EPA

Toxic Substances Control Act

Compliance/Enforcement Guidance Manual

Policy Compendium

U.S. Environmental Protection Agency
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and

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United States
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Pesticides and
Toxic Substances
Enforcement Division

EPA

Enforcement Facts and Strategy

PCB
Interim Measures Program

Enforcement Facts and Strategy
Polychlorinated Biphenyls (PCBs)
Interim Measures Program
August, 1981

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Background

In 1979, the Environmental Defense Fund brought a lawsuit in the U.S. Court of Appeals for the District of Columbia against the U.S. Environmental Protection Agency (EPA) regarding the PCB Ban Rule (40 CFR 761). The Court's decision on October 30, 1980, set aside the portion of the PCB rule which classifies the use of intact, non-leaking, PCB-containing transformers, capacitors, and electromagnets as uses of PCBs in a "totally enclosed manner." Since use of PCBs in other than a totally enclosed manner is unlawful under Section 6(e) of the Toxic Substances Control Act (TSCA) without an authorization from the Administrator, the Court ruling makes continued use of PCB-containing transformers, capacitors, and electromagnets illegal.

Because the effect of this decision would have seriously disrupted the distribution of electricity in this country, representatives of the electric utilities, chemical industry, Environmental Defense Fund, and EPA worked together to develop an Interim Measures Program. They petitioned the Court to stay its mandate for those who comply with the Interim Measures Program until the Agency is able to develop appropriate amendments to the PCB regulation. The Court granted the stay on February 12, 1981, leaving provisions of the PCB rule that the Court's decision had set aside still in effect for those who comply with the Interim Measures Program.

Under the Interim Measures Program, owners of certain PCB units must visually inspect them, record all leaks, and begin repair of any moderate leaks within two days of discovery. PCB and PCB-contaminated transformers posing an exposure risk to food and feed products must be visually inspected by their owners at least once a week, and any moderate leaks found must be reported to EPA within five days of discovery. All other PCB transformers must be visually inspected by their owners at least once every three months. The Program became effective on May 11, 1981.

A notice detailing the background and requirements of the Interim Measures Program was published in the Federal Register on March 10,1981. A notice clarifying certain aspects of the Program was published in the May 20, 1981 Federal Register.

Regulated Community

There are an estimated 140,000 PCB transformers still in service or in storage for reuse. Approximately one-third of these transformers are used by the electric utility industry; the other two-thirds are distributed among general industrial facilities and commercial buildings. Leaks from these transformers may result in PCB contamination of the environment. The estimated 3,600 PCB transformers and larger number of PCB-contaminated transformers in use in food and feed products facilities are particularly sensitive because leaks could result in widespread human or animal exposure.

All owners of PCB transformers and PCB-contaminated transformers which pose an exposure risk to food or feed products and owners of all other PCB transformers are subject to the requirements of the Interim Measures Program.

Summary of Requirements

Definitions

The definitions in the PCB Ban Rule (40 CFR Part 761) apply to the Interim Measures Program unless they are inconsistent with the definitions set forth below.

"Leak" means any instance in which a PCB unit has any quantity of PCBs on any portion of its external surface.

"Moderate leak" means any leak which results in any quantity of PCBs running off or about to run off the external surface of the PCB unit.

"PCB unit" means any PCB transformer or PCB-contaminated transformer in use or in storage for reuse.

"PCB unit posing an exposure risk to food and feed products" means a PCB unit used by a federally inspected meat, poultry product, or egg product establishment, or in a facility manufacturing, processing, packaging, or holding human food or animal feed, unless the PCB unit is in a location where a discharge of the dielectric fluid cannot contaminate the food and feed products or processes. The definition excludes retail establishments such as grocery stores and restaurants.

"Servicing" means repairing and cleaning or replacing the PCB unit to eliminate the source of the leak. Cleaning of the PCB unit means removing any unsolidified dielectric fluid on its external surface.

"Visual inspection" means to investigate for a leak of dielectric fluid on or around the PCB unit. Such inspection should not require shutdown of the unit being inspected, and the extent of the inspection will depend on the physical constraints of each PCB unit installatio-

PCB Units in Food and Feed Facilities

For PCB units (that is, PCB transformers or PCB-contaminated transformers) posing an exposure risk to food and feed products, the owner* must:

- Perform a visual inspection of each PCB unit at least once a week.
- Record all leaks.
- Begin servicing moderate leaks within two business days of observation of the leak.
- Report in writing all moderate leaks to the appropriate EPA Regional office. Reports must contain:
  - -- The location of the moderate leak;
  - -- The date the leak was observed;
  - -- An estimate of the extent of the leak; and
  - -- A description of the servicing performed, including dates.
- Maintain records containing inspection/servicing history for a period of three years, and make them available, upon request, to EPA. Records must contain the following information for each PCB item:
  - -- Its location;
  - -- The date of each inspection, including an identification of the person who performed it;
  - -- All leaks observed, the dates observed, and whether they were moderate leaks; and
  - -- A description of all servicing of the unit undertaken since the date of the first inspection under the Interim Measures Program, including dates of the servicing.

*NOTE: The user of a PCB unit posing an exposure risk to food or feed products must notify the owner of the unit that it is in a food and feed facility, and is responsible for compliance with the Interim Measures Program until he so notifies.

If the user fails to notify, the owner (e.g., the utility company) is not obligated to perform the compliance activities until the firm has other knowledge that the user's establishment is a food or feed facility with a PCB unit posing an exposure risk to food or feed products.

If a user informs the owner that a PCB unit may pose an exposure risk to food or feed products, the owner must make a determination, by inspection or other inquiry, whether the unit poses an exposure risk and is consequently subject to the weekly inspection requirement. Any PCB transformer (above 500 ppm PCBs) which is determined not to pose an exposure risk to food or feed products is subject to the quarterly inspection requirements for all PCB transformers.

All Other PCB Transformers in Use or Storage for Reuse

Owners of all other PCB transformers in use or storage for reuse (those which do not pose an exposure risk to food or feed products) must meet the inspection, servicing, and recordkeeping requirements set out above, but only with regard to PCB transformers. The visual inspections of PCB transformers in this category must be performed at least once every three months instead of at least once a week. No reporting of moderate leaks to EPA Regional offices is required.

Violations

As indicated earlier, the Court's decision invalidated that portion of EPA's regulations which characterized transformers, capacitors, and electromagnets as "totally enclosed." Since these uses of PCBs are not authorized, they would now be a violation of Section 6(e) of the Toxic Substances Control Act if the Court had not issued a stay of its decision. However, the Court stayed its decision only for those people who institute the Interim Measures Program. Accordingly, any person who does not comply with all of the requirements of the Interim Measures Program is using PCBs in violation of the prohibition in Section 6(e) of TSCA. The following is a list of the various ways in which the requirements of the Interim Measures Program can be violated.

- Failure to perform visual inspections. Since performing visual inspections is a prerequisite to performing other Program requirements, a company which fails to inspect some or all of its subject PCB units will also be in violation of the other requirements for the uninspected units. PCB and PCB-contaminated transformers are subject to the weekly inspection requirements if an exposure risk is posed to food or feed; all other PCB transformers are subject to the quarterly inspection requirements regardless of where the transformers are located.

  Variations of this violation category include:

  - Performing no visual inspections.
  - Performing visual inspections on only some of the subject PCB units.
  - Performing visual inspections at greater than the intervals specified.

- Failure to record all leaks. Included in this violation category are:

  - Not recording any leaks.
  - Recording only moderate leaks.
  - Not noting in records whether leaks are moderate.

- Failure to initiate servicing of moderate leaks within two business days of discovery. This violation category includes:
  - Not servicing moderate leaks at all.
  - Servicing only some moderate leaks.
  - Not adequately repairing the source of the moderate leak or cleaning the external surface of the PCB unit.
  - Initiating servicing of moderate leaks later than two business days of discovery.

- Failure to report moderate leaks to EPA within five business days of discovery (PCB units posing an exposure risk to food or feed products only). Variations of this violation category include:
  - Not reporting any moderate leaks.
  - Not reporting some moderate leaks.
  - Reporting moderate leaks to EPA later than five business days of discovery.
  - Providing incomplete information in the report to EPA.

- Failure to maintain required records. This category includes:
  - Maintaining no records.
  - Maintaining incomplete records.
  - Not initiating maintenance of records on the effective date of the Interim Measures Program.

- Falsification of reports or records.

Enforcement Objectives

As in the overall PCB enforcement program, the key objective of the strategy for enforcement of the Interim Measures Program is to ensure the proper disposal of PCBs and thereby prevent the risk of environmental contamination by PCBs.

Since moderate leaks, that is, those which are running off or about to run off the external surface of the PCB item, constitute improper disposal and could result in environmental contamination, EPA is especially concerned that such leaks be detected and repaired in a timely manner. The inspection and servicing requirements of the Interim Measures Program are designed to ensure that this occurs, while the reporting and recordkeeping requirements allow EPA to monitor compliance as well as gather additional information on the frequency and seriousness of PCB leaks.

Because the program was developed as a result of a court case and not as a result of a rulemaking activity, the first phase of implementation will involve wide-reaching efforts to inform the regulated community of the requirements. To augment publication of the Federal Register notice, efforts will be made to notify various industry categories through appropriate trade association and other communication channels.

Compliance monitoring will be directed initially at the utility and food and feed industries. The utility industry was selected because it controls approximately one-third of the PCB transformers, was a party to the development of the Interim Measures Program, and can be expected to be aware of the Program's requirements. The food and feed industry was selected because of the potential for human exposure to PCBs that could occur from leaks or spills which result in contamination of food or feed. Since the utilities own a large percentage of the transformers used by food and feed facilities under rental agreements with the utility companies, the compliance monitoring effort directed at utilities will extend to many food and feed facilities as well. Additional compliance monitoring will be directed toward food and feed establishments specifically.

In addition to the special compliance monitoring program for utilities and food and feed facilities, EPA will incorporate determination of compliance with the Interim Measures Program into its regular inspection program for enforcement of the PCB rule. These inspections are conducted under the neutral administrative inspection scheme developed for PCB rule compliance monitoring activities in the overall PCB enforcement strategy.

In some instances, reports or records of moderate leaks referred to the Agency under the Interim Measures Program requirements may indicate the potential for significant environmental contamination. Consequently, each moderate leak report will be evaluated by the Agency to determine if any followup response is needed to ensure adequate cleanup of the affected area. When food and feed establishments are involved, EPA will notify other appropriate Federal and State agencies to ensure that no contaminated products are entered into commerce.

As mentioned previously, moderate leaks of PCBs constitute improper disposal as defined in the PCB rule, and must be cleaned up in accordance with the requirements of that rule. The fact that a moderate leak has been reported to the Agency and the source of the leak repaired does not remove this liability, and failure to properly clean up is subject to the same penalties, defined in the overall PCB penalty policy, as would any other PCB spill. Penalties to be assessed for failure to comply with the inspection, repair, reporting, and recordkeeping requirements of the Interim Measures Program are discussed in a supplement to the PCB penalty policy.

Compliance Monitoring

Compliance monitoring for the Interim Measures Program is divided into two parts: a routine compliance monitoring program consisting of inspections conducted across the range of industrial categories subject to the requirements, and a records review effort directed specifically at the utility and food and feed industries.

Routine Compliance Monitoring

Routine on-site inspections for compliance with the PCB rule will continue in accordance with the neutral administrative inspection scheme developed by the Regions under the overall PCB enforcement strategy which identifies the major industrial categories controlling the vast majority of PCB equipment. The routine inspections will incorporate record checks to determine compliance with the Interim Measures Program as an element of regular PCB rule inspection procedures.

Utility companies and food and feed establishments have the highest priority for compliance efforts under the Interim Measures Program. However, many utility companies and food and feed establishments have been inspected during the past two years to determine compliance with the PCB rule. Because of limited Agency resources and the need to move forward with inspections in other segments of the regulated community, on-site re-inspections will not be scheduled specifically to determine compliance with the Interim Measures Program. Such companies may be re-inspected, however, if they are selected for on-site inspection through the Region's neutral administrative inspection scheme or for followup inspection due to previous violations. In such instances, compliance with the Interim Measures Program will be determined as part of the routine PCB rule inspection.

Records Review

In addition to the routine compliance monitoring effort for all industry categories subject to PCB rule requirements, a special effort will be directed at utilities and food and feed facilities because of the high priority given to ensuring compliance in these industries. This effort will consist of mailing letters requesting submission of records required by the Interim Measures Program for review in the Regional office. On-site inspections may be scheduled as a followup to this review.

- o Utility Facilities

  Each EPA Regional office should develop a formula for random selection of approximately five percent of utility company facilities in the Region. Then, letters should be sent to the parent utility companies, by certified mail, requesting submission of the records required under the Interim Measures Program as well as a copy of the annual document required by the PCB rule.

  The request should specify the facility(ies) for which records are sought, and the time period to be covered by the records submitted. By asking for different time periods at each facility the possibility of falsification of records is reduced while reducing the total number of records submitted.

If a utility company fails to respond by the specified date, a subpoena will be issued to secure the records. If the company still does not produce the records, a further investigation will be initiated to determine if the company has conducted the required inspections and servicing.

The facilities selected for records review should be divided into batches to receive mailings at different times during the year. The first series of letters to utility companies requesting records should not be mailed until mid-November, 1981, to allow sufficient time for at least two company-conducted inspections of each PCB transformer. (The first quarterly inspection should have been completed by August 10, 1981.)

o Food and Feed Facilities

In many instances, transformers located in food and feed facilities are actually owned by the local utility company. It is the owner who is responsible for compliance with the Interim Measures Program. Consequently, obtaining records for review requires a two-step process: first, identifying the owner of any PCB units in a food and feed facility subject to the requirements; and second, requesting the desired records.

Using lists of facilities provided by the Food and Drug Administration and the Department of Agriculture's Food Safety and Quality Service, the Region should randomly select five percent of the food and feed establishments in the Region where PCB units may be located.

If the Region has knowledge that a selected food or feed facility owns its own transformers, a letter should be sent requesting the annual document and required records covering approximately one month of weekly inspections. If there is no response, the procedures described for utility companies should be followed.

If the Region is unsure of the ownership of transformers at a selected food or feed facility, the letter to the facility should request submission of records and annual documents by those facilities owning their own transformers or the identity of the owner (e.g., the utility company) for those who do not. When the response is an identification of the owner, the Region should send a second letter to the owner requesting submission of the records and annual document.

The food and feed facilities selected for records review should be divided into batches to receive mailings at different times during the year. The first letters requesting annual documents and records from food and feed facilities can be sent as soon as the Region is ready to do so

since the weekly inspection requirement has been in effect for several months. (The first weekly inspection should have been completed by May 18, 1981.)

It should be noted that a food and feed facility may respond that it does not have any transformers subject to the requirements. Only PCB and PCB-contaminated transformers posing an exposure risk to food or feed products must be inspected weekly. All other PCB transformers (but not PCB-contaminated) at food and feed establishments must be inspected quarterly, regardless of where the transformers are located.

o Conducting the Records Review

The records submitted in response to the mailing will be reviewed, and some companies may be selected from this group for further investigation. In addition to evaluating records for completeness, dates of visual inspections and servicing will be checked to see if they were performed within the required timeframes. The number of transformers in the annual document will be checked against the number of transformers for which there are records of inspections.

Records from food and feed establishments will be checked for discrepancies between the information in the records regarding moderate leaks and what was (or was not) reported to EPA as required. If any company's records show an unusually high or low incidence of leaks or apparent inaccuracies or other deficiencies, the company may be selected for further investigation, possibly including an on-site inspection.

o Evaluation

To assist in measuring the effectiveness of the Interim Measures Program and the enforcement strategy, Regions should provide to the Pesticides and Toxic Substances Enforcement Division summaries based on their review of records submitted by the utility companies.

The summaries will show response rate to the requests for records, rate of compliance with individual requirements of the Program, and an analysis of the frequency of moderate leaks. Information from on-site inspections may also be included.

A format for preparing the summaries will be provided to the Regions by the Pesticides and Toxic Substances Enforcement Division. The summaries should be submitted at the end of the third quarter of FY 1982.

Interagency Cooperation

The Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Quality Service (FSQS) also have regulatory jurisdiction at food and feed establishments and independently carry out compliance monitoring efforts under their own programs. Because potential PCB contamination of food and feed products is also of interest to these agencies, the Regions are encouraged to develop a cooperative program to foster compliance with the Interim Measures Program.

Following is a suggested framework for such a cooperative effort which may be adapted as appropriate, depending upon Regional differences in degree of cooperation at the operational level.

- o Interagency Staff Briefing. Appropriate management and inspection personnel of the other agencies should be briefed about the PCB Interim Measures Program. Copies of this enforcement strategy and the Fact Sheet that is developed (see Voluntary Compliance, below) can be used to explain the Program.

- o Moderate Leak Reports. EPA will be receiving reports of moderate PCB leaks at food and feed facilities. The Regions should set up a mechanism for ensuring that all interested agencies are notified of the situation; this may include State agencies, if appropriate. This mechanism should also be used to coordinate the response to a moderate leak report to determine which, if any, agency(ies) will conduct an on-site inspection of the facility.

- o Facility List Sharing. FDA and FSQS have lists of facilities subject to their regulations. The EPA Region should work through their interagency contacts to obtain lists for use in selecting food and feed facilities for records review and on-site inspections.

- o Referral of Information. Food quality agency inspectors may observe leaks or other indications of noncompliance while conducting their routine inspections. They are encouraged to refer such information to EPA. To aid in this effort, EPA Regions may want to develop a screening tool that can be used by other agency inspection personnel to help identify potential noncompliance or other problems with regard to PCBs in food and feed facilities. EPA may also supply copies of the Fact Sheet for distribution by the inspectors when they are visiting food and feed facilities.

While the exact nature and extent of interagency cooperation should be determined at the Regional level, EPA Headquarters will assist in fostering such cooperation as necessary. Headquarters will make copies of educational materials available for use by the Regions and will provide assistance in the development of referral inspection guidance.

Voluntary Compliance/Awareness Effort

A notice regarding the Interim Measures Program was published in the Federal Register on March 10, 1981; a clarification was published on May 20, 1981. In addition, the utility industry has itself, in response to the Court mandate, undertaken an educational effort to inform its member companies about the Program's requirements.

To augment these activities, the Pesticides and Toxic Substances Enforcement Division is working with the Industry Assistance Office of the Office of Toxic Substances to disseminate information about the Program to other industry and economic sectors affected by its requirements. This effort includes contacting industry representatives personally, making copies of the Federal Register notices available for mailing to trade association members, developing and distributing a Fact Sheet for food and feed facilities, and providing draft articles describing the Program and enforcement strategy to industry publications.

