Tuskegee Institute, Alabama, April 9, 1974.

"Environmental Lead Contamination - Effect of Humans, Animals, Soil and Plants" presented at the Annual Epidemic Intelligence Service (EIS) Conference at the Center for Disease Control (CDC) in Atlanta, Georgia on April 9, 1973.

"Equine VEE Vaccination Survey, 1972" presented at the Annual EIS Conference at CDC in Atlanta, Georgia, April 13, 1973.

"The Epidemiology of Animal Bite Cases in the United States" presented at the Eleventh Annual Symposium, School of Veterinary Medicine, Tuskegee Institute, Alabama, April 12, 1976.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

Ex. 2
Moore

August 20, 1976

NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH
9600 FISHERS LANE
ROCKVILLE, MARYLAND 20852

Dear Colleague:

In a June 24, 1976 letter, Mobil Oil Corporation advised the National Institute for Occupational Safety and Health (NIOSH) of a possible association between occupational exposure to polychlorinated biphenyls (PCBs) and cancer in humans. Mobil Oil reported preliminary results of an epidemiologic analysis based on medical records of employees exposed to PCBs at their Paulsboro, New Jersey plant. This study was conducted by Professor Anita K. Bahn (School of Medicine, University of Pennsylvania) and is being reported by Dr. Bahn in a letter to the editor of the New England Journal of Medicine, August 19, 1976.

The study included two cohorts of Mobil employees who were reported to have had varying exposure to Aroclor 1254 (a mixture of PCBs). The cohort of research and development employees was exposed to PCBs between 1949 and 1957 and the cohort of refinery plant employees between 1953 and 1958. The extent of exposure of these workers to other chemicals is not known. The cancer incidence among these workers for the period 1957 through 1975 was determined using Mobil medical records. Because medical records for 37 employees were incomplete, these workers were excluded from this analysis.

Among the 92 workers in these two cohorts for whom adequate medical records were available, eight cancers (in seven workers) were observed between 1957 and 1975. Of these eight cancers, three were malignant melanoma and two were cancer of the pancreas. (This is significantly more skin cancer (melanoma) and pancreatic cancer than would be expected in a population of this size (based on the Third National Cancer Survey).) The remaining cancers were found at three other sites in two employees; sarcoma of the right thigh and multiple myeloma in one employee, and recto-sigmoid cancer in the other.



ADP 008945

Page 2 - Dear Colleague

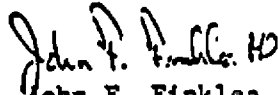
NIOSH is unaware of any other published animal or human data which suggest a correlation between exposure to PCBs and skin (melanoma) or pancreatic cancer. However, hepatomas (mice, Aroclor 1254) and hepatocellular carcinomas (mice, Kanechlor 500; rats, Aroclor 1260) have been reported in PCB feeding studies of laboratory animals.

Background information on PCBs has been summarized in the NIOSH Current Intelligence Bulletin on Polychlorinated Biphenyls issued to the occupational health community on November 3, 1975, and subsequently published in the Journal of Occupational Medicine, Volume 18, pages 109-113, February 1976. Since the NIOSH Bulletin was first issued, a number of large firms have introduced products (e.g., butylated monochlorodiphenyl oxide and dimethyl siloxane polymer) claimed to be fire resistant dielectrics which can serve as alternatives to PCBs. In addition, one of the large domestic transformer manufacturers announced that it will cease using PCBs as fire resistant transformer fluids at the end of this year. NIOSH would like to stress that alternatives for PCBs should be thoroughly studied to assess the consequences they may pose to human health.

To aid in evaluating PCBs as a potential occupational health problem, NIOSH would welcome receiving reports of studies regarding the possible association between exposure to PCBs and human cancer.

Your cooperation in this matter is appreciated.

Sincerely yours,


John F. Finklea, M.D.
Director

ACM C08940



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

AUG 20 1976

August 20, 1976

NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH
3600 FISHERS LANE
ROCKVILLE, MARYLAND 20852

Dr. W. B. Papageorge
Manager, Product Acceptability
Specialty & Process Chemicals
Monsanto Industrial Chemicals Co.
800 N. Lindbergh Boulevard
St. Louis, MO 63166

Dear Colleague:

In a June 24, 1976 letter, Mobil Oil Corporation advised the National Institute for Occupational Safety and Health (NIOSH) of a possible association between occupational exposure to polychlorinated biphenyls (PCBs) and cancer in humans. Mobil Oil reported preliminary results of an epidemiologic analysis based on medical records of employees exposed to PCBs at their Paulsboro, New Jersey plant. This study was conducted by Professor Anita K. Bahn (School of Medicine, University of Pennsylvania) and is being reported by Dr. Bahn in a letter to the editor of the New England Journal of Medicine, August 19, 1976.