Allocation of Responsibilities

Headquarters (PTSED)	Regions
1. Awareness Effort	1. Awareness Effort
PTSED will work with Office of Industry Assistance (OTS) to implement a strategy for informing the regulated community of Interim Measures Program requirements. (PSB)	
Materials will be made available to the Regions. (PSB)	Regions may perform additional educational activities.
2. Interagency Cooperation	2. Interagency Cooperation
PTSED will provide printed materials for use in briefing other agency staff. (PSB)	Regions will brief other agency personnel on the Interim Measures Program.
PTSED will provide assistance and guidance material, as needed, to foster interagency cooperation. (CMB)	Regions will obtain lists of food and feed facilities from FDA and FSOS.
	Regions will set up a mechanism for notifying food quality agencies about moderate leaks and determining which, if any, agency(ies) will conduct an on-site inspection.
	Regions will incporporate the PCB Interim Measures Program into the interagency Referral Inspection Program as appropriate.
3. Compliance Monitoring	3. Compliance Monitoring
3a. Records Review	3a. Records Review
PTSED will provide guidance on developing a formula for selecting facilities. (CMB)	Regions will prepare a randomly selected mailing list covering approximately 5 percent of utility and food and feed facilities.
PTSED will provide guidance and ample letters for use in equesting records. (CDLB)	Regions will mail records request letters to selected utilities and food and feed facilities.

Headquarters (PTSED)	Regions
PTSED will provide policy assistance if needed for the issuance of subpoenas. (PSB)	Regions will issue subpoenas to companies not complying with the request letters.
PTSED will provide guidance for the review of records submissions. (CMB)	Regions will review submitted records and may select some companies with incomplete records, unusually high or low incidence of leaks, or indicators of potential environmental contamination problems for on-site inspection. Such inspections may be complete PCB rule inspections.
3b. Reports of Moderate Leaks	3b. Reports of Moderate Leaks
	Regions will designate an individual to receive reports of moderate leaks from food and feed facilities.
	Regions will evaluate all reports to determine if an Agency response is needed. Response can range from a followup telephone call, to alerting food quality agencies, to an on-site inspection.
3c. Routine Compliance Monitoring	3c. Routine Compliance Monitoring
PTSED will prepare inspection procedures for compliance monitoring for the Interim Measures Program. (CMB)	Regions will include procedures to determine compliance with the Interim Measures Program in their routine PCB rule inspections.
4. Case Development	4. Case Development
PTSED will provide guidance on documentation required for proof of violations. (CDLB)	Regions will review records submitted by utility companies and inspection reports to determine violations.
PTSED will provide a supplemental PCB penalty policy and levels of action guidance for the Interim Measures Program. (PSB)	Regions will prepare notices of noncompliance or complaints in accordance with the supplemental PCB penalty policy and guidance.
PTSED will assist Regions in determining appropriate enforcement action and penalties, as needed, and concur in complaints. (CDLB)	Regions will submit complaints for PTSED concurrence.

Headquarters (PTSED)	Regions
5. Summary of Compliance	5. Summary of Compliance
PTSED will provide guidance on the preparation of summaries of compliance with elements of the Interim Measures Program. (PSB)	Regions will prepare summaries of responses to the records requests and compliance data, and forward to PTSED. Information from routine compliance monitoring may be included. The first summaries should be submitted at the end of the third quarter of FY 1982.
PTSED will prepare a national summary. (CDLB)	
PTSED will modify the enforcement strategy and procedures as needed. (PSB)	

PTSED--Pesticides and Toxic Substances Enforcement Division
PSB--Policy and Strategy Branch
CMB--Compliance Monitoring Branch
CDLB--Case Development and Legal Branch
OTS--Office of Toxic Substances
FDA--Food and Drug Administration
FSQS--Food Safety and Quality Service

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 14 1981

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Civil Penalty Cases Involving Use of PCBs in Hydraulic Systems

TO: Enforcement Division Directors
Air and Hazardous Materials Division Directors
Surveillance and Analysis Division Directors

Several administrative PCB penalty cases submitted by Region V for Headquarters review have raised issues which need clarification regarding the use authorization for PCBs in hydraulic systems. This memorandum will address two basic questions: 1) What evidence is necessary in order to charge a company with failure to test its hydraulic systems, and 2) Under what circumstances are charges for improper disposal of PCB hydraulic fluid appropriate.

Failure to Test

Under §761.31(e)(1) of the PCB Regulation, each person who owns a hydraulic system that ever contained PCBs must test for the concentration of PCBs in the hydraulic fluid.1/ In the situation where samples of hydraulic fluid analyzed by EPA show greater than 50 ppm PCBs and the company has not tested its machine, there is clearly a violation for failure to test. When the company has not tested its machine and samples show the PCB concentration to be less than 50 ppm, however, additional evidence must be obtained to show that the system ever contained PCBs. A charge for failure to test should not be brought if the PCB concentration of the hydraulic system is below 50 ppm unless there exists evidence such as the following:

- Company records show PCB purchases for the company's hydraulic machines;
- Records from Monsanto or another supplier indicate PCBs were sold to the company for its hydraulic machines;

1/ The phrase "ever contained PCBs" is interpreted to mean ever contained PCBs greater than 50 ppm in accordance with §761.1(b) -- "Unless it is otherwise specifically provided, the terms PCB and PCBs are used in this rule to refer to any chemical substances that contain 50 ppm (on a dry weight basis) or greater of PCBs..."

- An oral statement was made by company representative(s) that PCB fluid had been used in the hydraulic systems at one time; or

- Information regarding the age, size, or type of the hydraulic machines indicates that the systems had contained PCBs.

Disposal

Because hydraulic systems frequently leak, the issue of whether improper disposal of PCBs has occurred is often raised. After reviewing a number of cases, it appears that this disposal issue most often poses itself at three different stages in the hydraulics operation -- 1) when PCBs have leaked onto the floor from the hydraulic system; 2) when absorbent material containing PCBs is found in trenches or sumps near the machines; and 3) when PCB debris has been removed from the trenches or sumps. Each situation is discussed below:

A. When PCBs Have Leaked onto the Floor from the Hydraulic System

When oil (which has recently leaked out of the hydraulic system onto the floor) is found to be concentrated at greater than 50 ppm PCB, it can be argued that improper disposal has occurred. In a situation where the company has failed to provide containment around the machine or has not regularly cleaned the area, a charge for improper PCB disposal is appropriate. However, because the use authorization for PCBs in hydraulic systems acknowledges that the systems are other than totally enclosed, leaks should not be considered improper disposal if the company has taken reasonable steps to contain or clean up the oil before EPA's inspection. Depending on the type of PCB containment, however, a storage charge may be appropriate.

B. When Absorbent Material Containing PCBs is Found in Trenches or Sumps Near the Machines

In many hydraulics operations, oil which has leaked onto the floor from the machines is cleaned up with absorbent material and washed into trenches or sumps. Because this material is usually cleaned out of the sumps on a periodic basis, debris which is found to be concentrated at greater than 50 ppm would be considered stored for disposal in most instances. Charges for failure to properly store and mark PCBs would therefore be appropriate in situations where there is evidence that the material in the sump is periodically collected and disposed of. In the event that the sump drains into the sewer system, a disposal violation may exist if the material in the sump contains PCBs at greater than 50 ppm, and the material flowing out of the sump contains any detectable PCBs. This may be considered improper disposal if it can reasonably be argued that the PCBs in the sump are leaching into the liquid which is flowing out of the sump. In this case, the liquid is considered a PCB since the concentration is less than 50 ppm because of dilution [see §761.1(b)].

C. When PCB Debris Has Been Removed from the Trenches or Sumps

The question of whether improper disposal of PCBs has occurred is again raised in situations where the company practice is to collect PCB debris from the trenches or sumps to be discarded. If sampled debris is found to contain greater than 50 ppm PCBs and is observed in a dumpster or containers awaiting pick-up by a trash collector, a disposal charge is warranted. Without a sample, it would be difficult to determine the amount and concentration of PCB debris involved in past disposal. In the latter situation, bringing a disposal charge is discouraged. Although a charge for improper disposal is not recommended without a sample, a charge for improper storage of the debris in the sump may be appropriate if a sample shows the sump to contain greater than 50 ppm PCBs. If the volume and PCB concentration of material in the sump indicates that there may be a serious disposal problem, a follow-up inspection should be conducted in order to obtain more substantial evidence of a disposal violation.

I hope that this discussion of testing and disposal has clarified some of the issues raised in cases involving hydraulic systems. If you have further questions, please contact Marcie Kleban (8-755-7999) of my staff.

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Pesticides and Toxic Substances
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United States
Environmental Protection
Agency

Pesticides and
Toxic Substances
Enforcement Division

EPA

Enforcement Facts and Strategy

Premanufacture Notification

(PMN)

Premanufacture Notification (PMN)

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Foreword

The final enforcement strategy consists of three parts. Part I contains general introductory material. Part II contains general operational concerns such as establishing enforcement priorities and discussing the allocation of responsibilities. Part III contains program implementation materials and consists of three independent documents. These three documents are: (1) the Section 5 Inspectional Procedures which provide detailed inspection guidance to field staff members performing Section 5 inspections; (2) the Section 5 Neutral Administrative Inspection Scheme which presents a prioritized selection scheme for targeting Section 5 inspections; and (3) the Section 5 Penalty Policy Guidance which adapts the general TSCA Penalty Policy to the specific needs of Section 5. Each of these three documents can be detached and used separately by the appropriate Agency units.

Page numbering is organized by Part. The first digit of the page number refers to the Part, the second to the specific page within that Part (e.g., page 3-12 refers to page 12 in Part 3).

PART THREE: PROGRAM IMPLEMENTATION MATERIALS

Requirements and General Information

Contents

Section 5: Premanufacture Notification

Section 5 of the Toxic Substances Control Act (TSCA) and the Premanufacture Notification (PMN) regulations proposed under Section 5 of TSCA require chemical manufacturers, processors, importers, and exporters* to notify EPA before manufacturing processing, importing or exporting a new TSCA chemical (44 FR 59764). The proposed regulations will allow EPA to take regulatory action if any phase of the substance's manufacture, processing, distribution in commerce, use, or disposal presents an unreasonable risk to human health or the environment.

A new TSCA chemical is a substance that (1) does not appear in the Inventory of Existing Chemical Substances published by EPA under Section 8(b) of TSCA, (2) is not specifically excluded from TSCA mandate (pesticides, firearms, ammunition, food, food additives, drugs, cosmetics, devices, tobacco, tobacco products, and specified nuclear materials are not covered by TSCA), and (3) is not exempt or excluded from review under Section 5.

The purpose of Section 5 of TSCA is to provide EPA with the authority to quickly review and, if necessary, control new substances to prevent large-scale distribution before the substance's effect on health or the environment is determined. The Agency can control or, if necessary, ban a harmful substance before industries become dependent upon both its production and use. The Agency expects to receive from 200 to 400 Section 5 notices annually.

Section 5 Enforcement Strategy Overview

Section 5 and the proposed PMN Regulations require chemical manufacturers, processors, importers and exporters to notify EPA prior to the manufacture, processing, importation or exportation of a new TSCA substance. Section 5 then allows EPA to take regulatory action if any phase of the substance's

* While the interim policy for Section 5 does not require exporters to submit Section 5 notices, the final rules will probably require exporters to submit these notices.

manufacture, processing, distribution in commerce, use, or disposal presents either an unreasonable risk to public health or the environment or substantial or significant human exposure. Together these notification and regulatory action requirements prescribe the primary focus of OE's enforcement program, which is detection of "failure to notify" violations and detection of noncompliance violations.

As the success of the premanufacture notification process is vital to the overall effectiveness of TSCA, OE will treat Section 5 enforcement as a matter of the highest priority. Both Headquarters and the Regions will work to detect violations of the regulations and to take appropriate actions.

Regulated Industries

Manufacturers, processors, importers, and exporters are directly subject to the PMN requirements, unless specifically exempted. They must submit premanufacture notices when manufacturing, processing, importing or exporting a new TSCA substance. Commercial users are indirectly subject to the PMN requirements through the improper commercial use provision of

Section 15. An EPA survey indicates that there are approximately 10,000 chemical manufacturers. Of these firms, 150 have annual sales of over $100 million and account for 80 percent of industry sales. About two-thirds of chemical manufacturing firms have annual sales of less than $2.5 million.

While the figures for chemical processors are sketchy, current estimates indicate that there are about 100,000 processors in the United States.

There are no accurate figures available regarding the number of importers and exporters subject to the Section 5 requirements. According to the American Importers Association, there are at least 1,200 brokers and up to 35,000 importers that might be affected. The United States Department of Commerce estimates that 25,000 firms engage in exporting. Businesses that use chemicals commercially are also subject to regulation under the commercial use violation provision of Section 5.

Exemptions

EPA may, upon application, exempt from some or all of the PMN requirements a manufacturer, processor, importer, or exporter of any of the following:

- A new substance where the test data is being developed by another establishment,
- A new substance that is being test marketed,
- A new substance that the Administrator determines by rule to be not dangerous, or
- A substance that exists temporarily and will have no environmental or human exposure.

In addition, an automatic exemption is granted for a person manufacturing, processing, importing, or exporting a substance in small quantities solely for research and development.

Substances Excluded from Section 5 Review

Sections 720.2 and 720.13 of the proposed Section 5 regulations exclude several classes of substances from premanufacture review:

- Mixtures,
- Coproducts,
- Impurities,
- Byproducts and
- Chemical substances that occur incidental to intended production activities.

Requirements of the Section 5 Program

The proposed rules provide that notice can be accomplished by the submission of a completed Premanufacture Notice to the Office of Pesticides and Toxic Substances (OPTS). Firms are required to submit on this notice information known or reasonably ascertainable concerning:

- Chemical identity
- Production quantities
- Uses
- Byproducts
- Health and environmental effects
- Exposure
- Methods of disposal

Regulatory Options Under Section 5

After OPTS receives a Section 5 notice, it has, by statute, 90 days for review. (For good cause the review period can be extended an additional 90 days.) During the review period, EPA may initiate actions under Section 5(e) or Section 5(f) to regulate the chemical.

Section 5(e). EPA is authorized under Section 5(e) to issue a proposed order or apply directly to a U.S. District Court for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance. The agency may take action under Section 5(e) if:

- The information available is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance and either:
- The substance may present an unreasonable risk to health or the environment, or
- There may be either substantial environmental exposure, or substantial or significant human exposure to the substance.

A proposed order must be issued prior to 45 days before the expiration of the notice period. The affected firm has 30 days from receipt of the proposed order to object to the order. If no objections are made within the 30 days, the proposed order

becomes final and is enforceable once the PMN review period expires (usually about 15 days after this 30 day period). If proper objections are filed, the Agency must obtain an injunction in a U.S. District Court to regulate the substance. The injunction will also not be effective until the PMN review period has expired.

Section 5(f). The Agency may take action under Section 5(f) if it finds there is a reasonable basis to conclude that the substance will present an unreasonable risk of injury to health or the environment before a rule can be promulgated under Section 6 to protect against the risk. EPA may issue a proposed order or apply directly to a U.S. District Court for an injunction to prohibit the manufacture, processing, or distribution of the substance. (This is in contrast to Section 5(e) where the Agency may take action when the available information is insufficient to permit a reasonable evaluation. The purpose of the 5(e) action is to control the new substance until enough test data is generated to allow the Agency to reasonably evaluate the substance.)

A proposed order must be issued prior to 45 days before the expiration of the notice period. The affected firm has 30 days from receipt of the proposed order to object to the order. If no objections are made within the 30 days, the proposed order becomes final and is enforceable once the PMN review period expires (usually about 15 days after the 30 day period). If objections are filed, the Agency must obtain an injunction in a U.S. District Court to regulate the substance. The injunction will also not be effective until the PMN review period has expired.

Alternatively, Section 5(f) authorizes EPA to issue a proposed rule under Section 6(a) with any of the following requirements:

- Limit the amount of the substance which may be manufactured, processed, or distributed in commerce,
- Prohibit or limit the manufacture, processing, or distribution in commerce of a chemical substance for a particular use or for a particular use in excess of a specified concentration,
- Require that a substance be marked with use instructions or warnings,

- Require that the manufacturer monitor, keep records, or conduct tests to assure compliance with any requirement,

- Prohibit or limit any manner or method of commercial use,

- Prohibit or limit any manner or method of disposal.

Decision to Allow Production. Once the notification period expires, the manufacturer, processor, importer, or exporter may commence manufacture, processing, importation, or exportation of the substance subject to any requirements EPA has issued under Section 5(e) or Section 5(f). When manufacture, processing, importation or manufacture for export begins, EPA will add the chemical substance to the Inventory in accordance with Section 8(b)(1). Thereafter, any person may manufacture,process, or import the substance without giving EPA notice. Other manufacturers, processors, importers, or exporters who manufacture, process, import, or export the same substance are also subject to any EPA requirements imposed upon the original notice submitter.*

As premanufacture notification is not a certification process, lack of any regulatory action by EPA during the notification period does not prevent EPA from regulating the chemical at a future date. For certain chemicals, EPA may prefer to initiate followup action rather than regulate the chemical during the notification period. For example, the manufacture of a toxic chemical which the manufacturer states has limited exposure may not warrant immediate control action. However, if future uses or production changes increase exposure to the chemical, EPA may under TSCA initiate two kinds of followup actions.

- EPA is authorized under Section 8(a) to require the reporting of a wide variety of information. This can be used to track a substance once it clears Section 5.

- Under Section 5(a)(2), EPA may issue significant new use rules (SNURs) which would require manufacturers or processors to submit Section 5 notices if there are significant changes in a substance's use, production volume, exposure, etc.

* It is still unclear if EPA has the authority to impose these restrictions on other firms, but the weight of analysis favors the position stated in the text.

Other regulatory options available to EPA under TSCA after the notification period expires are the use of Section 6 concerning hazardous substances and Section 9 on the relationship to other Federal laws. EPA would use Section 6 primarily in cases where either:

- Additional data on a substance became available indicating negative impacts on health or environment,
- Followup activities indicated serious changes in exposure, or
- EPA was unable to regulate the substance under Section 5 within the Section 5 review period.

Section 9 would be used in cases where regulation of the chemical could best be accomplished by another EPA office or Federal agency (e.g., OSHA).

Timetable

An approximate timetable for implementation of Section 5 is given below. Testing guidelines and significant new use rules (SNURs) will be developed during 1980-81. OE will amend the enforcement strategy as these programs are developed.

Action	Date
Proposal of Section 5 Rules and Forms	January 10, 1979
Interim Policy	May 15, 1979
Publication of the Inventory	June 1, 1979
Effective Date of Section 5	July 1, 1979 (30 days after Inventory publication)
Reproposal of Section 5 Forms, and Some Rules Provisions	October 16, 1979
Interim Policy - Revised	Mid 1980
Final Section 5 Forms and Rules	Late 1980
Section 5 Testing Guidelines Proposed	1980
General Significant New Use Rules Proposed	1980

Interim Enforcement Policy

As indicated in the timetable, there will be several months of Section 5 enforcement before the final Section 5 rules and forms are issued. TSCA states that the requirements of Section 5 become effective 30 days after publication of the Inventory. This 30 day period expired on June 30, 1979. Despite the fact the Section 5 regulations were not final at that time, the Section 5 statutory requirements became effective July 1, 1979. Consequently, this period of time between the effective date of the statutory requirements and the effective date of the regulatory requirements will have no effect on the Section 5 enforcement program.

Enforcement

Objectives

The objectives of this enforcement strategy are to ensure that:

- Firms are submitting complete Section 5 notices for new substances they intend to manufacture, process, import, or export;
- Firms subject to Section 5(e) or Section 5(f) orders, rules, and injunctions are complying; and
- Firms are complying with the terms of their exemptions and PMN submissions.

Voluntary Compliance

because Agency enforcement resources are limited, the strategy includes outreach programs to encourage both voluntary compliance by industry and the reporting of violations by industry members, citizens, and workers. The Office of Enforcement (OE) is currently developing these programs with the cooperation of Office of Pesticides and Toxic Substances (OPTS) and Office of Public Awareness (OPA). The programs should be completed in FY 81.

The voluntary compliance portion of the outreach program will furnish the information industry members need for understanding TSCA requirements. This information will likely include interpretations and clarifications of specific regulatory

requirements as well as detailed compliance information where appropriate. While the outreach program will not restrain those chemical producers who knowingly violate TSCA, it will assist those industry members wishing to comply to remain within the law.

Types of Violations

Noncompliance with a Section 5(e) or Section 5(f) Order, Rule, or Injunction. Compliance with Section 5(e) or Section 5(f) orders or rules is required by Section 15(1)(C) which prohibits a firm from failing or refusing to comply with any Section 5 or Section 6 order or rule. Those firms subject to court injunction obtained under Section 5 are required by the nature of the proceeding to comply.

Commercial Use of an Illegally Produced Substance. If a firm knew, or had reason to know, that a chemical substance it used for commercial purposes was manufactured, processed, or distributed in commerce in violation of Section 5 or a Section 5 order, rule, or injunction, it has committed a commercial use violation. Improper commercial use of a new substance is an unlawful act under Section 15(2). (Note: OE will interpret the term "use for commercial purposes" broadly to include any use in manufacturing, processing, or distribution in commerce. This interpretation is consistent with the legislative intent of TSCA.)

Noncompliance with Test Marketing Exemption Restrictions. A firm may seek an exemption from PMN under Section 5(h)(1) in order to manufacture a new substance for test-marketing purposes. Under this exemption, the Administrator may impose restrictions on the test marketing of a substance (e.g., distribution limited to a three-state area). Failure to comply with these restrictions constitutes a violation of Section 15(1)(B) which provides that noncompliance with a Section 5 requirement is unlawful. Some test marketing violations may constitute a "failure to notify" violation. (See discussion of that violation category on page 1-10.)

Noncompliance with Research and Development Exemption Restrictions. A firm may produce a new substance in small quantities for the purpose of research and development* without submitting the substance for PMN review under a Section 5 (h)(3) exemption. Under this exemption, the firm must not:

* OPTS will resolve at a later time what the term "small quantities for research and development" means.

- Produce more chemical than is needed for research and development,

- Fail to adequately warn those employees working with the chemical if it or the Administrator knows or has reason to know that the substance presents any risk to health, and

- Use the research and development substance for nonresearch and nondevelopment uses. (This is more properly a "failure to notify" problem and is discussed under that violation.)

Noncompliance with these requirements constitutes a violation of Section 15(1)(B) which provides that noncompliance with a Section 5 requirement is unlawful.

Withholding Material Information from or Submission of Materially False or Misleading Information on a Section 5 Notice or Exemption Request. The withholding of material information from or the submission of materially false or misleading information on either of these two notices invalidates them. Not only do these Section 5 notices or exemption requests fail to satisfy the Section 5 requirements, but their submission is prohibited by Section 15(1)(B) or Section 15(3)(B). Should EPA decide not to regulate a substance or approve an exemption as a result of the withheld information or the false or misleading information, and the firm making the submission commercializes the substance, the firm would also be committing a "failure to notify" violation because the PMN review or exemption approval was invalid. (See discussion of failure to notify below.)

Failure to Notify. The failure by any firm described in Section 720.10 of the proposed rules to provide a valid PMN submission for any chemical described in Section 720.12 of the proposed rules constitutes a "failure to notify" violation. This action is prohibited both by Section 15(1)(B) of TSCA which makes it unlawful to fail or refuse to comply with any requirement prescribed by Section 5, and by Section 15(3)(B) which makes it unlawful to fail or refuse to submit notices as required by TSCA. The major variations of this violation involve unidentified substances, substances identified by lawful conduct, and substances identified by an associated violation.

- Unidentified Substance. The first variation is that a firm simply does not provide a Section 5 notice for the substance in question. This variation also includes those firms that could have avoided the Section 5 requirements by legitimately placing their substance on the Inventory, but who did not do so either because of a simple error or because of a deliberate attempt to circumvent TSCA. In either case, OE could take action under authority of Section 8(b) and/or Section 5. (See Inventory Reporting Enforcement Strategy Document.)

- Substances Identified by Lawful Conduct. The second major variation occurs when a firm commercializes a new substance under one of the following conditions: a requested exemption was denied, it never completed its Section 5 Notice, or it began production prior to the expiration of the notice period.

- Substance Identified by Associated Section 5 Violation. The third major variation results from or closely follows an associated substantive violation of Section 5. The three substantive violations are: withholding material information from or submission of materially false or misleading information or a Section 5 notice or exemption request, test marketing violation, or research and development violation.

  Withholding Material Information or Submission of False or Misleading Information. The first type results from the withholding of material information from or the submission of materially false or misleading information. While this constitutes a violation in itself, it also results in rendering the entire Section 5 notice or exemption request invalid. Thus any commercial production and distribution of the substance for a nonexempt purpose constitutes a failure to notify violation because the firm is essentially producing the substance without notice, or applicable exemptions.

  Commercial Production of a Research and Development Substance. The second type results from a research and development violation. Improper commercial production and/or distribution of a substance supposedly undergoing research and development not only is a violation of the research and development exemption, but it is also a failure to notify violation.

Production and Distribution in Excess of Test Marketing Restrictions. The third type results from the violation of a test marketing restriction on production. Overproduction and distribution constitutes a failure to notify for the extra amount produced. EPA could prosecute all these overproduction situations as both test marketing violations and failure to notify violations. While the Agency will always prosecute the test marketing violation, it will only prosecute the failure to notify violation when the permitted production and distribution is exceeded by 100 percent or more.

Bases for Targeting Inspections

In order to obtain the most efficient use of Agency resources, OE has developed a targeting scheme that focuses on likely violators. The bases for this targeting is presented in Table I on page 1-15.

Section 5 Notices. These notices will be the basis of targeting inspections for three different violations. OE will focus on defective notices or notices which indicate a significant level of projected production, importation, or exportation.

Section 5(e) or 5(f) Orders, Rules, or Injunctions. Any firm subject to a Section 5(e) or 5(f) order, rule, or injunction will probably be inspected to determine if the firm is in compliance with the applicable order, rule, or injunction.

Shipping Records. These records will be the basis of targeting inspections for improper commercial use violations. EPA will examine the shipping records of those firms that have violated Section 5 to determine which firms received the illegally produced substances. The recipients will then be inspected.

Exemption Requests and Approvals. A review of these requests may indicate a potential violation and thus warrant an inspection. At the same time, some of those substances subject to approved exemptions may still concern the Agency, and similarly warrant inspection. For example, if a test marketing exemption is granted, but it is not followed by a Section 5 notice at the end of the exemption period, the firm might be commercializing the substance in violation of Section 5.

Other Related Violations. In many cases, a firm will be inspected for a "failure to notify" or an improper commercial use violation because it has already violated a related portion of Section 5. If for example, a firm violated Section 5 by submitting a materially false or misleading statement in its notice, it would be further inspected to determine if it committed a "failure to notify" violation by commercializing the substance.

Outreach. Active participation of labor, trade, and environmental groups; private citizens; and industry members in the reporting of TSCA violations could significantly enhance the Agency's enforcement efforts. Involvement in TSCA enforcement will be enouraged by creating public awareness of regulatory requirements and the enforcement process. The Agency will develop and distribute booklets and other materials, encourage EPA participation in meetings, and sponsor citizen action projects. In addition, EPA is currently developing a system for handling worker and citizen complaints. Once completed, the program will be widely publicized.

Industry Characterization. OE is currently developing a characterization of the industry based on Standard Industrial Classification (SIC) codes. The purpose of this characterization is to enable OE to determine which firms are potential violators and then focus inspections on those firms. As a further check in this characterization, Office of Pesticides and Toxic Substances (OPTS) and OE will periodically review new chemical patent applications at the Patent Office to see if any chemicals are being developed without proper notification.

Violation Detection Methods

The primary detection methods for the discovery of major Section 5 violations are listed in Table 1. The violation detection program is tailored to meet the needs of the Section 5 enforcement program taking into account the number of potential violators, the difficulty of discovering a violation, and the available compliance monitoring resources.

Plant Inspections. The principal detection method will be plant inspections. The inspections will reveal violations at the establishment being inspected, and these violations will often lead to the detection of violations in other firms. (For example, the recipient of illegally produced substances may commit a commercial use violation.) Inspectors will need to examine plant records (production, shipping, storage, disposal,

etc.), and in some cases they may be required to take samples or observe plant operation. To perform these inspections effectively, inspectors will need special category confidential business information authorization. (See Program Implementation Materials Section for a presentation of the Section 5 inspection procedures.)

Subpoenas. The Agency may employ administrative subpoenas issued under TSCA Section 11(c) instead of plant inspections in situations where only a records inspection is necessary and the use of a subpoena would be more cost effective than an on-site inspection. Subpoenas may be particularly helpful in followup inspections of previous violators.

Inventory Checks. A firm that violates the requirement to report a substance for the inventory may also violate Section 5 (failure to notify). Consequently, some Section 5 violations will be detected by EPA inventory inspections.

Remedies

After a violation has been discovered and any investigations and inspections have been completed, OE must determine what types of enforcement action to take. The possibilities include issuance of a notice of noncompliance, assessment of administrative civil penalties, and initiation of civil or criminal court actions.

TABLE 1 -- Targeting Bases and Detection Methods

Violation	Basis for Targeting Inspections	Primary Detection Methods
Noncompliance with Sec. 5(e), Sec. 5(f), and Sec. 5(f)/Sec. 6(a) Orders, Rules, or Injunctions	Section 5 Notices, Orders, Injunctions, or Rules	Plant Inspections, Subpoenas
Commercial Use of an Illegally Produced Substance	Shipping Records of Other Firms that Violated Section 5	Plant Inspections
Noncompliance with Test Marketing Exemption Restrictions	Exemption Request and Approvals	Plant Inspections, Subpoenas
Noncompliance with R&D Exemption Restrictions	Outreach	Plant Inspections
Withholding Material Information or False or Misleading Information	Section 5 Notices or Exemption Requests	Plant Inspections
Failure to Notify	Industry Characterization, Outreach, Notices, Exemption Requests, Other Related Violations	Plant Inspections, Subpoenas, Inventory Checks

Operational Considerations and Priorities

Contents

Priorities

Because of the Agency's limited resources, it is important that OE establish violation priorities for directing enforcement efforts. For Section 5, the factors used for ranking violations were the degree of potential risk (measured in terms of toxicity and exposure) associated with the violation, and the effect of the violation on the integrity of the TSCA program. The following table gives the general priority ranking for violations. This table is meant only as a guide to decision making and is not a rigid OE policy.

Priority	Violation
1	Noncompliance with Section 5(e) or Section 5(f) orders, rules, or injunctions
2	"Failure to notify"
3	Witholding material information from or submission of materially false or misleading information on a Section 5 notice or exemption request
4	Noncompliance with test marketing exemption restrictions
5	Noncompliance with R & D exemption restrictions

Note: "Use for improper commercial purposes" violations have the same priority as the underlying violations that resulted in the commercial use violations. For example, if a firm violated a test marketing restriction, and the Agency suspects that the recipient of the test marketed substance committed a commercial use violation, the priority for investigating this potential violation is the same as for a test marketing violation, the associated violation.

OE recognizes that as the Agency gains experience in administering the Section 5 enforcement program, these priorities may be modified to reflect that experience. If OE determines that the prosecution of a high priority violation is not significantly contributing to the enforcement effort, or if OE feels that there is a high degree of compliance with the associated requirement, then OE will re-order the priorities.

Administrative Considerations

Allocation of Responsibilities

The primary role of Headquarters in the enforcement of Section 5 will be working with OPTS in reviewing notices, coordinating the overall enforcement effort, and taking appropriate regulatory actions. Since Headquarters will be the only place where all PMN submissions will be reviewed, Headquarters will be primarily responsible for targeting inspections and providing technical information to execute those inspections. The Regions will have the responsibility for performing inspections and gathering evidence. The case preparation and case litigation responsibilities will be evenly divided between the Regions and Headquarters. The Regions will take three categories of cases:

- Noncompliance with a Section 5(e) or Section 5(f) order, rule, or injunction,
- Commercial use of an illegally produced substance, and
- Noncompliance with test marketing restrictions.

Headquarters will take the other three categories:

- Failure to notify,
- Withholding material information from or submission of materially false or misleading information on a Section 5 notice or exemption request, and
- Noncompliance with research and development restrictions.

(See Table 2 on page 2-4.)

The case preparation and litigation responsibilities are divided this way in order to best utilize Agency resources. The Regions will be responsible for the Section 5(e)/5(f), commercial use and test marketing violations because they require minimal involvement from headquarters in developing the cases. The latter three categories are far more technical in nature than the first three categories. Any case development for these three violations will require a significant amount of input from OPTS. Consequently, these latter three violations were assigned to Headquarters.

While it is clear that the Regions are best suited to handle the three categories of cases mentioned above, the shortage of Regional resources in FY 80 and FY 81 will compel Headquarters

to either assist the Regions in case preparation and litigation responsibilities or assume them if necessary. Over the first two years of the program, Headquarters involvement in the Regional case responsibilities will gradually evolve into an advisory role. This will be accomplished by first reassigning Headquarters attorneys to perform Section 5 enforcement work. Then as the Regions assume their portion of the case preparation and litigation reponsibilities, the involved Headquarters attorneys will be reassigned back to their intended functions. In any case, close cooperation between Headquarters and the Regions, particularly in this interim period, is vital to the success of the Section 5 enforcement effort.

Program Integration

Through the compliance monitoring activities related to the enforcement of Section 5, OE will obtain compliance monitoring information involving other EPA enforcement programs. For example, an inspector looking through a plant's records on a Section 5 enforcement investigation may turn up records relating to other parts of TSCA, or, if a pesticide is involved, the Federal Insecticide, Fungicide and Rodenticide Act. In addition, an inspection for the discharge of chemical wastes into the environment may reveal violations of the water, air or solid waste pollution control regulations. Thus, it is important for all those involved in Section 5 enforcement to communicate non-Section 5 compliance monitoring information to the appropriate division of EPA.

At the same time, other EPA enforcement programs will be obtaining compliance monitoring information relevant to the Section 5 enforcement effort. This information will be communicated to us by those EPA staff administering those programs. This will be particularly so with Section 8(b) Inventory inspections. A failure to report an eligible substance for the inventory determination strongly suggests that the manufacturer in question has also committed a failure to notify violation.

Table 2

Headquarters and Regional Roles

Violation	Targeting Inspections	Conducting Inspections	Evidence Gathering	Case Preparation & Litigation
Failure to Notify	HQ lead Regions support	Regions lead HQ support	Regions lead HQ support	HQ lead Regions support
Noncompliance with orders, rules, and injunction of Sec. 5(e), Sec. 5(f), and Sec. 5(f)/Sec. 6(a)	HQ lead Regions support	Regions lead HQ support	Regions lead HQ support	Regions lead* HQ support
Withholding material information from or submission of false or misleading information on Section 5 notice or exemption request	HQ lead Regions support	Regions lead HQ support	Regions lead HQ support	HQ lead Regions support
Commercial use of an illegally produced substance	HQ lead Regions support	Regions lead HQ support	Regions lead HQ support	Regions lead* HQ support
Noncompliance with test marketing restrictions	HQ lead Regions support	Regions lead HQ support	Regions lead HQ support	Regions lead* HQ support
Noncompliance with R & D restrictions	HQ lead Regions support	Regions lead HQ support	Regions lead HQ support	HQ lead Regions support

*The shortage of Regional resources in FY 80 and FY 81 will compel Headquarters to either assist the Regions in case preparation and litigation responsibilities or assume these responsibilities if necessary.

Program Implementation Materials

Contents

Introduction to Part Three

The program implementation materials are provided in three separate documents. The first document, Section 5 Inspection Procedures, provides general and violation specific inspection guidance. The TSCA Base Manual, Volume 1 should be referred to for general TSCA inspection information on pre-inspection preparation, entry, opening conference, and closing conference. The second document, Neutral Administrative Inspection Scheme for Section 5, presents a plan for targeting Section 5 inspections consistent with the Supreme Court's decision in Marshall v. Barlow's, Inc., 436 U.S. 307, 98 S. Ct. 1816 (1978). It will guide both Headquarters and the Regions in selecting firms for inspections and will serve as a supporting document in a request for an administrative warrant for a Section 5 inspection. The third document, Section 5 Penalty Policy, adapts the general TSCA penalty policy to the specific needs of Section 5. The Section 5 Penalty Policy will offer guidance to Regional and Headquarters attorneys in assessing penalties for violations. This document provides matrices for measuring the degree of violation and a penalty assessment example.

3a

Section 5
Inspection Procedures

Introduction

Inspection Objectives

The objectives of Section 5 inspections are to:

- Determine if firms are submitting their new chemical substances for Section 5 review;
- Determine if the firms subject to Section 5(e) or Section 5(f) rules, orders, and injunctions are complying with their terms;
- Determine if firms are complying with the terms of their exemptions and Section 5 notices; and
- Determine the amount of substance involved in each violation to facilitate penalty calculation.

General Preparation Considerations

- Pre-Inspection Preparation. Depending upon the type of inspection involved, the inspector will need to obtain and review certain documents prior to conducting an inspection.

The inspector should carefully consider what he will be trying to determine during the inspection and where the relevant information or material might be located in the facility to be inspected. In conjunction with this step, the inspector should review the background of the targeted establishment in terms of the kind of plant (by SIC code), its production history, its violation history, and inspectors' comments from previous visits.

The inspector should prepare the necessary equipment such as sampling apparatus, portable copier, camera, and protective equipment. (See TSCA Inspection Manual, Volume One, Chapter 3 for a detailed discussion of pre-inspection preparation.)

Depending upon the type of inspection involved, the inspector will need to obtain and review certain documents prior to conducting an inspection.

Verification Inspections. Inspections focused on verifying statements in Section 5 notices or exemption requests will require the inspectors to become familiar with the statements to be verified and the form which contains them.