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PLAINTIFF'S
EXHIBIT

976

ADM CG8947

Page 2 - Dear Colleague

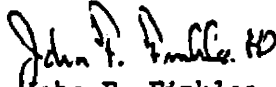
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To aid in evaluating PCBs as a potential occupational health problem, NIOSH would welcome receiving reports of studies regarding the possible association between exposure to PCBs and human cancer.

Your cooperation in this matter is appreciated.

Sincerely yours,


John F. Finklea, M.D.
Director

ADM CCE94E

Mobil Oil Corporation

Copy for J.C. Waber

~~100-101111~~
ODG-GJL

150 EAST 42ND STREET
NEW YORK, NEW YORK 10017

~~File~~ file

June 25, 1976

George Roush, Jr., M.D.
Medical Director
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63166

Dear George:

As of this date I have informed NIOSH of our findings at Mobil's Paulsboro Refinery

Enclosed is a copy of my letter to Dr. Finklea plus a copy of the PCB Research Study done by Dr. Anita Bahn at the University of Pennsylvania.

May I repeat my appreciation of your sharing your data with me.

Cordially yours,

Harry

Harry A. Sinclair, M.D.
Medical Director

HAS:bh

Enclosures



ADM 008949

24 June 1976

Dr. John F. Finklea, Director
National Institute of Occupational
Safety & Health
Parklawn Bldg.
5600 Fisher Lane
Rockville, Maryland 20014

Dear Dr. Finklea:

Enclosed you will find information from one of our employee health surveillance programs that suggests a possible association of exposure to polychlorinated biphenyls (PCB's) during a period from 1949-58 and cancer (specifically, melanoma and pancreatic cancer).

We are aware that at least one of these chlorinated hydrocarbons (Arochlor 1254) has been shown to be carcinogenic by oral administration in two species of experimental animals (mice, rats). To the best of our knowledge, there have been no prior reports implicating human cancer during the manufacture or industrial use of PCB's.

A preliminary evaluation of our small cohort suggests the overall cancer incidence observed is higher than for the population at large, but does not exceed the expected death rate for chemists. However, because of the possible occupational health significance of these preliminary findings, we call this to your attention in connection with your investigation of more extensive and longer term industrial PCB exposure.

Yours truly,

Harry A. Sinclair, M.D.
Medical Director

HAS:jd
Enclosure

PLAINTIFF'S
EXHIBIT

978

ADM C08950

(i) Measure the exposure monthly of the employee so exposed; and
 (ii) Institute control measures as required by paragraph (D) of this section; and

(iii) Individually notify, in writing, within five days, every employee who is found to be exposed to chlorodiphenyl (54 percent chlorine) above the permissible exposure. The employee shall also be notified of the corrective action being taken to reduce the exposure to at or below the permissible exposure.

(7) If two consecutive employee exposure measurements taken at least one week apart reveal that the employee is exposed to chlorodiphenyl (54 percent chlorine) below the action level, the employer may terminate measurement for the employee.

(8) For purposes of this paragraph, employee exposure is that which would occur if the employee were not using a respirator.

(c) Methods of measurement.

(1) An employee's exposure shall be obtained by any combination of long term or short term samples which represents the employee's actual exposure averaged over an eight-hour work shift (See Appendix B (iv) of this section).

(2) The method of measurement shall have an accuracy, to a confidence level of 95%, of not less than that given in Table 1.

Table 1

Concentration

Required Accuracy

Above permissible exposure

$\pm 25\%$

At or below permissible exposure

and above the action level

$\pm 35\%$

At or below the action level

$\pm 50\%$

(d) Compliance. (1) No employee shall be exposed to chlorodiphenyl (54 percent chlorine) above the permissible exposure as defined in paragraph (a) (1) of this section.

(2) Employee exposures to airborne concentrations of chlorodiphenyl (54 percent chlorine) shall be controlled to at or below the permissible exposure by engineering and work practice controls:

(i) Engineering and work practice controls shall be instituted to reduce exposures to at or below the permissible exposure, except to the extent that such controls are not technically feasible.

(ii) Wherever engineering and work practice controls are not sufficient to reduce exposures to at or below the permissible exposure, they shall nonetheless be used to reduce exposure to

the lowest level feasible and shall be supplemented by respirators in accordance with paragraph (d)(4) of this section.

(3) Engineering controls. (i) When mechanical ventilation is used to control exposure, measurements which demonstrate system effectiveness, for example, air velocity, static pressure, or air volume, shall be made at least every three months. Measurements of system effectiveness shall also be made within five days of any change in production, process, or control which might result in an increase in airborne concentrations of chlorodiphenyl (54 percent chlorine).

(ii) Spray finishing operations shall be performed in accordance with § 1910.94(c).

(4) Compliance with the permissible exposure shall not be achieved by the use of respirators except:

(i) During the time period necessary to install or implement engineering or work practice controls; or

(ii) In work situations in which engineering and work practice controls are technically not feasible; or

(iii) To supplement engineering and work practice controls when such controls fail to reduce airborne concentrations of chlorodiphenyl (54 percent chlorine) to at or below the permissible exposure; or

(iv) For operations which require entry into tanks or closed vessels; or

(v) In emergencies.

(5) Where respirators are needed and permitted under this paragraph to reduce employee exposure, the employer shall select and provide the appropriate respirator from Table 2 and shall ensure that the employee uses the respirator provided.

TABLE 2 RESPIRATORY PROTECTION FOR CHLORODIPHENYL (54 PERCENT CHLORINE)

CONDITION	PERMISSIBLE RESPIRATORY PROTECTION
Vapor Concentration	
5 mg/M3 or less	Any supplied-air respirator with a full facepiece, helmet or hood.
	Any self-contained breathing apparatus with a full facepiece.
Greater than 5 mg/M3 or entry and escape from unknown concentrations	Self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode.
	A combination respirator which includes a Type C supplied-air respirator with a full facepiece operated in pressure-demand or other positive pressure or

continuous-flow mode and an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive pressure mode.
(Supplied-air suits may be necessary)

Fire Fighting

Self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode.

Escape

Any gas mask providing protection against pesticides.

Any escape self-contained breathing apparatus.

(6) Respirators shall be approved by the Mining Enforcement and Safety Administration (formerly Bureau of Mines) or by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(7) The employer shall institute a respiratory protection program in accordance with § 1910.134(b), (d), (e), and (f).

(e) Fire and safety. (1) The employer shall familiarize himself with the information contained in the Substance Technical Guidelines (Appendix B of this section) for chlorodiphenyl (54 percent chlorine).

(2) For the purpose of compliance with § 1910.157, chlorodiphenyl (54 percent chlorine) is classified as a Class B fire hazard.

(3) For the purpose of compliance with § 1910.106, liquid chlorodiphenyl (54 percent chlorine) is classified as a Class IIIB combustible liquid.

(4) Sources of ignition such as smoking or open flames are prohibited where chlorodiphenyl (54 percent chlorine) presents a fire or explosion hazard.

(5) Chlorodiphenyl (54 percent chlorine) shall be stored so as not to come in contact with strong oxidizers.

(f) Personal protective equipment. (1) Employers shall provide and ensure that employees use impervious clothing, gloves, face shields (eight-inch minimum) and other appropriate protective clothing necessary to prevent any possibility of skin contact with liquid chlorodiphenyl (54 percent chlorine). Face shields shall comply with § 1910.133(a) (2), (a) (4), (a) (5), and (a) (6).

(2) Employers shall ensure that clothing contaminated with liquid chlorodiphenyl (54 percent chlorine) is placed in closed containers for storage until it can be discarded or until the employer provides for the removal of chlorodiphenyl (54 percent chlorine) from the clothing. If the clothing is to be laundered or otherwise cleaned to remove the chlorodiphenyl (54 percent

chlorine), the employer shall inform the person performing the operation of the hazardous properties of chlorodiphenyl (54 percent chlorine).

(3) Employers shall ensure that non-impervious clothing which becomes contaminated with liquid chlorodiphenyl (54 percent chlorine) be removed promptly and not reworn until the chlorodiphenyl (54 percent chlorine) is removed from the clothing.

(4) Employers shall provide and ensure that employees use splash-proof safety goggles (cup-cover type dust and splash safety goggles) which comply with § 1910.133(a)(2)-(a)(6) where liquid chlorodiphenyl (54 percent chlorine) may contact the eyes.

(g) Spills and disposal. In the event that liquid chlorodiphenyl (54 percent chlorine) is spilled the employer shall immediately provide available ventilation and then clean up the spill.

(h) Sanitation. (1) Employers shall ensure that employees whose skin becomes contaminated with liquid chlorodiphenyl (54 percent chlorine) immediately wash or shower with soap or mild detergent and water to remove any chlorodiphenyl (54 percent chlorine) from the skin.