Compliance with Restrictions Inspections. Inspections focused on compliance with Section 5(e), Section 5(f), or exemption restrictions will require the inspector to become familiar with these documents. Review of Secton 5(e) and Section 5(f) orders, rules, and injunctions or Section 5 exemption restrictions will indicate to the inspector what chemicals to look for and what restrictions, if any, have been imposed ou the chemical's production.

- Entry. See procedures presented in TSCA Inspection Manual, Chapter 3, Section 2.

- Pre-Inspection Conference. Before beginning an inspection, the inspector should discuss the focus of the inspection during the opening conference with the firm's management representative. The inspector should inquire as to how the firm's records are formatted and organized. This will save both the firm and the inspector a significant amount of time. Next, the inspector and the management representative should arrange a schedule for interviewing employees

relevant to the inspection, and for reviewing the documents or plant processes in question. This will allow the inspector to operate efficiently and keep his interference with the plant's operation at a minimum.

As a final point, the inspector should make an effort to relieve any concern the management representative might have about the inspection. It is particularly important to clarify questions about confidential business information.

- Closing Conference. Upon completion of an inspection, the inspector should meet with the facility officials to wrap up the inspection. The inspector should issue the necessary receipts, fill in any gaps in his information, and again allay any fears about the release of confidential business information. (See TSCA Base Manual for detailed discussion at pages 3-61 to 3-63.)

Section 5 Violations List

- Noncompliance with Section 5(e) and Section 5(f) orders, rules, and injunctions
  - Total production ban
  - Restricted production, distribution, or use
- Commercial use of an illegally produced substance
- Noncompliance with test marketing exemption restrictions
  - Production, distribution or use restriction
  - Recordkeeping violation
- Noncompliance with research and development exemption restrictions
  - Overproduction
  - Failure to adequately warn employees
  - Failure to use substance for research and development

- Withholding material information from or submission of materially false or misleading information on a Section 5 notice or exemption request

- Failure to notify

  - Unidentified new substance
  - Substance identified by lawful conduct
  - Substance identified by associated Section 5 violation
    Withholding information from or submitting false or misleading information
    Noncompliance with test marketing restrictions
    Noncompliance with the terms of a research and development exemption.

Interrelated Violations. Although the Section 5 violation categories and subcategories are distinct, several of them are closely related. This is particularly so in the failure to notify and commercial use violations. Three variations of the failure to notify violation will result from or closely follow other substantive Section 5 violations. The three substantive violations are withholding material information from or submission of materially false or misleading information on Section 5 notice or exemption request, test marketing violations, and research and development violations. For discussion of these issues, see Substance Identified by Associated Section 5 violation on pages 3-14 and 3-15 of this guidance.

A similar interrelationship occurs between all the violation categories and commercial use violations. By definition, a commercial use violation does not occur unless there is a preceding Section 5 violation. This issue is discussed under the commercial use of an illegally produced substance guidance on page 3-6.

Violation Specific Inspection Guidance

The following section presents guidance for conducting Section 5 inspections. Although there are only six main violation categories, there are variations within each category. These six violation categories and their variations are discussed below. The violations are not listed in order of priority. (See Operational Considerations and Priorities Section for a discussion of inspection priorities.)

Noncompliance with Section 5(e) and Section 5(f) Orders, Rules, and Injunctions

There is a wide range of possible violations due to the large variety of possible orders, rules, and injunctions. The objective of these inspections is to determine compliance with the terms of these orders, rules, and injunctions. The enforcement effort for this violation will focus on the firm submitting the notice and any other firms that might be producing the substance.* The procedures for these inspections will vary with the terms of the applicable order, rule, or injunction.

- Total Production Ban. If one of these actions imposes a total ban on production, the inspector will need to know the trade name, generic name(s), and chemical specific name of the substance in question. This information will be sent to the Region prior to the inspection. The inspector will look for the particular chemical in the firm's shipping, production, or storage records. Should the inspector find evidence of a violation, he should photocopy all relevant records and take a sample if possible.

- Restricted Production, Distribution, or Use. In those cases where a substance's production, distribution, or use is restricted, but not banned, the inspector will check compliance with the applicable restrictions. Consequently, the focus of the inspection will depend upon the type of restriction. The majority of these compliance inspections will probably involve the review and photocopying of disposal, shipping, storage, production, and sales records. In those cases where the Administor has imposed effluent or emission limitations, the inspector will need to take samples.

* It is still unclear if EPA has the authority to impose these restrictions on other firms, but the weight of analysis favors the position stated in the text.

Commercial Use of an Illegally Produced Substance

If a firm knows or has reason to know that a substance it uses for commercial purposes was manufactured, processed, or distributed in commerce in violation of Section 5 or a Section 5 order, rule, or injunction, it has committed an improper commercial use violation. OE will interpret "use for commercial purposes" broadly to include any use in manufacturing, processing, or distribution in commerce. Thus, anytime an inspector finds a substantive violation of Section 5, he or she should examine that firms shipping records to determine what firms, if any, received the illegally produced substance. The objective of inspecting for this type of violation is to detect the presence of an illegally produced substance, and then to obtain evidence indicating whether the inspected firm knew or had reason to know that the substance was produced in violation of Section 5.

- Presence of the Illegally Produced Substance. The inspector should look for the presence of substances produced in violation of Section 5 by examining shipping records, purchase orders, and storage records. For each firm selected for inspection, Headquarters will provide a printout of all substances that a firm has reported for the Inventory, the CAS number of each substance (if available), and the Inventory form number (if available).

  Review of Plant Records. The inspector will first check the names of the substances in the plant's records against this Headquarters list. If any substances are not on the list, the inspector will check the substance(s) in question against the Inventory itself, both the confidential and nonconfidential parts of the inventory. (The firm is required to furnish the chemical specific name upon request.)*

* If a firm has placed the substance on the Inventory, the Section 8(b) regulations require it to furnish the chemical specific name upon request. Section 710.1(c) states:

> Each person who reports under these regulations shall maintain records that document information reported under these regulations and in accordance with the Act, permit access to, and the copying of such records by EPA Officials [42 Federal Register 64,575 (1977)].

For those substances that were not placed on the Inventory, an inspector may still request the chemical specific name on the basis of Sections 8(a) and 11(b).

Analysis of Records. If the substance is:

(1) not on the Inventory,

(2) commercially used by the firm inspected,

(3) covered by TSCA (i.e., not a pesticide, food, food additive, drug, cosmetic, device, specified nuclear material, firearm, ammunition, tobacco, or tobacco product),

(4) covered by the Section 5 regulations (i.e., not a mixture, coproduct, impurity, byproduct, or a chemical substance that occurs incidental to intended production activities),

(5) not covered by a Section 5 exemption,

then the establishment has met the first requirement of using a substance that was provided to that firm in violation of Section 5.* See proposed Section 5 regulations, Section 720.2, Section 720.13, Section 720.14, and Section 720.15 [44 Federal Register 2264-68 (January 10, 1979)].

* Until the closing of the revised Inventory, processors may process a substance for TSCA purposes that was not reported for the Inventory but was either manufactured for research and development prior to July 1, 1979 or was manufactured at any time for a non-TSCA use.

Targeting Considerations. An inspector may be directed to a certain establishment because it was listed as a recipient of some illegally produced chemicals in the shipping records of another violator. In such cases, much of the inspection work is simplified as the inspector is looking for a specific substance. Conversely, if a commercial use violation is discovered without the aid of previous violations, the inspector should examine the violator's records to determine the source of the improperly produced substance. If a source is discovered, it should be inspected. As in the previous situation, the inspector examining the suspected distributor is looking for a specific substance.

- Knowledge of Violation. Should the inspector find evidence that an establishment is commercially using a TSCA substance that is neither contained on the Section 8(b) Inventory nor a TSCA exempt substance, he must look for evidence of knowledge. Knowledge can be presumed in nearly all cases because the Section 5 and Section 8 statutory and regulatory requirements appear in the Federal Register. Regulated industries are presumed to know the contents of relevant regulations and notices that appear in the Federal Register. While most firms will be unable to defeat the presumption of knowledge, this presumption can be strengthened if the firm was on an EPA mailing list or attended any EPA meetings relevant to the regulation in question. (Headquarters would be responsible for establishing these points.) The regional inspector could add support to the case by:

  (1) establishing whether the firm in question belonged to any trade association,

  (2) reviewing a firm's files for memoranda or other written evidence recognizing the illicit nature of a substance's production, and

  (3) reviewing a firm's files for Federal Register notices indicating that a substance was still undergoing PMN review or was banned by a Section 5(e) or Section 5(f) order, rule, or injunction.

If evidence of knowledge is not available at the plant, it may be necessary to subpoena such material from corporate headquarters or wherever the information is kept. In this situation, the inspector would give the problem to the enforcement staff of the Regional Office.

Noncompliance with Test Marketing Exemption Restrictions

A firm may test market a new substance without submitting the substance for Section 5 review under a Section 5(h)(1) test marketing exemption. The firm must still submit a request containing sufficient information to allow the Agency to determine whether the substance might pose an unreasonable risk during test marketing. Under this exemption, the Administrator may impose appropriate restrictions on the test marketing of the substance. There are two types of restrictions: those that restrict production, distribution, disposal, or use of the substance and those that require recordkeeping.

- Restrictions on Production, Distribution, or Use

  The objective of these inspections is to determine compliance with the restrictions in the test marketing exemption. The restrictions (if any) will dictate to the inspector what aspects of the substance's production and distribution are to be monitored. If the exemption limits production to 1,000 lbs. per month, the inspector will check shipping, production, and sales records to determine how much of the substance is really being produced. If the exemption limits distribution to a two-state area, the inspector should examine shipping records to determine if any of the destinations were outside of this two-state area. The firm may also have committed a failure to notify violation. For a discussion of the failure to notify issue, see the inspectional procedures for that violation on page 15.

- Record Keeping Requirements. The objective of these inspections is to establish whether the firm is keeping those records required by a test marketing exemption. The inspector should review any recordkeeping requirements stated in the test marketing exemption approval or accompanying letter and then determine if the records kept by the firm meet those requirements.

Noncompliance with Research and Development Exemption Restrictions

A firm may produce a new substance for the purpose of research and development without submitting the substance for Section 5 review under a Section 5(h)(3) research and development exemption. Under this exemption, the firm must comply with certain statutory requirements. Three violations of this exemption are possible.

- Overproduction
- Failure to adequately warn employees
- Failure to use the substance for research and development.

The objective of these inspections is to determine if the manufacturer is complying with the statutory restrictions relevant to the research and development exemption. (Note that this is an automatic exemption. Consequently, there will be no exemption request to guide the inspection.)

The procedures for these inspections will vary with the type of violation the inspector is looking for, although the inspector should look for all three of the previously mentioned prohibitions for possible violations whenever a firm claims a research and development exemption. Such a claim may be made, for example, following a failure to notify inspection where a new substance is found.

- Overproduction. The inspector should review the firm's production records to determine how much of the substance is being produced. Then he should consult with OPTS following the inspection to determine if the amount produced exceeds what is reasonably required for research and development. If any overproduction violation is established, the inspector should also review the firm's shipping, sales, and storage records to determine if the firm is commercially distributing the substance for a nonresearch and development use. Overproduction strongly suggests illegal commercial distribution of the substance. Any such distribution constitutes a failure to notify violation.

- Inadequate Warnings. The inspector first must determine if the substance is suspected of being hazardous. The firm might volunteer this information. If it does not, the inspector should

present his information to OPTS following the inspection for a hazard determination. If the substance is hazardous, the inspector should review what warnings were given to the firm's employees. (If they are written out, they should be photocopied.) Then the inspector should interview those employees who worked with the new substance to determine (1) if they were all warned, (2) the extent of the warning, and (3) if the employees understood the warning.

- Nonresearch and Development Use. The last violation, not using a new substance for research and development, occurs when a manufacturer claims that the new substance it is producing is only being used for research and development. Thus, it would claim the automatic exemption. The inspector should verify this claim by examining the manufacturer's evidence of research and development such as research data on the substance in question or contracts to perform research and development on the substance. These documents should be photocopied. If the evidence of research and development seems questionable, the inspector should review the firm's production, shipping, and sales records to see if any of it is being commercially distributed for non-research and development purposes.

  The absence of research and development data or contracts strongly suggests a research and development violation. If the inspector finds evidence of improper commercial distribution, the firm has clearly committed both this violation and a "failure to notify" violation. For discussions of the latter violation, see the inspectional procedures below.

Withholding Material Information from or Submission of Materially False or Misleading Information on a Section 5 Notice or Exemption Request

This violation occurs as a result of the withholding of material information from or submission of materially false or misleading information on a Section 5 notice or exemption request. A statement is material if the Agency would have or in fact did rely on it in making its decision not to regulate a new substance or allow an exemption. Headquarters will direct what parts of the Section 5 notice or exemption request need

verification. The inspector must take the Section 5 notice, the exemption requests or excerpts of these documents into the facility and verify the information contained in certain portions of the form. For example, the inspector may wish to see if the substance is being disposed of in accordance with procedures stated in the Section 5 notice, or if waste gases are being scrubbed prior to release into the air.

- Review of Section 5 notices and exemption requests. The inspector will need to review the appropriate forms before conducting the inspection in order to become familiar with the parts of the forms that require attention.

- Verification. In verifying the information in the forms, the inspector may have to photocopy relevant records, and take process emission and effluent samples.

Failure to Notify

The inspector will be looking for evidence that a new substance is being manufactured, processed, imported, or exported for non-exempt purposes. This violation has three major variations which will require three different inspectional approaches. The approach will dictate the procedure for this inspection.

- Unidentified New Substance. The first approach is used where the inspector does not suspect any violation but discovers a new substance being improperly produced. There are five steps to follow in this type of inspection.

  Printout. For each firm selected for inspection, Headquarters will provide a printout of all substances that this firm has reported for the Inventory, their CAS numbers (if available), and their inventory reporting form number (if available).

  Examine Records. The inspector should examine shipping records (bills of lading, purchase forms, etc.) storage records, and production records for new substances.

  Inventory Status. The inspector should then determine if any of the substances are not on the Inventory. The inspector would first check each chemical in the records against the printout.

Substances Not on Inventory. If there are substances not on the printout, then the inspector should obtain the chemical specific name for these substances and compare them to the Section 8(b) Inventory, both the confidential and nonconfidential parts, and any supplements. (The firm must provide the chemical specific name of the substance on request. See footnote at page 3-6.)

Establishing a Violation. If there are substances that are: (1) not on the Inventory, (2) covered by TSCA (i.e., not a pesticide, food, food additive, drug, cosmetic, device, specified nuclear material, firearm, ammunition, tobacco, or tobacco product), (3) covered by the Section 5 regulations i.e., not a mixture, coproduct, impurity, byproduct, or a chemical substance that occurs incidential to production activities, and (4) not covered by a Section 5 exemption, the inspected estblishment has committed a "failure to notify" violation*. [See proposed regulations for Section 5, Section 720.2, Section 720.13, Section 720.14, and Section 720.15 at 44 Federal Register, 2264-68 (January 10, 1979).]

- Identified New Substances. In the second approach for failure to notify violations, the Agency will be looking for a specific new substance that is being illegally produced in a particular establishment. For example, the establishment was denied an exemption from Section 5 review, the notice for the chemical was rejected as deficient and never resubmitted, or the Agency is routinely checking the records of Section 5 notice submitters for premature production. In these cases, there is a significant possibility that the firm in question has produced the new substance without a complete Section 5 review.

* Until the closing of the revised Inventory, processors may process a substance for TSCA purposes that was not reported for the Inventory but was either manufactured for research and development prior to July 1, 1979 or was manufactured at any time for a non-TSCA use.

Chemical Names. To perform this inspection, the inspector will need to know the trade name, generic name(s), and the chemical specific name of the new substance.

Review of Records. The inspector will then look for the particular chemical in the firm's shipping, production, or storage records. Should the inspector find evidence of a violation, he should photocopy all relevant records and take a sample if possible.

- Substance Identified by Associated Section 5 Violation. In the third approach, the inspection will result from some other Section 5 violation (withholding information or submitting a false or misleading submission, improper test marketing, and improper research and development). The initial violation will lead inspectors to suspect that a "failure to notify" has also occurred. In these situations, the exact chemical the inspector is looking for is known.

  Withholding Information from or Submission of False or Misleading Information. If the firm submitting the invalid notice or exemption request begins producing the new substance for commercial distribution, it has committed a failure to notify violation. Once an inspector detects a withholding information or a false and misleading violation, he should examine the firm's production and shipping records to see if the substance was commercially distributed.

  Noncompliance with Test Marketing Restrictions. If the exemption holder produces more than the limit stated in its exemption, then it has violated the terms of its test marketing exemption. If the overproduction exceeds the stated limit by 100 percent and the excess is commercially distributed, then the EPA will consider it also a failure to notify violation. The inspector needs only to review the firm's production and shipping records to ascertain the extent of the overproduction.

Noncompliance with the Terms of a Research and Development Exemption. If a firm claims it is manufacturing and/or distributing a new substance under a research and development exemption, but the evidence demonstrates that some or all of it is not being used for research and development, that firm has probably committed a violation of the terms of its research and development exemption and a failure to notify violation. The evidence gathered by the inspector for the research and development violation will also establish the failure to notify violation.

3b

Section 5 Neutral Administrative Inspection Scheme

Two neutral administrative inspection schemes for use in targeting TSCA Section 5 inspections are discussed in the following section. The Section 5 notice review program is in its initial stages and many of the program elements will not become fully operational until some time in late FY 80. Thus, the Office of Enforcement (OE) is proposing both an initial scheme to cover this interim period and a final one to become effective when the Section 5 program is fully operational.

There are seven violation categories in Section 5:

1. Noncompliance with a Section 5(e) or Section 5(f) order, rule, or injunction;

2. "Failure to notify" EPA of the manufacture or importation of a new substance;

3. Withholding material information from or submitting materially false or misleading information on a Section 5 notice or exemption request;

4. Using a substance produced in violation of Section 5 for commercial purposes;

5. Noncompliance with the terms of a test marketing exemption;

6. Noncompliance with the terms of a research and development exemption; and

7. Violation of Significant New Use Rules (SNURs).

During the first several months of operation, OE anticipates that the only active violation categories will be: noncompliance with Section 5(e) and Section 5(f) orders, rules, or injunctions, "failure to notify", withholding material information from or submitting materially false or misleading information on a Section 5 notice or exemption request, and commercial use of an improperly produced substance. Thus, OE's initial efforts will focus on these four categories. When the other categories become active sometime in FY 81, OE will shift to the final neutral administrative inspection scheme which includes the other violation categories. OE recognizes that the schemes will change as the Agency develops expertise in handling the enforcement of Section 5.