(2) Employers shall ensure that employees do not eat or smoke in areas where liquid chlorodiphenyl (54 percent chlorine) is handled, processed or stored.

(3) Employers shall ensure that employees who handle liquid chlorodiphenyl (54 percent chlorine) wash their hands thoroughly with soap or mild detergent and water before eating, smoking or using toilet facilities.

(i) Training and information. (1) Each employer who has a workplace in which chlorodiphenyl (54 percent chlorine) is present shall keep a copy of this regulation with Appendixes A, B and C at the workplace. This material shall be made readily available to affected employees.

(2) Each employer who has employees exposed to chlorodiphenyl (54 percent chlorine) above the action level or employees who may have skin or eye contact with liquid chlorodiphenyl (54 percent chlorine), or employees who work where an accidental spill of chlorodiphenyl (54 percent chlorine) may occur, shall annually:

(i) Inform affected employees of the information contained in the Substance Safety Data Sheet for chlorodiphenyl (54 percent chlorine) (Appendix A of this section);

(ii) Advise affected employees as to the signs and symptoms of exposure to chlorodiphenyl (54 percent chlorine).

(iii) Instruct affected employees to advise the employer of the development of signs and symptoms of exposure to chlorodiphenyl (54 percent chlorine) which are listed in Appendix A of the section; and

(iv) Provide training to ensure that employees understand the precautions of safe use, emergency procedures, and the correct use of protective equipment relative to chlorodiphenyl (54 percent chlorine).

(j) Medical surveillance. (1) The employer shall provide medical procedures as required by this paragraph. All medical procedures shall be performed by or under the supervision of a physician at no cost to the employee.

(2) The employer shall make available to each employee who is to be exposed to liquid chlorodiphenyl (54 percent chlorine) or airborne concentrations of chlorodiphenyl (54 percent chlorine) at or above the action level, without regard to the use of respirators, a medical examination which shall include the following:

(i) A medical history and physical examination with emphasis on the liver and skin.

(ii) A profile of liver function.

(3) The employer shall obtain from the physician, as a record of the examination, the following information:

(i) A written opinion which conforms with paragraph (j) (7) of this section.

(ii) A record of results of liver function tests.

(4) The employer shall make available to each employee, exposed to chlorodiphenyl (54 percent chlorine) in excess of the action level at 12 months from the date of the employee's first exposure, and at every 12 months of exposure in excess of the action level thereafter, a medical examination which must include the following:

(i) A medical history and physical examination (see paragraph (j) (2) (i) of this section).

(ii) Tests of liver function (see paragraph (j) (2) (ii) of this section).

(5) The employer shall obtain from the physician, as a record of the periodic examination, the following information:

(i) A written opinion which conforms with paragraph (j) (7) of this section.

(ii) A record of results of liver function tests.

(6) The employer shall provide to the examining physician the following information:

(i) A copy of this regulation with its Appendixes A, B, and C for chlorodiphenyl (54 percent chlorine);

(ii) A description of the employee's duties as they relate to his exposure to chlorodiphenyl (54 percent chlorine);

(iii) A description of any personal protective equipment and respirators required to be used;

(iv) The results of any measurement which may indicate the affected employee's exposure;

(v) The affected employee's anticipated exposure; and

(vi) Upon request of the physician, any available information from previous medical examination of the affected employee.

(7) (i) The physician's written opinion shall be a signed statement by the examining physician specifically stating: (A) Whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of the employee's health from exposure to chlorodiphenyl (54

percent chlorine) or would directly or indirectly aggravate any detected medical condition;

(B) Any recommended limitations upon the employee's exposure to chlorodiphenyl (54 percent chlorine), including limitations upon the use of personal protective equipment and respirators;

(C) That the employee has been informed by the physician of any detected medical conditions which require further medical examination or treatment.

(ii) The physician's written opinion shall not reveal specific medical findings or diagnoses unrelated to exposure to chlorodiphenyl (54 percent chlorine).

(iii) The employer shall provide the employee with a copy of the physician's written opinion.

(8) No employee shall be exposed to liquid chlorodiphenyl (54 percent chlorine) or airborne concentrations of chlorodiphenyl (54 percent chlorine) in such a way as would put the employee at increased risk of material impairment of his health from such exposure. This determination may be based on the physician's written opinion.

(9) The employer shall provide emergency and follow up medical examinations and treatment for any employee injured through exposure to chlorodiphenyl (54 percent chlorine).

(10) If the examining physician chooses to use alternative medical examinations to those specified in paragraphs (j) (2) and (4) of this section, the employer may accept such alternative medical surveillance examinations as meeting the requirements of this part provided that the employer:

(i) Obtains a statement from the examining physician setting forth the alternative medical examinations and the rationale for substitution and evidence that they will be equally effective.

(ii) Informs each exposed employee of the fact that alternative medical examinations to those required in paragraphs (j) (2) or (4) of this section are to be made available.

(11) If an employee refuses any required medical examination, the employer shall inform the employee of the possible health consequences of such refusal and obtain a signed statement from the employee indicating that the employee understands the risks involved by refusing to be examined.

(12) No medical procedure which would be performed pursuant to this section need be performed if records of a previous such procedure performed within the past six months are acceptable to the examining physician.

(k) Recordkeeping. (1) Exposure determination. (i) The employer shall keep an accurate record of all determinations required to be made pursuant to paragraph (b) (1) of this section.

(ii) The record shall include the written determination required in paragraph (b) (2) of this section.

(iii) This record shall be maintained until replaced by a more recent record.

(2) Exposure measurements. (i) The employer shall keep an accurate record of all measurements taken to determine employee exposure to chlorodiphenyl (54 percent chloride).

(ii) This record shall include:

(A) The date of measurement;

(B) Operations involving exposure to chlorodiphenyl (54 percent chloride) which are being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy, including the method, results and date of calibration of sampling equipment;

(D) Number, duration, and results of samples taken; and

(E) Name, social security number and exposure of the employee monitored.

(iii) This record shall be maintained until replaced by a more recent record but in no event for less than one year.

(3) Mechanical ventilation. (i) When mechanical ventilation is used as an engineering control, the employer shall maintain an accurate record of the measurements demonstrating the effectiveness of such ventilation required by paragraph (d) (3) of this section.

(ii) This record shall include:

(A) Date of measurement;

(B) Type of measurement taken;

(C) Result of measurement.

(iii) These records shall be maintained for at least one year.

(4) Employee training and information. (i) The employer shall keep an accurate record of all employee training and information required by paragraph (i) of this section.

(ii) This record shall include:

(A) Date of training;

(B) Name and social security number of employee trained;

(C) Content or scope of training provided.

(iii) This record shall be maintained until replaced by a more recent record.

(5) Medical surveillance. (i) The employer shall keep an accurate record of employee medical surveillance required by paragraph (j) of this section.

(ii) The record shall include:

(A) Results of tests required by paragraph (j) (2) and (j) (5) of this section;

(B) Any employee medical complaints relative to exposure to chlorodiphenyl (54 percent chloride);

(C) A copy of information provided to the physician pursuant to paragraph (j) (6) (ii), (iii), (iv), (v), and (vi) of this section.

(D) Physician's written opinion; and

(E) A signed statement of any refusal to be examined.

(iii) This record shall be maintained for the duration of the employment of the affected employee.

(6) Access to records. (i) All records required to be maintained by this section shall be made available upon request to authorized representatives of the Assistant Secretary of Labor

for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health.

(ii) Employee exposure determination and exposure measurement records required to be maintained by this section shall be made available to employees and former employees and their designated representatives.

(iii) Employee medical records required to be maintained by this section shall be made available upon written request to a physician designated by the employee or former employee.

(1) Employee observation of measurement. (1) The employer shall give affected employees or their representatives an opportunity to observe any measurement of employee exposure to chlorodiphenyl (54 percent chloride) which is conducted pursuant to this section.

(2) When observation of measurement of employee exposure to chlorodiphenyl (54 percent chloride) requires entry into an area where the use of personal protective devices, including respirators, is required, the observer shall be provided with and required to use such equipment and comply with all other applicable safety procedures.

(3) Without interfering with the measurement, observers shall be entitled to:

(i) Receive an explanation of the measurement procedure.

(ii) Visually observe all steps related to the measurement of the airborne concentration of chlorodiphenyl (54 percent chloride) that are being performed at the place of exposure; and

(iii) Record the results obtained.

NOTE: The information contained in the following appendixes is advisory in nature and is not intended, by itself, to create any additional obligations not otherwise imposed or detract from any existing obligation.