Interim Inspection Scheme

- Noncompliance with Section 5(e) or 5(f) Orders, Rules, or Injunctions

  1. Inspect all firms subject to such orders, rules, or injunctions

- Failure to Notify*

  1. All members that are the subject of improper production tips and/or complaints

  2. All firms that applied unsuccessfully for Section 5 exemptions

  3. All firms that have initiated but never completed a Section 5 notice submission because of uncorrected defects in the submission

  4. All firms with a history of both new chemical production and of highly toxic substance production

     (a) All firms with primary manufacture in SIC code 2869
     (b) All firms with primary manufacture in SIC code 2865
     (c) All firms with primary manufacture in SIC code 2821

* All the firms in Failure to Notify subcategory 4 are the same as those in Commercial Use Violations subcategory 3. Consequently, selected firms should be checked for both violations when they are inspected.

5. All firms whose Section 5 notice submissions have been extended

- Withholding Material Information from or Submission of Materially False or Misleading Information on a Section 5 Notice or Exemption Request

  1. All category members that are the subject of "withholding information" or "false or misleading" complaints and/or tips

  2. Firms whose PMN form indicated significant levels of projected production, importation, or exportation

- Commercial Use of an Illegally Produced Substance*

  1. All firms that are the subject of commercial use tips and/or complaints

  2. All firms listed as recipients of improperly produced chemcials

  3. All firms with a history of both new chemical production and of highly toxic substance production

     (a) All firms with primary manufacture in SIC code 2869
     (b) All firms with primary manufacture in SIC code 2865
     (c) All firms with primary manufacture in SIC code 2821

* All the firms in Failure to Notify subcategory 4 are the same as those in Commercial Use Violations subcategory 3. Consequently, selected firms should be checked for both violations when they are inspected.

Discussion of Interim Scheme

The interim scheme presented above is divided first into four violation categories. Each of these categories is divided further into criterion-defined subcategories. The criteria used are neutral inspection triggers, and they define subcategories of the violation categories. In the interim scheme's "failure to notify" violation, for example, there are five subcategories. Three of them are: (1) all category members who are the subject of failure to notify complaints or other information indicating a failure to notify violation,* (2) all firms that have applied unsuccessfully for Section 5 exemptions, and (3) all firms that have initiated but never completed Section 5 submissions because the forms were rejected as deficient and never remedied.

Priorities and Resources

The order of the violation category and of the subcategories indicates the priority among the categories and subcategories. The violation priorities are based upon the seriousness of the violation. The subcategory priorities are based upon the likelihood that the members of a particular subcategory would commit that violation. If the Agency has insufficient resources to do a complete compliance monitoring program, enforcement efforts in lower priority violations should be reduced. If a Region's resources are still insufficient to cover the remaining violation categories, the lower priority subcategories in the remaining violation categories should be eliminated. Each Region must evaluate what resources will be available for Section 5 inspections and then decide how much of the scheme can be carried out. These decisions must be documented so that a court reviewing a Region's Section 5 inspection will see that it is based on neutral criteria and not post hoc rationalizations.

* OE recognizes that many of these complaints will furnish adequate probable cause to obtain a civil probable cause warrant regardless of this scheme. They are included here so that this scheme can be used as a tool for the allocation of all inspectional resources.

For those Regions unable to execute the full interim scheme, the following modifications are suggested:

- Failure to Notify

  Only subcategory 4 will require a significant amount of resources. Thus, a Region would only inspect in order of priority:

  - All those firms in subcategories 1, 2, and 3,
  - All those firms in subcategory 4(a) (SIC Code 2869),
  - All those firms in subcategory 4(b) (SIC Code 2865) only if all the firms in 4(a) have been inspected.
  - All those firms in subcategory 4(c) (SIC Code 2821) only if all the firms in 4(b) have been inspected.

- Commercial Use of an Illegally Produced Substance

  Only subcategory 3 will require a significant amount of resources. Thus a Region would only inspect in order of priority:

  - All those firms in subcategories 1 and 2,
  - All those firms in subcategory 3(a) (SIC code 2869),
  - All those firms in subcategory 3(b) (SIC code 2865) only if all the firms in 3(a) have been inspected,
  - All those firms in subcategory 3(c) (SIC code 2821) only if all the firms in 3(b) have been inspected.

It should be noted that if any these triggering criteria produce a subcategory that is too large, the selections in that subcategory can be randomized. For example, if there are only enough resources to inspect 50 percent of the members of a subcategory, the Regional Inspection Division will select half of the category members on a random basis.

Discussion of Final Scheme

Sometime in FY 81, OE will issue the final neutral administrative inspection scheme for Section 5. The final scheme will contain two additional violation categories, test marketing violations and research and development violations. This does not mean that we will not prosecute these violations if they are found prior to the issuance of the final scheme but only indicates that OE will have no affirmative monitoring programs for these violations until FY 81. (At some point in the future, OE will add violations of significant new use rules (SNUR) to the targeting scheme. The general SNUR program will probably not be fully opperational until late FY 81 at the earliest. Nevertheless, there will probably be SNURs for specific chemicals some time this year.)

Another significant change in the final scheme will be the incorporation of random subcategories in all but one of the violation categories. This will facilitate the statistical evaluation of the targeting scheme's effectiveness. (See Evaluation of Targeting Scheme, below, for a discussion of this evaluation.)

Evaluation of Targeting Criteria

Since the Agency will not have enough resources to inspect every firm regulated under TSCA, it is crucial that those groups of firms most likely to violate Section 5 be inspected. The subcategories under each violation address this concern, but it is possible that those criterion-defined subcategories might produce a group of firms no more likely to violate TSCA than if the firms were selected at random. Thus, it is important to periodically review the effectiveness of the targeting criteria.

OE can review these criteria by statistically evaluating the violation rates of each criterion-defined subcategory in comparison with the random subcategory of the same violation category. The violation rates of each subcategory will be statistically compared to the random subcategory. (If a firm is selected both in a criterion-defined subcategory and the random subcategory, the results will be counted in both.) In this way, OE will determine if there is a significant difference between the rate of violation of a particular criterion-defined subcategory and the random selection of the members in that entire violation category. If there is no significant difference, then OE will realize that the criterion in question should be dropped.

3c

Section 5
Penalty Policy Guidance

The Section 5 penalty policy is based upon the general TSCA Civil Penalty Policy of March 10, 1980. The authority to issue civil penalties is found in Section 16 of TSCA. Under Section 16, the Agency determines penalties in a two step process. First, EPA determines a "gravity based penalty" (GBP) based upon four statutory factors: nature, extent, circumstances, and gravity of the violation or violations. These factors are incorporated into the General TSCA Penalty Matrix (Matrix I on page 3-25). This matrix allows the determination of the gravity based penalty. The Agency then adjusts the GBP upward or downward by the violator's ability to pay, ability to continue in business, violation history and degree of culpability. In addition, the penalty may be adjusted by "other factors as justice may require".

This document contains two sections. The first is a summary of the Section 5 penalty policy. It allows the case preparation officer to efficiently determine the GBP and then make the appropriate adjustments. The second section, is a detailed explanation of the Section 5 penalty policy.

Summary of the Policy

Determining the Gravity Based Penalty

The gravity based penalty, based on nature, extent, and circumstances of the violation is determined by the General TSCA Penalty Matrix reprinted on page 3-25 (Matrix I). The case preparation officer will determine the 1) nature, 2) extent,

and 3) circumstances of the violation separately by using this summary. The case preparation officer will then plug these values into the general matrix. This will yield the gravity based penalty. The GBP will be adjusted through the application of the other factors stated in Section 16 of TSCA. The application of those adjustment factors is found in the general TSCA Penalty Policy of March 10, 1980 on pages 9-16.

Nature of the Violation

The nature of TSCA violation depends on whether the violation relates to chemical control, control-associated data-gathering, or hazard assessment. It is important to make this determination first as the other three initial factors depend on this determination. (See Matrices II and III on pages 3-27 and 3-28 respectively.) The following lists place the violation types in their respective nature determined categories.

1) Chemical Control Violations
   - Noncompliance with Section 5(e) or Section 5(f) orders, rules, or injunctions (those aspects dealing with the actual control of the substance)
   - Noncompliance with research and development exemption restrictions (noncompliance with the adequate warning requirement)
   - Commercial use of an illegally produced substance
   - Noncompliance with test marketing exemption restrictions (those aspects dealing with the actual control of the substance)

2) Control-Associated Data-Gathering Violations
   - Noncompliance with Section 5(e) or Section 5(f) orders, rules, or injunctions (those aspects dealing with record keeping)
   - Noncompliance with test marketing exemption restrictions (those aspects dealing with record keeping)

Matrix I

General TSCA Penalty Matrix

CIRCUMSTANCES (PROBABILITY OF DAMAGES)		EXTENT OF POTENTIAL DAMAGE		
		A MAJOR	B SIGNIFICANT	C MINOR
HIGH RANGE	1.	$25,000	$17,000	$5,000
	2.	20,000	14,000	3,000
MID RANGE	3.	15,000	10,000	1,500
	4.	10,000	7,000	1,000
LOW RANGE	5.	5,000	3,000	500
	6.	2,000	1,500	250

3) Hazard Assessment Violations

- Failure to notify (all violations)
- Withholding material information from or submitting false or misleading information on a Section 5 notice or exemption request
- Noncompliance with research and development exemption restrictions (overproduction)
- Any violation not listed in the above three categories

Extent of Violation

Extent is based upon the amount of substance involved in the violation and the nature of the violation. The case preparation officer should use the nature determination from the previous page and select the appropriate nature category in Matrix II. Then he or she should select the appropriate weight column and read up the column for the extent determination.

Circumstances of the Violation

The circumstances determination is based upon the probability that harm could have actually taken place. Matrix III provides the following levels for measuring circumstances:

Levels 1 and 2 (High)	-	the violation is likely to cause damage
Levels 3 and 4 (Medium)	-	there is a significant chance that damage,will result from the violation
Levels 5 and 6 (Low)	-	there is less likelihood that damage will result from the violation than from a level 3 or 4 violation.

MATRIX II

Extent Level

	A Major	B Significant	C Minor
Chemical Control	>200 lbs. >90.9 kg	>100 lbs to ≥200 lbs. >45.45 kg. to ≥90.9 kg.	0 to 100 lbs. 0 to 45.45 kg.
Control-Associated Data-Gathering	>1,500 lbs. >681.81 kg.	>500 lbs. to ≥1,500 lbs. >227.27 kg. to ≥681.81 kg.	0 to 500 lbs. 0 to 227.27 kg
Hazard Assessment	>1,500 lbs. >681.81 kg.	>500 lbs. to ≥1,500 lbs. >227.27 kg. to ≥681.81 kg.	0 to 500 lbs. 0 to 227.27 kg

Notes in using Matrix II

1) Production records will generally serve as the extent basis in the following violation categories:

   - Failure to notify (all violations)
   - Noncompliance with Section 5(e) or 5(f) orders, rules, or injunctions
   - Noncompliance with test marketing exemption restrictions
   - Noncompliance with research and development exemption restrictions (all variations)

If the underlying violative conduct does not relate to production, another more appropriate record should be employed to determine extent. If, for example, the violator disposes of 5,000 lbs. of the substance in violation of the terms of a 5(e) order, then the disposal record is the basis of the penalty.

2) The basis of extent in a commercial use violation will be the amount of illegally produced substance received by the violator.

3) If those records specified above are unavailable, the penalty should be assessed on those records that are available.

MATRIX III

Circumstances

Nature of Violation	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Chemical Control Violations	a) 5(f) substance included in a retail product and/or distributed to consumers b) 5(e), test marketed or illegal commercial use of substance distributed to consumers	a) 5(f) substance processed by another firm b) 5(e), test marketed or illegal commercial use of substance included in a retail product but not distributed to consumers	a) 5(f) substance which did not leave violator's premises b) 5(e), test marketed or illegal commercial use of substance that was processed by another firm	a) 5(e), test marketed or illegal commercial use of a substance that did not leave violator's premises		
Control Associated Data - Gathering Violations	Serious impairment and the missing data is unavailable	Serious impairment but the data is available	Important impairment and the data is unavailable	Important impairment but the data is available	Less than important impairment and the data is unavailable	Less than important impairment, but the data is available
Hazard Assessment Violations	Failure to notify or withholding/false or misleading violations where substance was distributed to consumers	Failure to notify or withholding/false or misleading violations where substance was not distributed to consumers			Research and development overproduction where some or all of the production not accounted for	Research and development overproduction where all of production accounted for

The factors used in considering circumstances vary with the nature of the violation. These factors are presented below and summarized in Matrix III on page 3-28. The case preparation officer should use the previously determined nature designation and select the appropriate nature category in Matrix III. Then he or she should select the appropriate circumstances found in that category and read up the column for the circumstances determination. The appropriate circumstances are determined by a two step procedure. First an initial circumstance level is set. Then adjustment factors are applied to increase or decrease the level of circumstances.

Chemical Control Violations. The determination of circumstances depends on severity (the initial circumstance level) and exposure (the adjustment factor).

1) Initial Circumstance Level:

- For noncompliance with 5(f) orders, rules, or injunctions, the initial circumstances level is 2.

- For the other violations in this category, the initial circumstances level is 3.

2) Adjustment Factors:

- If the substance never left the violator's premises, reduce the initial determination by one level.

- If the substance was further processed by another firm, the initial circumstances level remains the same.

- If the substance was packaged for commercial distribution but never shipped to the retail distributor, the circumstance level increases by one level.

- If any of the product was distributed to consumers or was released uncontrolled into the environment, the circumstance level will be increased by two levels.

Control-Associated Data-Gathering Violations. There are two factors to consider in determining the circumstances level for these violations: 1) the degree to which the Agency's ability to monitor and/or evaluate the substance is impaired (the

initial circumstance level) and 2) the availability of the missing information from other sources (the adjustment factor).

1) Initial Circumstance Level:

- If the violation seriously impairs the Agency's ability to monitor and/or evaluate a substance, the circumstance level will be 2.
- If the violation impairs the Agency's ability to monitor and/or evaluate a substance in an important way, the circumstance level will be 4.
- If the violation impairs the Agency's ability to evaluate and/or moniter a substance in a less than important way, the level will be 6.

2) Adjustment Factor

- If the missing information cannot be produced by the firm within five working days, the circumstance determination will be increased by one level.

Hazard Assessment Violations. The overriding consideration in a circumstances determination in this violation category is the type of violation involved (the initial circumstance level). The second consideration is the presence of aggravating factors (the adjustment factors).

1) Initial Circumstance Level

- Failure to notify and withholding false or misleading information violations automatically receive a level of 2.
- Overproduction of a research and development substance receives a level of 6.
- Any hazard assessment violation not listed above receives an initial level of 4.

2) Adjustment Factors

- Should any of the substance produced pursuant to failure to notify, or withholding false or misleading information violations be distributed to consumers, the circumstance range would be increased to the highest level.

- For the overproduced research and development substance, if the violator cannot account for all the overproduced substance at the time of inspection, or if some of it reaches consumers then the circumstance level is increased to level 5.

Gravity

No separate determination is needed for the gravity factor because this has already been taken into consideration by the other three factors.

Adjusting the Gravity Based Penalty

Follow the adjustment factor application instructions as presented in the general TSCA penalty policy document, "TSCA Civil Penalty System" of March 10, 1980 at pages 9-16. The only addition to these instructions will be in adjustment factor 4, economic gains from noncompliance. Here the penalty should equal the gross sales of the illegally produced product. The penalty should, in any case, not exceed the $25,000 per day statutory limit following the application of adjustment factor 4.

Imposing Penalties on a Per Day Basis

Violations that are designated "continuing" may be penalized on a per day basis; noncontinuing ones are penalized for one day only. The following are two lists of violations; one list contains continuing violations and the other contains noncontinuing violations. The criteria for separating these violation types into these two categories are found on page 3-40. In continuing violation situations, the penalty will be assessed on the basis of the amount of substance involved in that 24 hour period.

Continuing Violations

- Noncompliance with Section 5(e) and Section 5(f) orders, rules, and injunctions (those aspects dealing with controlling the substance).

- Noncompliance with research and development exemption restriction (violation of overproduction requirement).

- Commercial use of an illegally produced substance.
- Noncompliance with test marketing exemption restriction (those aspects dealing with controlling the substance).
- Failure to notify.

Noncontinuing Violations

- Noncompliance with test marketing exemption restriction (record keeping aspects).
- Noncompliance with Section 5(e) or 5(f) orders, rules, or injunctions (record keeping aspects).
- Noncompliance with research and development exemption restriction (violation of the adequate warning requirement).
- Withholding material information from or submission of false or misleading information on a Section 5 notice or exemption request.

When a penalty is assessed on a per day basis for a continuing violation, care must be taken to assure that the adjustment factors for "government clean up costs" and "economic benefits from noncompliance" are spread over the entire penalty since these figures are calculated by looking at the entire violative situation. For example, if a continuing violation lasted four days and generated $40,000 in government clean up costs, $10,000 in costs should be added to each day's penalty (although each day would still be limited to a maximum $25,000).

Example

A hypothetical firm was found to be producing a new TSCA substance that had never been submitted to EPA for PMN review. The violator voluntarily recalled all shipments of the new substance. The firm had produced 2,000 pounds per day of the substance over a two month period and had grossed $150,000 from mostly local sales of the product, but none of it reached consumers. The violator was aware of the PMN requirements as it had been fined two years earlier for producing a substance before expiration of its PMN review. The facts indicate that the violator mistakenly believed that it was producing a

substance that was already on the inventory. The gross annual sales of the firm is $3,500,000. (The penalty is worked out on the worksheet at page 3-34.)

This is a hazard assessment type violation. The extent is major as the violator produced 2,000 lbs. per/day of the substance. The circumstance analysis requires consideration of the type of violation involved and the presence of any aggravating factors. The initial circumstance assignment is 2 because the violation requires a high determination in each case. This initial determination is not adjusted upward because none of the new product reached consumers. This results in a gravity based penalty (GBP) of $20,000 per day.

The violator had sufficient knowledge to recognize that his conduct constituted a violation of Section 5. Had the firm taken greater care in adhering to the requirements of Section 5, the violation would have been prevented. Consequently, there is a level 2 culpability which yields no initial adjustment to the GBP. But the recall of the product by manufacturer is evidence of a good attitude and the penalty is adjusted down by 15%.

The firm has one prior violation. It is not an identical violation (production prior to notice expiration, a variation of failure to notify), but they are "closely similar" as both involve the illegal manufacture of a new substance. Thus, the penalty is adjusted upward by 50 percent. The sum of this adjustment upward and the culpability adjustment factor is an adjustment upward of 35% (50% - 15% = 35%). The penalty is increased to $27,000. This exceeds the maximum allowable penalty of $25,000; therefore, the penalty is reduced by $2,000 to reach that amount.

The violation took place over a two-month period of time. The penalty amount is multiplied by 60 days to yield $1,500,000. There were no government clean up costs from the violation as all the shipments were voluntarily recalled. The economic gain was $150,000. The penalty far exceeds this amount and need not be adjusted to reflect the economic gain.

The violator claims it cannot pay that large a fine and proves that its gross sales is only $3,500,000 anually. The 4 percent gross sales yields a figure of $140,000. Thus, the penalty would be $140,000.