APPENDIX A

SUBSTANCE SAFETY DATA SHEET
FOR CHLORODIPHENYL (54 percent chlorine)

- I. SUBSTANCE IDENTIFICATION
- A. Substance: Chlorodiphenyl (54 percent chlorine)
 - B. Permissible Exposure: 0.5 milligram of chlorodiphenyl (54 percent chlorine) per cubic meter of air (mg/cu m) averaged over an eight-hour work shift.
 - C. Appearance and Odor: Pale yellow viscous liquid with mild hydrocarbon odor.
- II. HEALTH HAZARD DATA
- A. Ways in Which the Chemical Affects Your Body: Chlorodiphenyl (54 percent chlorine) can affect your body if you inhale it or if it comes in contact with your eyes and skin or if you swallow it. It may be absorbed through the skin. Every effort should be made to prevent skin, eye, oral or inhalation contact with this material.
 - B. Effects of Overexposure:
 - 1. Chlorodiphenyl (54 percent chlorine) may cause irritation the eyes, nose and throat, and an acne-like skin rash. It may also injure your liver resulting in such effects as fatigue, dark urine and yellow jaundice. Repeated skin contact with the liquid may cause skin irritation.
 - 2. Reporting Signs and Symptoms: You should inform your employer if you develop any signs or symptoms and suspect they are caused by exposure to chlorodiphenyl (54 percent chlorine).
- III. EMERGENCY FIRST AID PROCEDURES
- A. Eye Exposure: If chlorodiphenyl (54 percent chlorine) gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.
 - B. Skin Exposure: If chlorodiphenyl (54 percent chlorine) gets on your skin, immediately wash the contaminated skin using soap or mild detergent and water. If chlorodiphenyl (54 percent chlorine) soaks through your clothing, remove the clothing immediately and wash the skin using soap or mild

detergent and water. If irritation persists after washing, get medical attention.

- C. Breathing: If you or any other person breathes in large amounts of chlorodiphenyl (54 percent chlorine), move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.
- D. Swallowing: When chlorodiphenyl (54 percent chlorine) has been swallowed get medical attention immediately. If medical attention is not immediately available get the affected person to vomit by having him touch the back of the throat with his finger or by giving him large amounts (one pint or more) of warm salt water (two tablespoons of salt per pint of water). Do not make an unconscious person vomit.
- E. Rescue: Move affected person from the hazardous exposure. If the exposed person has been overcome, notify someone else and put into effect the established emergency rescue procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the locations of the equipment before the need arises.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

- A. Respirators: Respirators are not the best way to control exposure to chlorodiphenyl (54 percent chlorine). You can only be required to wear them for routine use if your employer is in the process of installing controls or control measures prove inadequate. You may be required to wear respirators for non-routine activities or in emergencies. If respirators are worn, they must have a Mining Enforcement and Safety Administration (MESA) or National Institute for Occupational Safety and Health (NIOSH) approval label. (Older respirators may have a Bureau of Mines approval label.) For effective protection, respirators must fit your face and head snugly. Respirators should not be loosened or removed in work situations where their use is required. If you can smell chlorodiphenyl (54 percent chlorine) while wearing a respirator, the respirator is not working correctly; go immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.
- B. Supplied-air suits: In some work situations the wearing of supplied-air suits may be required. Your employer should instruct you in their proper use and operation.

- C. Protective Clothing: You must wear impervious clothing, gloves, face shield or other appropriate protective clothing to prevent any possibility of skin contact with liquid chlorodiphenyl (54 percent chlorine). Replace or repair impervious clothing that has developed leaks.
- D. Eye Protection: You must wear splash-proof safety goggles (cup-cover type dust and splash safety goggles) where eye contact to liquid chlorodiphenyl may occur.
- V. PRECAUTIONS FOR SAFE USE, HANDLING AND STORAGE
 - A. Chlorodiphenyl (54 percent chlorine) is a combustible liquid and its vapors can form explosive mixtures with air at elevated temperatures.
 - B. Chlorodiphenyl (54 percent chlorine) must be stored in tightly closed containers in a cool, well ventilated area away from heat, sparks, flames and strong oxidizers.
 - C. Sources of ignition such as smoking and open flames are prohibited wherever chlorodiphenyl (54 percent chlorine) is handled, used or stored in a manner that could create a potential fire or explosion hazard.
 - D. If your skin becomes contaminated with liquid chlorodiphenyl you must immediately wash or shower using soap or mild detergent and water to remove any chlorodiphenyl (54 percent chlorine) from the skin.
 - E. You must promptly remove any non-impervious clothing that becomes contaminated with liquid chlorodiphenyl (54 percent chlorine) and this clothing must not be reworn until the chlorodiphenyl (54 percent chlorine) is removed from the clothing.
 - F. You must not eat or smoke in areas where liquid chlorodiphenyl (54 percent chlorine) is handled, processed or stored.
 - G. If you handle liquid chlorodiphenyl (54 percent chlorine), you must wash your hands thoroughly with soap or mild detergent and water before eating, smoking or using toilet facilities.
 - H. Fire extinguishers, where provided, must be readily available and you should know where they are and how to operate them.
 - I. Ask your supervisor where chlorodiphenyl (54 percent chlorine) is used in your work area and for any additional plant safety and health rules.
- VI. ACCESS TO INFORMATION
 - A. Each year your employer is required to inform you of the information contained in this Substance

Safety Data Sheet for chlorodiphenyl (54 percent chlorine). In addition, your employer must instruct you in the safe use of chlorodiphenyl (54 percent chlorine), emergency procedures, and the correct use of protective equipment.

- B. Your employer is required to determine whether you are being exposed to chlorodiphenyl (54 percent chlorine). You or your representative have the right to observe employee exposure measurements and to record the results obtained. If your employer determines that you are being overexposed, he is required to inform you of the exposure and of the actions which are being taken to reduce your exposure.
- C. Your employer is required to keep records of exposure determinations, exposure measurements, and medical surveillance. Your employer is required to make records of exposure determinations and your exposure measurements available to you or your representative upon your request. Your employer is required to release your medical records to your physician upon your written request.

APPENDIX B

SUBSTANCE TECHNICAL GUIDELINES
FOR CHLORODIPHENYL (54 percent CHLORINE)

I. PHYSICAL AND CHEMICAL DATA

A. Substance Identification

1. Synonyms: Polychlorinated biphenyl; PCB
2. Formula: $C_{12}H_5Cl_5$ (approximately)
3. Molecular weight: 326 (approximately)

B. Physical Data

1. Boiling point (760 mm Hg): 365 - 390 C (689 - 734 F)
2. Specific gravity (Water = 1): 1.5
3. Vapor density (air = 1 at boiling point of chlorodiphenyl (54 percent chlorine): 11.2
4. Melting point: 10 C (50 F) (Pour point)
5. Vapor pressure at 20 C (68 F): 0.00006 mm Hg
6. Solubility in water, % by weight at 20 C (68 F): insoluble
7. Evaporation rate (butyl acetate = 1): much less than 1
8. Appearance and odor: Pale yellow viscous liquid with mild hydrocarbon odor.

II. FIRE, EXPLOSION AND REACTIVITY HAZARD DATA

A. Fire

1. Flash point: 222 C (432 F)
2. Autoignition temperature: none to boiling point
3. Flammable limits in air, % by volume: not available
4. Extinguishing media: Foam, dry chemical, carbon dioxide
5. Special fire-fighting procedures: Do not use a solid stream of water since a stream will scatter and spread the fire. Use water spray to cool containers exposed to a fire.
6. Unusual fire and explosion hazards: Liquid chlorodiphenyl (54 percent chlorine) is a combustible liquid. At elevated temperatures its vapors can form explosive mixtures with air. All ignition sources must be controlled when chlorodiphenyl (54 percent chlorine) is used, handled stored in a manner that may create a potential fire or explosion hazard.
7. For purposes of complying with the requirements of 29 CFR 1910.106, liquid chlorodiphenyl (54 percent chlorine) is classified as a Class IIIB combustible liquid.

B. Reactivity

1. Conditions contributing to instability: Heat
2. Incompatibilities: Contact with strong oxidizers may cause fires and explosions.

3. Hazardous decomposition products: Toxic gases and vapors (such as hydrogen chloride and carbon monoxide) may be released in a fire involving chlorodiphenyl (54 percent chlorine).

4. Special precautions: Chlorodiphenyl (54 percent chlorine) will attack some forms of plastics, rubber and coatings.

III. SPILL, LEAK, AND DISPOSAL PROCEDURES

A. If chlorodiphenyl (54 percent chlorine) is spilled or leaked, the following steps should be taken:

1. Remove all ignition sources.
2. Ventilate area of spill or leak.
3. Collect for reclamation or absorb in vermiculite, dry sand, earth or a similar material.

B. Persons not wearing protective equipment should be restricted from areas of spills or leaks until cleanup has been completed.

C. Waste disposal methods: Chlorodiphenyl (54 percent chlorine) may be disposed of by absorbing in vermiculite, dry sand, earth or a similar material and disposing in a secured sanitary landfill.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. Exposure above the action level: Measurements taken for the purpose of determining employee exposure under this section are best taken such that the average 8-hour exposure may be determined from a single eight-hour sample or two (2) 4-hour samples. Several short time interval samples (up to 30 minutes) may also be used to determine the average exposure level. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee). Sampling and analyses may be performed by instruments such as detector tubes certified by NIOSH under 42 CFR part 84. Portable direct-reading instruments, dosimeters, or gas and vapor adsorption tubes with subsequent chemical analyses. The method of measurement must determine the concentration of chlorodiphenyl (54 percent chlorine) to plus or minus 35%.