CIVIL PENALTY ASSESSMENT WORKSHEET

Name of Respondent: _____
Address of Respondent: _____
_____

(1) Complaint I.D. Number: _____
(2) Date Complaint Issued: _____
(3) Date Answer Received: _____
(4) Date Default Order Sent: _____
(5) Date Consent Agreement Signed: _____
(6) Date Final Order Sent: _____
(7) Date Remittance Received: _____

1.	Gravity Based Penalty (GBP) from matrix . . .		$ 20,000
2.	Percent increase or decrease for culpability	-15 %	
3.	Percent increase for violation history .	50 %	
4.	Add lines 2 and 3	35 %	
5.	Multiply GBP by percentage total on line 4 .		$ 7,000
6.	Add lines 1 and 5 (subtract line 5 from line 1 if negative percentage)		$ 27,000
7.	Enter line 6 amount or $25,000 whichever is <u>less</u>		$ 25,000
8.	Multiply line 7 by the number of days of violation		$ 1,500,000
9.	Government clean-up costs, if any		$ 0
10.	Economic gains from non-compliance, if appropriate		$ 0
11.	Add lines 8 through 10		$ 1,500,000
12.	Total of other adjustments as justice may require		$ 0
13.	Add (or substract) line 13 to (from) line 12*		$ 1,500,000
14.	Maximum penalty for small firm (4% of gross receipts) if applicable and the information is available		$ 140,000

*Line 13 should be the proposed penalty for a given violation unless the small firm factor is applied. The procedure is repeated for each violation.

Detailed Background of the Section 5 Penalty Policy

This section states the rationale behind the policy summarized in the first portion of this document.

Nature of the Violation

The nature of a Section 5 violation depends on whether the violation deals with chemical control, control-associated data-gathering, or hazard assessment.

1. Chemical control regulations are aimed at minimizing the risk presented by a chemical substance by placing constraints on how the substance is handled. Subsections 5(e) and 5(f) authorize a wide variety of chemical control requirements from labelling restrictions to total manufacturing bans. Subsection 5(h)(1) authorizes the Administrator to impose restrictions upon the manufacture or processing of a test marketed substance. Violations of those restrictions that place constraints on how a substance is handled fall into this category. Subsection 5(h)(3) obligates a firm producing a substance under a research and development exemption to give adequate warning to employees if that substance is dangerous. This, too, is a constraint on a substance's handling and is included in this category. Such a violation is more a worker protection law than a toxic substance control law and may ultimately be enforced by the Occupational Safety and Health Administration. However, for penalty policy purposes, OE will consider it a chemical control question.

2. Control-associated data-gathering requirements are recordkeeping and/or reporting requirements associated with a chemical control regulation. These requirements enable the Agency to evaluate the effectiveness of the regulation and to monitor compliance. Some Section 5(e) and Section 5(f) orders, rules, or injunctions would fall into this category (e.g. Section 5(e) order that requires the manufacturer to keep records of all purchases of the regulated substance). Some test marketing exemption restrictions would also fall into this category as Section 5(h)(1)(B) authorizes the Administrator to impose, among other things, recordkeeping and/or reporting requirements.

3. Hazard assessment requirements are used to develop and gather information necessary to weigh the risks and benefits presented by particular chemical substances and to impose chemical control requirements when appropriate. This category includes violations for failure to notify, withholding information from or submission of false or misleading information, and failure to comply with a research and development exemption (overproduction). Although the last item does not fit precisely into the hazard assessment category, for purposes of the Section 5 penalty policy it shall be placed in this category.

Extent of the Violation

Extent is used to take into consideration the degree, range, or scope of the violation. Matrix I provides three levels for measuring extent. The three levels are based upon the amount of substance involved in the violation. This amount will be determined by the volume of substance involved in the underlying action that resulted in the violation. Thus if a firm manufactured 30,000 lbs. of a substance without going through premanufacture review, the penalty will be assessed on the basis of the production records which indicate 30,000 lbs. illegal production. Production records will generally serve as the penalty basis in the following violation categories:

- Failure to notify (all variations)
- Noncompliance with Section 5(e) or 5(f) orders, rules, or injunctions
- Noncompliance with test marketing exemption restrictions
- Noncompliance with research and development exemption restrictions (all variations)

If a firm disposes of a substance in violation of test marketing restriction or Section 5(e) injunction, then the amount illegally disposed is the basis of the penalty.

The basis for the penalty in the commercial use violation would be the amount of substance received by the violator.

It should be noted that if those records specified above are unavailable, the penalty should be assessed on those records that are available.

The three levels, major, significant, and minor are based on the standard shipping container of dry substances, the 100 lb. bag. For the chemical control violations, which are generally more serious than the violations in the other two categories, the penalty size increases rapidly for each bag. The violations in the other two categories are generally less serious and the penalty assessment increases more slowly. Thus the production of three bags of substance in violation of a hazard assessment requirement is consdered minor whereas the same amount produced in violation of a chemical control requirement is considered major. The rationale behind these levels is as follows:

Level A (Major)	- Potential for serious damage to health or the environment
Level B (Significant)	- Potential for less than serious but more than minor damage to health or the environment
Level C (Minor)	- Potential for minor damage to health or the environment

Application of the Extent Factor to Section 5

1) Chemical control violations. The potential for harm is greatest in this category because the Agency will have either knowledge or concerns that the substance may be harmful. Thus an amount of a substance that is considered minor in the two other categories may be considered major here. A minor designation covers amounts from 0 to 100 lbs. (0 to 45.45 kg.); a significant designation covers amounts greater than 100 lbs. to 200 lbs. (45.45 kg. to 90.90 kg.); the major designation is assigned to amounts greater than 200 lbs. (90.90 kg.).

2) Control-associated data-gathering. Since production, distribution, etc. is always allowed, the penalties escalate more slowly than for the chemical control category violations: minor is 0 to 500 lbs. (0 to 227.27 kg.); significant is greater than 500 lbs. to 1,500 lbs. (227.27 kg. to 681.81 kg.); major is greater than 1,500 lbs. (681.81 kg.).

3) Hazard assessment. In this category, the Agency can neither assume that the substance is harmless nor harmful. Thus the extent values will be the same as those in the control-associated data-gathering category: minor is 0 to 500 lbs. (0 to 227.27 kg.); significant is greater than 500 lbs. to 1,500 lbs. (227.27 kg. to 681.81 kg.); and major is greater than 1,500 lbs. (681.81 kg.).

Circumstances of the Violation

Circumstances are used in the penalty policy to determine the probability of harm actually occuring. In other words, a variety of facts surrounding the violation as it occurred are examined to determine whether the circumstances of the violation are such that there is a high, medium, or low probability that damage will occur. The case preparation officer will first use the nature determination to select the appropriate nature category on Maxtrix III (See page 3-28). Then the officer would select the appropriate circumstances in that category. Those circumstances involve a two step process. The initial level is set by the overriding circumstance and adjusted upward or downward depending on other less crucial factors. The matrix provides the following levels for measuring circumstances (probability):

Level 1 and 2 (High) - the violation is likely to cause damage

Level 3 and 4 (Medium) - there is a significant chance that damage will result from the violation

Level 5 and 6 (Low) - there is less likelihood that damage will result from the violation than from Level 3 or Level 4 violation.

Application of the Circumstances Factor to Section 5

I) Chemical control. For these violations, the initial circumstance level is based on the severity of the violation. When the toxicity of the substance in question is unknown as in noncompliance with Section 5(e) actions, noncompliance with a research and

development exemption restriction on adequate warning, improper commercial use of an illegally produced substance, and noncompliance with a test marketing exemption restriction on the use of a substance, the penalty policy will assign an initial level of 3.

When the Agency determines that a substance's toxicity is unreasonable, as in all 5(f) actions, the toxicity level will be 2. These initial circumstance evaluations are adjusted by the degree of environmental exposure. If the substance never left the violator's premises, the circumstance range is reduced one level. If it was processed in another facility but went no further, the level remains the same. If the substance was included in a retail product but never sold to the public, the circumstance evalution will be increased by one level. If any of the product was distributed to consumers or was released uncontrolled into the environment, the level will be increased by two.

2) Control-associated data-gathering. For these violations there are two factors to consider: (a) the extent to which the Agency's ability to monitor and/or evaluate the substance is impaired and (b) the availability of the missing information. Violations that seriously impair the Agency's ability to monitor or evaluate a substance will receive an initial circumstance level of 2. If the violation impairs the ability to monitor and/or evaluate in an important way, the initial circumstance level will be 4. If the impairment is in a less than important way, then the level will be 6. In all of these cases, if the missing information cannot be produced by the firm within 5 working days of the inspection, the circumstance level will be adjusted upward by one.

3) Hazard assessment. The overriding consideration in this category is the type of violation involved. Failure to notify and withholding/false or misleading violations present such a serious likelihood of damage that they will automatically be assigned an initial circumstance level of 2. If any of the product is distributed to consumers, the circumstances range will be adjusted upward to the highest level. Overproduction of a research and development substance is a much less serious

violation and is assigned an initial circumstance level of 6. If the violator cannot account for all the overproduced substance at the time of inspection, or if some of the product reaches consumers, then the circumstance range is adjusted upward to the 5 level.

Gravity of the Violation.

Gravity refers to the overall seriousness of the violation. As used in this penalty system, gravity is a dependent variable (i.e., the evaluation of nature, extent, and circumstances will yield a dollar figure on the matrix that is the gravity based penalty).

Continuing Violations.

TSCA provides not only that civil penalties may be assessed up to $25,000 but that each day a violation continues is a separate violation for which penalties maybe assessed. Thus TSCA could allow for very large penalties. For some violations, these large penalties will be appropriate. For either purely technical violations or for violations whose underlying action was completed within one 24 hour period, these large penalties would not be appropriate. Should a firm fail to keep adequate records for a few months as required by the terms of a test marketing exemption or a Section 5(e) rule, the violation could result in a penalty as large as $1,500,000. Consequently, the Agency should generally not penalize Section 5 violations falling into the control-associated data-gathering category, research and development exemption restriction violations (overproduction) and withholding/false or misleading violations. The other violations are inherently more serious threats to public health or the environment and will be subject to the larger penalty that a per day analysis would provide.

Continuing violations are as follows:

- Noncompliance with Section 5(e) and Section 5(f) orders, rules, and injunctions (chemical control aspects)
- Noncompliance with research and development exemption restrictions (violation of adequate warning requirement)
- Commercial use of an illegally produced substance

- Noncompliance with test marketing exemption restrictions (chemical control aspects)

- Failure to notify

Noncontinuing violations are as follows:

- Noncompliance with test marketing exemption restrictions (control-associated data-gathering aspects)

- Noncompliance with Section 5(e) and 5(f) orders, rules, and injunctions (control-associated data-gathering aspects)

- Noncompliance with research and development exemption restrictions (overproduction)

- Withholding material information from or submitting materially false or misleading information on a Section 5 notice or exemption request

When a penalty is assessed on a per day basis for a continuing violation, care must be taken to assure that the adjustment factors for "government clean up costs" and "economic benefits from noncompliance" are spread over the entire penalty since these figures are calculated by looking at the entire violative situation. For example, if a continuing violation lasted four days and generated $40,000 in government clean up costs, $10,000 in costs should be added to each day's penalty (although each day would still be limited to a maximum $25,000 penalty).

COMPLIANCE STRATEGY FOR THE TSCA §5 (h)(4) PREMANUFACTURE NOTICE EXEMPTION FOR CHEMICALS USED IN OR FOR INSTANT PHOTOGRAPHIC OR PEEL-APART FILM ARTICLES

COMPLIANCE STRATEGY FOR THE TSCA §5(h)(4) PREMANUFACTURE NOTICE EXEMPTION FOR CHEMICALS USED IN OR FOR INSTANT PHOTOGRAPHIC OR PEEL-APART FILM ARTICLES

OVERVIEW

Under section 5(h)(4) of the Toxic Substances Control Act (TSCA), EPA may, upon application and by rule, exempt a new chemical substance from some or all of the section 5 premanufacture notice requirements if the Administrator determines that the substance will not present an unreasonable risk of injury to health or the environment. On June 4, 1982, the Agency published a final rule at 47 Federal Register 24308 (40 CFR Part 723). This rule is an exemption under TSCA section 5(h)(4) from the premanufacture notice requirements of section 5(a)(1)(A) for the manufacture and processing of new chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles under certain conditions. These conditions include: (1) submission of an exemption notice when manufacture begins, (2) compliance with certain requirements to limit exposure, and (3) compliance with recordkeeping requirements found in the rule. The exemption is limited to the manufacturers of instant photographic or peel-apart articles who manufacture and process new chemical substances used in or for the manufacture or processing of these articles. A peel-apart film article containing a new chemical substance may not be distributed in commerce or used until a premanufacture notice under section 5(a)(1)(A) is submitted and the review period has ended. The effective date of the rule is July 6, 1982.

A new chemical substance manufactured under the terms of the exemption will not be added to the TSCA Chemical Substance Inventory. However, a firm may elect to submit a premanufacture notice (PMN) for a chemical covered by the exemption, and the chemical will be placed on the inventory after the notice review period ends and manufacturing begins unless EPA takes action, such as issuance of a section 5(e) or section 5(f) order.

Only two firms are believed to be eligible at present for this exemption. Inspections to insure compliance with this rule will be incorporated into the section 5 inspection program.

Failure to comply with the terms of the exemption constitutes a violation of section 15(1)(B) which provides that noncompliance with a section 5 requirement or rule is unlawful.

REQUIREMENTS OF THE RULE

Applicability

This rule establishes the conditions for an exemption from PMN requirements. In order to manufacture or process a new

chemical substance used in or for instant photographic film articles, a manufacturer has the option of complying with the exemption or submitting a premanufacture notice for the specific chemical to EPA 90 days prior to manufacturing or processing the chemical substance.

This exemption applies only to manufacturers of instant photographic or peel-apart film articles who:

1) manufacture the new chemical substances used in or for the manufacture or processing of the instant photographic or peel-apart film articles;

2) submit an exemption notice when manufacture begins;

3) limit manufacture and processing of a new chemical substance to the site(s) listed in the exemption notice;

4) comply with conditions of the exemption in paragraphs (e), (f), (g), (h) and (j) of section 723.175; and

5) do not distribute in commerce or use a peel-apart film article containing a new chemical substance until submission of a premanufacture notice under section 5(a)(1)(A) of the Act and until the review period for the notice has ended without EPA action to prevent distribution or use.

Notice Requirement

A notice must be submitted to EPA when manufacture of the new chemical substance under the exemption begins. Table I lists the information which must be included in the notice. The notice must be addressed to the Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, EPA, 401 M St. S.W., Washington, D.C. 20460.

Requirements to Limit Exposure

All manufacturing, processing, and use operations involving the new chemical substance must be performed in a demarcated, special production area under the conditions found in Table II until the substance has been incorporated into a wet mixture, photographic article, or instant photographic or peel-apart film article.

The following activities are allowed outside the special production area provided the conditions given in Table II for these activities are met:

1) Removal of the new chemical substance from the special production area for storage between operational steps or for transportation to another special production area. §723.175(e)(8)

2) Incorporation of a wet mixture containing the new chemical substance into a photographic article or instant photographic or peel-apart film article. §723.175(f)

3) Incorporation of a photographic article into the instant photographic or peel-apart film article. §723.175(g)

Although labeling is required for removal or transportation of the new chemical substance from the special production area, no labeling is required if the substance has been incorporated into a photographic article, or if it is contained in a sealed reaction vessel or pipeline, or if it has been incorporated into an instant photographic or peel-apart film article. While the rule does not specifically exclude wet mixtures from labeling, the intent was that labeling not be required for wet mixtures.

Other Requirements

Other conditions of the exemption relate to environmental release, waste treatment, and recordkeeping. These requirements are given in Tables III and IV. In addition to maintaining the records listed, the manufacturer must make the records available to EPA upon written request by the Director of the Office of Toxic Substances (OTS). These records must be provided within 15 working days of receipt of the request. This in no way relieves the manufacturer from having to make these records available during inspections conducted in accordance with TSCA section 11.

AMENDMENT AND REPEAL

The regulation provides for amending or repealing any term of the exemption by formal rulemaking if EPA determines that activities under the exemption may present an unreasonable risk. EPA may also amend the exemption to enlarge the category or reduce the restrictions. Furthermore, the Director of the Office of Toxic Substances may prohibit the use of the exemption if he or she determines that the manufacture, processing, distribution in commerce, use or disposal of the substance may present an unreasonable risk. This prohibition can be accomplished without formal rulemaking. §723.175(m)

REGULATED INDUSTRY

The regulated industry consists of those companies who 1) manufacture or process a new chemical substance used in or for instant photographic or peel-apart film articles and 2) manufacture the article and 3) submit an exemption notice. EPA is aware of only two companies which meet the first two requirements - Polaroid and Eastman Kodak. Therefore, they are the only two companies expected to be eligible for the exemption. Each of these firms has several sites where chemicals may be manufactured under the exemption. The designation of the location of manufacturing sites is required

in the exemption notice.

ENFORCEMENT

ENFORCEMENT GOALS

The goal is to assure compliance with the terms of the exemption.

VIOLATIONS

° NOTICE VIOLATIONS

Withholding material information or submitting false or misleading information.

Failure to file an exemption notice when other exemption conditions are met.*

Late notice.

(*Failure to file a notice when other exemption conditions are not met is a PMN violation rather than an exemption violation.)

° EXPOSURE LIMITS

Exceeds exposure limits, as determined by EPA's monitoring.

Exceeds exposure limits, as reflected by company's records.

Failure to take steps to limit exposure.

° MONITORING

Failure to monitor.

Failure to monitor properly, e.g., unsuitable sample methods, incorrect intervals, improper location.

° ENGINEERING CONTROLS & EXPOSURE SAFEGUARDS

No engineering controls and exposure safeguards used where required.

Inadequate engineering controls and exposure safeguards used where required.

No labeling where required.

Improper or incomplete labeling where required.

° RESPIRATORY PROTECTION

Proper respirators not provided for individuals in Special

Production Area (SPA).

Respirators not worn by individuals in SPA.

Quantitative fit test not performed.

° TRAINING

No training program.

Not all required individuals attend.

Inadequate/incomplete training program.

° HYGIENE

Appropriate facilities for changing and washup not provided.

Food, beverages, tobacco products, or cosmetics allowed in SPA.

Inappropriate standards of hygiene which do not limit exposure.

° WORK PRACTICES

Improper spill/release control.

Written procedures for responding to emergency situations not immediately accessible to employees in SPA.

Materials for emergency situations not immediately accessible to employees in SPA.

Practices do not limit exposure to appropriate level.

Spills or unanticipated releases of a wet mixture not controlled by trained personnel wearing appropriate protective clothing and equipment.

° PERSONAL PROTECTION DEVICES

Improper clothing or equipment.

° CAUTION SIGNS

No signs.

Improper signs.

° ENVIRONMENTAL RELEASE AND WASTE TREATMENT

Waste not handled as hazardous waste.

Wastewater or discharge not pretreated.

Wastewater or discharge not properly pretreated.

Process emissions not vented through appropriate control devices.

° RECORDKEEPING

Records not kept.

Records incomplete.

° RECORDS SUBMISSION

Records not submitted.

Records not submitted on time.

° PROHIBITION

Prohibition violated.

° AMENDMENTS

Violation of an amendment.
There have been no amendments at this time.

INSPECTIONS

Neutral Administrative Inspection Scheme

All sites where chemicals are being manufactured/processed or records are kept under this exemption will be inspected on a periodic basis. The Region should inspect each site after an initial exemption notice is submitted for that site, preferably within 120 days after the notice is submitted. If no violations are found, the Region should inspect again approximately one year from the date of the first inspection. If no violations are found during the second inspection, then the Region should re-inspect each site approximately every two years.

If violations are found, the Region should reinspect the site within 120 days. This should continue until two consecutive inspections are conducted and no violations are found. After that, the Region should inspect the site approximately every two years.

Inspections may also be conducted at other companies/sites based on tips or referrals.

Scheduling Inspections

Prior to scheduling inspections, the Region should contact the company to discuss when the exempt chemicals will be manu-

factured, where the records are kept, and a time frame as to when EPA could inspect. A specific inspection date need not be arranged with the company. Unannounced inspections are considered desirable to assure compliance with this exemption.

ADMINISTRATIVE CONSIDERATIONS

Allocation of Responsibilities

Office of Toxic Substances

The Office of Toxic Substances will:

1. Review the exemption notices.

2. Have the Management Support Division make two copies of the exemption notice and other relevant information, including the name and phone number of the Notice Review Manager and a statement of any OTS questions or concerns, and notify the Document Control Officer in the Pesticides and Toxic Substances Enforcement Division (PTSED) within 15 working days after receipt of an exemption notice that the documents are available.

3. Have the Notice Review Branch provide the Management Support Division with the information referenced in #2.

4. Provide technical support to PTSED and to the Regions when needed via PTSED.

5. Designate a contact person(s) to participate at PTSED's request in the review of inspection reports or case files involving possible violations of the exemption.

6. Provide expert witnesses as needed.

Pesticides and Toxic Substances Enforcement Division (PTSED)

The Pesticides and Toxic Substances Enforcement Division will:

1. Forward copies of the exemption notices to the Regions including technical information relevant to the individual notices and any OTS concerns.

2. Provide technical support to the Regions, including guidance for conducting inspections and coordinating with OTS and the Office of Legal and Enforcement Counsel (OLEC) to resolve technical or legal questions.

3. Review inspection reports and keep OTS informed regarding compliance with the exemption regulation.

4. Revid concur on civil cases prepared by the Regions. Thisudes forwarding the cases for concurrence to OLEC as red.

5. Coore other TSCA §5 inspectional activities with thisram.

6. Arramor expert witnesses.

7. Make mmendations to OTS regarding amendments, repeal, or prition of use of the exemption.

Regions

The Regionill:

1. Contacne company after receiving a copy of the exemption n:e from PTSED to determine when the exempt chemicill be manufactured, where the records are kept, a time frame for inspection.

2. Schedulinspections based on the neutral administrative inspect scheme in this strategy.

3. Performe inspections and gather evidence.

4. Send a irtesy copy of the inspection report to the Complia Monitoring Branch of PTSED.

5. Prepare sultant civil cases and litigate such cases. (Criminacases are to be handled according to guidance issued bOLEC concerning TSCA criminal cases.)

Program Integrati

During an insection to determine compliance with the exemption, the inspector shoud also inspect for compliance with other TSCA §5 requirements. Prir to conducting an inspection to verify compliance with the exemption the Region should contact PTSED regarding other TSCA §5 submissionactivities of the company.

Through the cmpliance monitoring activities related to the enforcement of TSCA §5, the inspector may obtain compliance monitoring information involving other EPA enforcement programs. For example, an inspector may turn up violations relating to other parts of TSCA or of the water, air, or solid waste pollution control regulations. Thus, it is important for all those involved in Section 5 enforcement to communicate non-Section 5 compliance monitoring information to the appropriate office in EPA.

TABLE I

INFORMATION REQUIRED IN THE EXEMPTION NOTICE

1. NAME OF MANUFACTURER - §723.175(i)(1)(i)

2. SITES AND LOCATIONS WHERE THE SUBSTANCE WILL BE MANUFACTURED AND PROCESSED - §723.175(i)(1)(i)

3. CHEMICAL IDENTITY - §723.175(i)(1)(ii)

4. IDENTITY OF IMPURITIES REASONABLY ANTICIPATED §723.175(i)(1)(iii)

5. DESCRIPTION OF PHYSICAL AND CHEMICAL PROPERTIES §723.175(i)(1)(iv)

6. IDENTITY OF BY-PRODUCTS AND VOLUME OF EACH - §723.175(i)(1)(v)

7. ESTIMATE OF ANTICIPATED MAXIMUM ANNUAL PRODUCTION VOLUME §723.175(i)(1)(vi)

8. ALL INFORMATION AND TEST DATA ON THE NEW CHEMICAL SUBSTANCE'S HEALTH AND ENVIRONMENTAL EFFECTS THAT ARE KNOWN TO OR REASONABLY ASCERTAINABLE BY THE MANUFACTURER - §723.175(i)(1)(vii)

IDENTITY AND DESCRIPTION OF THE ARTICLE THAT WILL CONTAIN THE THE NEW SUBSTANCE - §723.175(i)(1)(viii)

10. DESCRIPTION OF METHODS USED TO CONTROL AND TREAT WASTEWATER OR DISCHARGE RELEASED TO A POTW OR OTHER RECEIVING BODY OF WATER. IDENTITY OF POTW OR OTHER RECEIVING BODY OF WATER. §723.175(i)(1)(ix)

11. CERTIFICATION THAT THE MANUFACTURER IS FAMILIAR WITH AND WILL COMPLY WITH THE TERMS OF THE EXEMPTION - §723.175(i)(1)(x)

ACRONYMS USED IN TABLES

POTW - Publicly Owned Treatment Works

TWA - Time Weighted Average

SPA - Special Production Area

E II

REQUIREMENTS TO LIMIT EXPOSURE

	SPECIAL PRODUCTION AREA (SPA)	AREA ADJACENT TO SPA	REMOVAL FOR STORAGE OR	PROCESSING WET MIXTURES OUTSIDE SPA	INCORPORATION INTO ARTICLES
POSURE MITS	Air Concentration - TWA 10 ppm for gases and vapors 50 ug/m for particulates Allowable TWA excursion of 50% above for 30 minutes or less. §723.175(e)(1)	Must not exceed limit for waiver of respirator protection in SPA. §723.175(e)(10)	Must limit exposure. §723.175(e)(8)		Must take measures to limit exposure during operation using engineering controls, training, hygiene, work practice and personal protective devices. §723.175(g)
NITORING* When suitable sampling and analytical methods exist.	Must monitor using suitable sample method. Monitor first 3 eight-hour work shifts involving the manufacture or processinng of each new chemical substance; then, 1 eight-hour shift per month during production run during period of maximum employee exposure. If in compliance for 3 months, monitor only every 6 months unless there is a change in process, process design, or equipment (then begin monitoring again). Samples must represent worker's breathing zone. §723.175(e)(3)(A) (See this section for details of monitoring.)	Periodic monitoring same as for SPA in areas where it is reasonable to expect a risk of inhalation exposure. §723.175(e)(10)			

ECORDS REQUIRED TO BE MAINTAINED

TABLE I
REQUIREMENTS TO LIMIT EXPOSURE

	SPECIAL PRODUCTION AREA (SPA)	AREA ADJACENT TO SPA	REMOVAL FOR STORAGE OR TRANSPORTATION	PROCESSING WET MIXTURES OUTSIDE SPA	INCORPORATION INTO ARTICLES
ITORING* hen suitble sampling and nalytical ethods o not xist.	A surrogate chemical substance possessing comparable physical chemical properties under similar manufacturing and processing must be used to assure compliance with exposure limits. §723.175(e)(3)(B)	Same as for SPA. §723.175(e)(3)(B)			
INEERING TROLS & OSURE EGUARDS	Controls and safeguards must be used to ensure compliance with exxposure limits. §723.175(e)(4)		Labeling required. Must include identity or code, statement of any known hazards, handling instructions, first aid information, spill control directions, and DOT notations. §723.175(e)(9)	Must limit exposure, to the new chemical substance. §723.175(f)(1)	Controls and safeguards must be used to limit exposure to the new chemical substance. §723.175(g)
PIRATORY TECTION*	Respirator required for each individual. Quantitative fit test before first use. Waiver if monitoring shows 8-hr TWA of the new chemical substance is less than 1 ppm for gases and vapors and 5 ug/m for particulates with allowable TWA excursion above for 30 minutes or less. §723.175(e)(2)				

TABLE II
REQUIREMENTS TO LIMIT EXPOSURE

	SPECIAL PRODUCTION AREA (SPA)	AREA ADJACENT TO SPA	REMOVAL FOR STORAGE OR TRANSPORTATION	PROCESSING WET MIXTURES OUTSIDE SPA	INCORPORATION INTO ARTICLES
\INING)GRAM*	Required before employee can enter. Must cover known physical-chemical and toxicological properties of chemicals handled in the SPA, procedures for using personal safegaurds, hygiene, handling procedures, emergencies, and spills. §723.175(e)(5)(i)			Required for employees handling wet mixtures. Must cover procedures for using personal exposure safeguards, hygiene, handling procedures, emergencies and spills. §723.175(f)(2)(i)	
;IENE	Facilities for changing and washup must be provided. No food, beverages, tobacco products, or cosmetics allowed in the Special Production Area. §723.175(e)(5)(ii)			Appropriate standards that limit exposure must be used by employees handling the wet mixtures. §723.175(f)(2)(ii)	Hygiene must limit exposure. §723.175(g)
RK ACTICES	Must be designed to ensure compliance with exposure limits. Spills or unanticipated emissions must be controlled by trained personnel wearing suitable protective clothing or equipment, such as chemical-resistant coveralls, protective eyewear,and gloves. Written procudures and all materials necessary for emergency situations must be immediately accessible. §723.175(e)(5)(iii)			Must be designed to limit exposure to the new chemical substance. Spills or unanticipated releases must be controlled by trained personnel wearing protective clothing and, where necessary, respirators or chemically impervious clothing. §723.175(f)(2)(iii)	Work practices must limit exposure. §723.175(g)

RECORDS REQUIRED TO BE MAINTAINED

TABLE II
REQUIREMENTS TO LIMIT EXPOSURE

	SPECIAL PRODUCTION AREA (SPA)	AREA ADJACENT TO SPA	REMOVAL FOR STORAGE OR TRANSPORTATION	PROCESSING WET MIXTURES OUTSIDE SPA	INCORPORATION INTO ARTICLES
ONAL ECTION CES	Workers in the SPA must wear suitable protective clothing or equipment, such as chemical-resistant coveralls, protective eyewear, and gloves. §723.175(e)(6)			Workers engaged in the processing of wet mixtures must wear suitable protective clothing or equipment such as coveralls, protective eyewear, respirators, and gloves. §723.175(f)(3)	Personal protective devices must be used to limit exposure. §723.175(g)
ION S	Area must be clearly posted. Sign must restrict entry to trained personnel equiped with appropriate personal exposure safeguards. §723.175(e)(7)				

CORDS REQUIRED TO BE MAINTAINED

TABLE III

ENVIRONMENTAL RELEASE AND WASTE TREATMENT

° RELEASE TO LAND - §723.175(h)(1)

Process waste from manufacturing and processing operations in the special production areas are considered hazardous waste and must be handled in accordance with 40 CFR Parts 262 through 267 and Part 122 and Part 124.

° RELEASE TO WATER - §723.175(h)(2)

Wastewater or discharge must be pretreated before release to a POTW or other receiving body of water. To release to a POTW, pretreatment must prevent structural damage to, obstruction of, or interference with the operation of the POTW. For direct release, treatment must be appropriate for the substance's properties.

° RELEASE TO AIR - §723.175(h)(3)

All process emissions must be vented through appropriate control devices.

TABLE IV

RECORDKEEPING*

- PRODUCTION RECORDS - §723.175(j)(1)(i)

  Annual Production Volume**
  Date manufacture began

- EXPOSURE MONITORING - §723.175(j)(1)(ii)

  Record of all monitoring including:

  - Chemical identity
  - Date of monitoring
  - Actual monitoring data for each monitoring location and sampling
  - Reference to or description of collection and analytic techniques

  If manufacturer does not monitor, records of reasons for not monitoring and the methods used to determine compliance with exposure limits must be kept.

- TRAINING AND EXPOSURE RECORDS - §723.175(j)(1)(iii)

  Records of worker's participation in required training.
  Records to demonstrate regular use of personal exposure safeguards, including results of personal exposure monitoring.
  Results of quantitative fit test for respirator.
  Any additional information related to worker's exposure.

- TREATMENT RECORDS - §723.175(j)(1)(iv)

  Method of treatment if manufacturer releases treated wastewater or discharge containing a new chemical substance to POTW or receiving body of water.

*Records must be kept for 30 years following the final date of manufaacture.

*Although not required to be kept by the regulation, information as to the estimated annual sales volume should also be requested by the inspector.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 25 1979

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Inventory Enforcement Strategy

TO: Enforcement Division Directors
Air and Hazardous Materials Division Directors
Surveillance and Analysis Division Directors
Toxics Coordinators

Attached is the final strategy for enforcement of the inventory reporting regulations. The strategy incorporates comments received earlier from Headquarters and Regional personnel. Major changes from the initial draft include a more specific delineation of compliance monitoring priorities, allocation of responsibility between Headquarters and the Regions, and a revision of the civil penalty assessment procedure in accordance with the overall TSCA civil penalty policy currently under development by contractor.

PTSED expects to have developed the first inspection schedules for the Regions one month after the inventory is published in June 1979.

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division

INVENTORY REPORTING REGULATIONS
FINAL ENFORCEMENT STRATEGY

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INVENTORY REPORTING REGULATIONS
FINAL ENFORCEMENT STRATEGY

I. Summary

Inventory reporting regulations were promulgated under §8(a) of the Toxic Substances Control Act (TSCA) on December 23, 1977. The major objective of the regulations is to allow EPA to acquire information necessary for the compilation of an inventory of chemical substances currently manufactured, imported, or processed for a commercial purpose in the U.S., as required by TSCA §8(b). An initial inventory based on reports from manufacturers of chemical substances and importers of chemical substances in bulk will be published in May 1979. Thereafter, processors of chemical substances and importers of chemical substances in mixtures or articles will be given an opportunity to report any eligible substances not included on the initial inventory. This information will be included in the revised inventory, to be published in 1980.

Once the initial inventory is published, anyone wishing to manufacture a chemical substance or import in bulk any substance not on the inventory must notify EPA at least 90 days in advance. Substances which complete this premanufacture notification process and are manufactured for a non-exempt *commercial purpose will be added to the inventory.

This document contains the strategy of the Office of Enforcement (OE) for enforcing the inventory reporting regulations. It discusses the regulation requirements, violations, priority compliance monitoring activities for FY79 and 80, case preparation and penalty assessment procedures as well as the allocation of responsibilities between Headquarters and the Regions.

Headquarters will have the major responsibility for selecting subjects for compliance monitoring while the Regions will be responsible for conducting inspections and case preparation.

In FY79 OE will concentrate its major efforts on detecting reporting of substances excluded from the inventory 1) because manufactured or imported solely for research and development or 2) because not manufactured or imported after January 1, 1975. OE will also attempt to identify persons who failed to report for the initial inventory as required and whose substances are being reported by processors during the revised inventory reporting period. In FY80, after publication of the revised inventory, OE will use its resources primarily to respond to reports of inventory reporting violations.

* See definition in proposed premanufacture notification requirements (44 FR 2242).

II. Strategy Development

A. Regulation

1. Objectives

The inventory reporting regulations promulgated under §8(a) of TSCA have two primary objectives.

First the regulations require information necessary for compilation of the inventory of chemical substances required by TSCA §8(b). TSCA §8(b) requires that the Administrator compile, keep current and publish a list of chemical substances currently manufactured or processed for a commercial purpose in the U.S. Since the term "manufacture" includes "to import into the customs territory of the U.S.," the inventory will also include chemical substances imported for a commercial purpose. Any substance not on the inventory is a "new" chemical substance. Under the §5 premanufacture notification requirement, a manufacturer of any new chemical must notify EPA before he can manufacture it for a non-exempt commercial purpose.

The inventory will be a continually expanding list. The initial inventory is expected to include over 95% of chemical substances eligible for reporting. Publication of the initial inventory will trigger premanufacture notification for manufacturers and importers of chemical substances in bulk. Substances which complete the premanufacture notification process and are to be manufactured for a non-exempt commercial purpose will be added to the inventory. For a 210 day period after publication of the initial inventory, additional chemicals may also be added to the list by processors, users and certain importers.

Secondly, under authority of TSCA §8(a)(1)(A), these regulations require reporting of production and site information which is reasonably necessary for establishing a profile of the chemical industry, monitoring chemical substances in the environment, and setting Agency priorities for implementing other provisions of TSCA.

2. Requirements

a. The initial inventory

Manufacturers and importers had to report for the initial inventory concerning all chemicals they manufactured or imported for a commercial purpose in 1977 if (1) thirty percent or more, by weight, of the products manufactured or imported consisted of the types described under Standard Industrial Classification (SIC) Group 28 or 2911, or 2) the total pounds of reportable substances equaled one million pounds or more. In addition, manufacturers and importers had to report concerning any chemical that was manufactured

at a single site or imported during 1977 in quantities greater than 100,000 pounds. Companies which fell within the criteria had to report:

1) the identity of each chemical substance,

2) for any polymer, the identity of at least those monomers used at greater than two percent (by weight) in the manufacture of that polymer,

3) whether each substance reported was manufactured or imported,

4) the site(s) where the substance was manufactured or imported, whether the manufacture was site limited, and

5) the amount (in broad ranges) manufactured at each site or imported during 1977.

Small manufacturers and importers did not have to report production volume or the site(s) where a substance was manufactured or imported. A manufacturer or importer qualified for this exception if its total annual sales in 1977 were less than $5 million. However, the range of production volume of any substance produced in quantities greater than 100,000 pounds during 1977 had to be reported regardless of total annual sales.

Persons not required to report for the inventory could, nonetheless, report any substance they had manufactured or imported for a commercial purpose since January 1, 1975. To avoid potential premanufacture notification, such persons were responsible for ensuring that eligible chemicals they manufactured or imported were reported by someone.

All information for the initial inventory had to be reported by May 1, 1978. On April 17, 1978, the Agency announced that a manufacturer or importer unable to meet this deadline because of extenuating circumstances might be granted an extension not to exceed June 1, 1978.