B. Exposure above the permissible exposure: The monitoring and measurements under this section should be essentially the same as described under paragraph (IV) (A). Laboratories performing chemical analyses should be accredited in Industrial Hygiene Chemistry by the American Industrial Hygiene Association. The method of measurement must determine the concentration of

chlorodiphenyl (54 percent chlorine) to plus or minus 25%.

- C. Methods: Methods meeting the above accuracy requirements are available from NIOSH.
- D. Qualified Persons: Since many of the duties relating to employee protection are dependent on the results of monitoring and measuring procedures, employers should assure that the evaluation of employee exposures is performed by a competent industrial hygienist or other technically qualified person.

V. MISCELLANEOUS PRECAUTIONS

- A. Store chlorodiphenyl (54 percent chlorine) in tightly closed containers in a well ventilated area away from heat.
- B. Employers should advise employees of all areas and operations where exposure to chlorodiphenyl (54 percent chlorine) could occur.

VI. COMMON OPERATIONS

Common operations in which exposures to chlorodiphenyl (54 percent chlorine) is likely to occur are: during its use as a transformer fluid; for impregnating papers, cloths, etc. for heat, moisture and chemical resistance properties; as a heat transfer fluid, lubricant, and wax extender; in the compounding of sealing compounds and printing inks; as a plasticizer; in the manufacture of insecticides, pesticides and fungicides; in cutting oils; and during its production.

APPENDIX C - MEDICAL SURVEILLANCE GUIDELINES

I. ROUTE OF ENTRY

Inhalation; skin absorption.

II. TOXICOLOGY

Chlorodiphenyl (54 percent chlorine) vapor is toxic to the liver. Rats exposed to 5.4 mg/m³ for 7 hours daily for 4 months showed increased liver weight and injury to liver cells; 1.5 mg/m³ for 7 months also produced histopathologic evidence of liver damage which was considered to be of a reversible character. The vapor and the liquid are moderately irritating to the eye; contact with skin leads to removal of natural fats and oils with subsequent drying and cracking of the skin. A single case of an acne-form dermatitis (chloracne) due to exposure to chlorodiphenyl of unspecified chlorine content has been reported but the period of exposure was not indicated.

III. SIGNS AND SYMPTOMS

Eye and skin irritation; acne-form dermatitis; based on animal data it may cause liver injury.

IV. SPECIAL TESTS

None in common usage.

V. TREATMENT

Remove from exposure. Flush eyes with water and wash skin with soap and water. If swallowed and the person is conscious, induce vomiting. Give artificial resuscitation if indicated. Recovery is usually rapid and complete.

VI. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. GENERAL

Most reported effects of chlorodiphenyl (54 percent chlorine) are caused by its capacity to affect the liver and produce an acne-form dermatitis. Skin absorption occurs. It is important that the physician becomes familiar with plant operating conditions in which exposure to chlorodiphenyl (54 percent chlorine) occurs. Those with skin disease may not tolerate the wearing of

protective clothing and those with chronic respiratory disease may not tolerate the wearing of negative pressure respirators.

B. PREPLACEMENT

The following medical procedures must be made available to each employee who is exposed to chlorodiphenyl (54 percent chlorine): chlorine:

1. A complete history and physical examination -- The purpose is to detect preexisting conditions that might place the exposed employee at increased risk, and to establish a baseline for future health monitoring. Examination of liver and skin should be stressed.
2. Liver function tests -- Chlorodiphenyl (54 percent chlorine) may cause liver damage. A profile of liver function shall be obtained by utilizing a medically acceptable array of biochemical tests.

C. PERIODIC EXAMINATIONS

The above medical examinations are to be repeated on an annual basis.

References

1. American Conference of Governmental Industrial Hygienists: "Chlorodiphenyl, 54 percent Chlorine," Documentation of the Threshold Limit Values for Substances in Workroom Air (3d ed., 2d printing), Cincinnati, 1974, p. 52.
2. Hygienic Guide Series: "Chlorodiphenyls," American Industrial Hygiene Association Journal, 26:92-94, 1965.
3. Olivier, N.: "Chloracne," Archives of Dermatology, 99: 127-128, 1969.