Persons beginning manufacture or importation of a chemical substance during the period between May 1, 1978 and the effective date of the premanufacture notification requirements are required to submit an inventory report when manufacture or importation begins.

b. The revised inventory

Publication of the initial inventory will be followed be publication of a revised inventory. Reporting for the revised inventory is not mandatory. During the 210 day reporting period, however, any eligible chemical substance not on the initial inventory may be reported by those who (1) have processed or used the chemical for a commercial purpose since January 1, 1975 or (2) have imported the chemical as part of a mixture or article since January 1, 1975. (The latter persons were also able to report for the initial inventory). Such persons need only report chemical identity, polymer information, and whether they import and/or process the substances reported. They are encouraged, however, to report site and production data as well. By reporting during this period, processors and users will protect themselves from prosecution under TSCA §15(2) for using a substance in violation of the premanufacture notification requirements of §5. Importers of chemical substances as part of mixtures avoid going through premanufacture notification by reporting during this period.

c. Reporting by trade associations or other agents

A trade association or other agent could not report for anyone required to report for the initial inventory.

A trade association could report for any of the following persons:

1) anyone who has manufactured or imported a chemical substance for a commercial purpose since January 1, 1975 and who was not required to report for the initial inventory.

2) any processor or user of a chemical substance who chooses to report for the revised inventory.

3) anyone who imports a chemical substance as part of a mixture or article and chooses to report for the revised inventory.

d. Prohibited reporting

Certain substances may not be reported for either the initial or revised inventory. These include:

1) chemicals which are manufactured or imported solely for the purpose of research and development (R & D). Chemical quantities of less than 1,000 pounds/year are presumed to be for research and development purposes.

2) chemicals not manufactured, imported, or processed for a commercial purpose since January 1, 1975.

These substances include pesticides, tobacco products, nuclear materials, firearms, and foods, drugs, cosmetics, or medical devices.

4) mixtures.

In addition chemicals which are not considered to have been manufactured, imported, or processed for a commercial purpose per se are excluded from the inventory. Examples of such chemicals are impurities, by-products which have no commercial purpose themselves, chemicals which are not intentionally removed from the equipment in which they were manufactured, and certain other incidental chemicals (see 710.4(d)(3)-(8)).

e. Recordkeeping requirements

All persons who report under the inventory regulations must keep records substantiating all information reported. In addition, trade associations, in their capacity as agents for persons subject to these regulations, must keep records indicating which manufacturer, importer, or processor will be able to document to EPA that reported chemicals were manufactured, imported, or processed since January 1, 1975.

f. Confidentiality

Manufacturers, importers, and processors may claim any item of reported information to be confidential, including the specific chemical identity. Confidentiality claims must accompany the reported information and must be substantiated by a signed certification statement. EPA will not disclose a confidential chemical identity to inquiring chemical manufacturers unless they can show a bona fide intent to manufacture the particular chemical (section 710.7(g)).

3. Regulated Industry

A characterization of the chemical industry performed for EPA indiates that 10,000 manufacturers comprise the industry. 150 of these firms with sales of $100 million account for 80% of industry sales.

There are no accurate figures available regarding the number of importers subject to the inventory reporting requirements. According to the American Importers Association, there are at least 1200 brokers and up to 35,000 importers who might be affected.

4. Inventory Development Timetable

The following is a timetable of major dates in implementation of the inventory. Related Federal Register publications are listed in Appendix J.

Dec. 23, 1977	Promulgation of final inventory reporting requirements
May 1, 1978	Deadline for submission of forms for initial inventory
June 1, 1978	Extended deadline for submission of reporting forms
May 1979	Publication of initial inventory
June 1979	Premanufacture notification for manufacturers and importers of chemical substances in bulk
May 1979	Complete computer system (Informatics) operational
February 1980	Publication of revised inventory
March 1980	Premanufacture notification for importers of chemical substances as part of a mixture

B. Strategy Development

1. Objectives

The major objectives of a program for enforcement of the inventory reporting requirements are:

a. to help ensure the integrity of the inventory so that it will act as an effective guide for premanufacture notification under TSCA §5.

b. to ensure the accuracy of production and site information which will be used by EPA to set priorities for implementing other sections of TSCA.

The inventory will be the sole basis for triggering the premanufacture notification requirement under TSCA §5. The site and production information reported, however, will probably not be the only elements used in the determination of priorities for implementing other TSCA sections. Therefore, the Office of Enforcement will use its limited resources primarily to reach the first objective.

2. Priority Violations

Potential violations ranked in order of their concern to OE are:

a. reporting excluded substances

b. reporting false information

c. failure to report at all

d. failure to maintain records

e. failure to include all information

f. failure to report on time

g. clerical errors

This strategy ranks each potential violation on the basis of the economic incentive for its commission, its impact on the implementation of §5 and, to a lesser degree, on its impact on the abilities of the Agency to carry out effectively other objectives of TSCA.

a. Reporting Substances Excluded from the Inventory

Thirty days after publication of the initial inventory, any person who wishes to manufacture or import in bulk a chemical substance not on the inventory must comply with the premanufacture notification requirements of TSCA §5. If a §4 testing rule is applicable to a new chemical substance, a person must have the required test data before he can submit a premanufacture notice. In addition submission of premanufacture notification may delay, limit, or prohibit production of a substance under §5(e) or §5(f). A person would have a major economic incentive to report for the inventory any chemical substance he intends to manufacture or import in the future to avoid §5 requirements.

R & D substances and substances not manufactured, imported or processed since January 1, 1975 are excluded from the inventory by statute. Congress intended these substances to go through the premanufacture notification process before being manufactured or imported for a commercial purpose. Substances not currently under the jurisdication of TSCA are also excluded. (See II A.2.d.3) If these categories of substances (particularly the former two) are included in the inventory, the success of the premanufacture notification process will be jeopardized. Because of the great economic incentive for committing this violation and the great impact of the violation on §5 implementation, OE considers reporting excluded substances the most important inventory violation.

b. Reporting False Information

Some persons may submit false data with respect to production volume and whether the substance is distributed for commercial purposes outside the production site. The inventory reporting regulations required reporting of production volume only in broad ranges. However, a company might report a much lower production volume to avoid public concern over the production site of large quantities of potentially hazardous chemicals. A substantially higher production volume might be reported for R & D chemicals or substances not manufactured since January 1, 1975 to avoid premanufacture notification requirements.

A company might report that a substance is not site limited to avoid premanufacture notification which might be required if later distribution outside the production site is covered by a significant new use rule. There is no major economic incentive for reporting false data aside from that associated with avoidance of premanufacture notification. To the extent that submission of false data would result in frustration of the premanufacture notification process, it will be considered a major violation.

To the extent that submission of false data might impact implementation of other TSCA provisions, it will be considered a lesser violation.

c. Failure to Report at All

Unless a person is certain someone else will report a substance he manufactures or imports, there is little economic incentive for failing to report for the inventory. This is particularly true since by reporting a person avoids the necessity for premanufacture notification.

Failure by a manufacturer or importer to report on chemical substances as required will be considered a serious violation based on its effect on the ability of the Agency to carry out effectively other sections of the Act. Failure to report a substance that has not been reported by anyone will be considered a serious violation. Failure to report a substance already included in the inventory will be consider only a technical violation.

d. Failure to Maintain Records

Manufacturers, importers, processors and trade associations are required to keep certain records as described in I.A.2.e above. There is no major economic incentive for committing this violation. Failure to keep such records will result in a presumption that information submitted to the Agency is inaccurate. Since the Agency must be able to rely on the information submitted to carry out TSCA §5 as well as other

sections of the Act, failure to maintain records particularly with respect to production years and use for a commercial purpose will be considered a serious violation.

e. Failure to Include All Information

Manufacturers and importers whose total annual sales exceed $5 million must report on production volume and whether the chemicals is site-limitated. There is no major economic incentive for committing this violation unless it is to hide an excluded substance. To the degree that the omission could affect the success of the premanufacture notification program, it will be considered a major violation.

f. Failure to Report on Time

There is no major economic incentive for a failure to report on time. Although late reporting is preferable to failure to report at all, it remains a violation.

g. Clerical Errors, Internal Inconsistencies, Other Missing Information

Reporting errors of a clerical nature will not be the target of enforcement actions.

3. Compliance

a. Voluntary Compliance

An effective program aimed at informing the affected industry of the inventory reporting requirements was undertaken by the Office of Industry Assistance. The general public would have little interest in this regulation.

Based on comments received during the comment period for the proposed regulations, national public interest groups are well-informed of the requirements. Any additional attempts to reach local interest groups should be confined to discussion of the inventory as it relates to §5 requirements.

b. Compliance Monitoring

1) Discovery Tools

Tools potentially available to EPA for discovery of violations of the inventory reporting regulations include the following:

a) inventory data

b) non-inventory data bases on manufacturers and importers of chemical substances

c) reports of violations

- o from private individuals/companies
- o from other government agencies
- o from other EPA offices

d) on-site inspection/investigation

Of these, the on-site inspection/investigation is the only tool which can be relied on alone as the basis for filing a complaint. Generally, OE will have to monitor compliance with the inventory reporting regulations by developing a neutral inspection schedule based on indications of potential violation from the inventory itself, random selection from the inventory, outside allegations of violation and indications of violation discovered in the course of other TSCA or EPA inspections.

2) Application of Tools to Specific Violations

a) Reporting Excluded Substances

i) R & D Substances

EPA may select persons for inspection because it suspects them of having reported a substance manufactured or imported solely for research and development. Such a selection may be made based on one or a combination of the following methods:

- o OTS will select from the inventory any substances produced or imported in quantities of less than 1000 lbs/year and reported by known manufacturers or importers of R & D substances.
- o OTS will select from the inventory those chemical substances which were assigned new Chemical Abstract Service (CAS) numbers.
- o OE will select from the National Enforcement Investigation Center (NEIC) violation list (Appendix A) manufacturers or importers reporting for the inventory who have a history of violating other EPA reporting or registration requirements.
- o Informatics will compare the inventory with lists of substances manufactured prior to 1977 (see International Trade Commission (ITC) and Stanford Research Institute (SRI) lists in Appendix A) to isolate substances appearing on the inventory but <u>not</u> listed elsewhere as having been manufactured prior to 1977. This method is of limited

value for several reasons. There are no specific listings for imported substances. Because the ITC listing excludes substances produced in quantities of less than 5000 lbs. and both ITC and SRI listing are incomplete, a failure to appear one either list may not indicate a violation.

ii) Substances Not Manufactured, Processed, or Imported Since January 1, 1975

To determine which substances reported for the inventory might not have been manufactured or processed since 1975, the inventory will be compared with ITC and SRI data for 1975, 1976, and 1977. Informatics will make this comparison and transfer the results through PTSED to the regions for further investigation.

Since these lists are incomplete, substances isolated may not be in violation. A percentage of the manufacturers of substances isolated, however, will be included in a regional inspection schedule along with a random selection of importers who reported for the inventory.

iii) Chemical Substances Used Solely for Non-TSCA Purposes

To isolate substances improperly reported because they are used solely for non-TSCA purposes, Informatics could compare the inventory with lists of substances from Treasury (tobacco and firearms), Nuclear Regulatory commission (nuclear materials), FDA (foods, drugs, cosmetics) and OPP (pesticides).

Chemical substances used in products regulated by these agencies may also have other uses appropriate for regulation under TSCA. Therefore, EPA would have to conduct inspections to verify whether substances isolated in this manner have reportable uses. This approach consumes more resources than it merits given the potential rewards.

b) Reporting False Information

There are no complete or accurate public data available outside the inventory on production volume per chemical substance or on site limitation. The only way to discover substantial variation from reported production ranges or false reporting of site limitation is through books and records inspections. OE could include manufacturers, processors and importers in inspection schedules based on reports of violation or random selections from the inventory.

c) Failure to Report at All

The most difficult violation to discover will be a failure to report at all. Outside allegations of violation, isolation of manufacturers or importers of chemical substances reported for the revised inventory by users and processors, and a comparison of inventory reports with available listings

may yield some suspects for inclusion in the inspection schedule. The available listings, to the degree that they are useful at all, can only indicate possible violations.

Manufacturers

Manufacturers are listed by SIC code in the following compilations (See Appendix A):

i) Dun and Bradstreet

ii) PTS/EIS

iii) OSHA

iv) PCS

Chemicals are listed by manufacturer in the following compilations:

i) SRI

ii) ITC

iii) ORD

None of these listings is complete and none makes a distinction between manufacturers and processors.

Failure to report by those who exceed the poundage criteria will also be difficult to detect. The lists available for comparative purposes (ITC, ORD, SRI) are incomplete and generally indicate only production capacity not actual production volume.

Sales figures are generally listed by chemical or chemical group and not always by manufacturer (ITC, Dun and Bradstreet). Although some sales figures by manufacturer are included in the ORD list, this information is incomplete and is limited to 400 organics which are likely to be included in the inventory.

Importers

To bring chemicals into the U.S. after premanufacture notification requirements go into effect importers must sign a certification indicating that each imported chemical substance is in compliance with all TSCA requirements.

To determine whether importers have unlawfully failed to report, EPA will rely on Customs Inspectors to notify EPA when entry forms do not contain the necessary certification. Customs will hold the shipment or release it under bond until certification is verified. If the importer cannot supply documentary proof of compliance with inventory requirements, the substance will be refused entry.

Non-documentary verification of the accuracy of certification will be more difficult. Actual sample analysis of substances as a means of verification is expensive and time consuming unless the basic identity of the substances is known. Sampling/analysis will be restricted to cases presenting a strong suspicion of violation.

d) Failure to Maintain Records

This violation can be discovered only through on-site inspections.

e) Failure to Include All Information

To isolate those manufacturers and importers who have omitted site and production data and are in violation because they have incorrectly described themselves as small (total annual sales of less than $5 million), Informatics could compare sales information in the Dun & Bradstreet and PTS/EIS lists against information reported for the inventory. Dun and Bradstreet and PTS/EIS list sales by manufacturer and SIC code. A comparison might also be made with the sales information for the 400 organics included in the ORD list. All listings, however, are incomplete.

To isolate an otherwise small manufacturer or importer who should have reported production and site information for a particular substance because it was manufactured or imported in quantities of over 100,000 pounds, Informatics could compare inventory production information with production capacity data on the SRI lists.

Since all manufacturers/importers are not included in the available lists and the information included is not reliable, OE would have to inspect a percentage of those persons whose forms have missing information as well as those about whom OE has received allegations of violation.

f) Failure to Report on Time

OE will search for manufacturers and importers who failed to report as required and whose substances are being reported by processors during the revised inventory reporting period in the following manner:

i) OTS will select a random number of processors reporting for the revised inventory and turn the list over to OE for further investigation.

ii) OE will request from each processor a certification that he is not also a manufacturer of the substance.

iii) If the processor is not a manufacturer of the substance, OE will request a list of the processor's suppliers.

iv) OE will contact each supplier and ask for certification that he was not required to report for the initial inventory (i.e., substance was not manufactured/imported after January 1, 1975)

v) OE will conduct a routine records inspection of a percentage of the suppliers identified.

vi) If OE finds an alleged violator, his name will be turned over to the Premanufacture Review Division at the same time case preparation is begun to bring an enforcement action for violation of the inventory reporting regulations.

g) Clerical Errors, Internal Inconsistencies, Other Missing Information

Clerical errors, internal inconsistencies, or missing information such as signatures, names and addresses, principal technical contacts, registry numbers, or EPA code numbers discovered on the form are being handled by the Chemical Abstract Service (CAS), which has contracted for the responsibility of compiling the inventory. When such clerical mistakes are observed, CAS will either return the form or communicate directly with the company by letter. Should these procedures be unsuccessful in resolving the matter, the appropriate EPA Regional Office could be called in to assist. As indicated earlier, reporting errors of a clerical nature will not be the target of enforcement actions.

3. Priority Compliance Monitoring Activities

Since a major function of the inventory is to act as a trigger for the premanufacture notification process, OE will place its major emphasis on those compliance monitoring activities 1) designed to insure the integrity of this function and 2) which can reasonably be undertaken given available resources (see II.B.3.b.2)). With this purpose in mind, compliance monitoring activities in order of priority are:

a) those designed to detect inclusion of R & D substances.

b) those designed to detect inclusion of substances not manufactured since January 1, 1975.

c) those designed to detect failures to report on time.

d) those conducted in response to reports of any of the inventory reporting violations.

Subjects will be selected for compliance monitoring on the basis of the neutral inspection schemes described in (II B.3.b.2)).

Thorough compliance monitoring prior to initial inventory publication would ideally insure the integrity of the published inventory as a §5 trigger and prevent confusion resulting from post publication deletions. Practically, OE can do little to enforce the inventory prior to initial publication.

OE will conduct its inventory enforcement program primarily during the period between publication of the initial inventory and publication of the revised inventory.

The following table indicates the emphasis OE will place on inventory reporting compliance monitoring activities after inventory publication.

% Allocation of Resources Available for Inventory Enforcement

Stage	CM Activity	% of Total Resources
After Initial Inventory Publication	Affirmative CM for R & D Substances	40%
	Affirmative CM for Substances Not Manufactured or Imported after 1975	30%
	Affirmative CM for for Late Submissions	20%
	Responsive CM to Reports of Other Violations	10%
After Revised Inventory Publication	Affirmative CM for R & D Substances	____
	Affirmative CM for Substances Not Manufactured or After Imported 1975	____
	Responsive CM to Reports of Other Violations	100%

III. Strategy Implementation

A. Program Management

1. Allocation of Responsibility

The following table summarizes the allocation of responsibility for management and implementation of the inventory enforcement program.

	Headquarters		
	PTSED	OTS	Regions
R & D Substances			
o Select Subjects	X	X	
o Notify Regions	X		
o Conduct Inspections			X
o Prepare Cases	X*		X*
Substances Not Manufactured or Imported After 1975			
o Select Subjects	X	X	
o Notify Regions	X		
o Conduct Inspections			X
o Prepare Cases			X
Reports of Violation			
o Investigate Reports	X	X	X
o Conduct Inspections			X
o Prepare Cases	X*		X
Late Submissions			
o Identify Subjects	X	X	
o Send Notices	X		
o Conduct Inspections			X
o Prepare Cases			X

*Headquarters will take over case preparation for R & D substances where 1) more than one region is involved or 2) the R & D determination is a complex one.

The allocation of responsibilities illustrated in the table is based on a) special expertise, and ease of access to data, and b) resources required for a given activity compared with c) resources actually available.

a. Special Expertise and Ease of Access to Data

Headquarters OE will be responsible for working with OTS to select subjects for compliance monitoring activities because of the greater ease of access to inventory data as well as other data required in making the selections.

b. Resource requirements

Resources will be required for selecting subjects from inventory and non-inventory data bases, for inspection/ investigation, and case preparation as follows:

1) Selection of subjects

a) Inventory data

OE will use several approaches to select candidates for inspection from data submitted for the inventory:

i) During the revised inventory reporting period, OTS will forward to OE on a monthly basis a list of processors who have reported. OE will go through the steps described in II B. 3. b. 2) f) to determine whether any of the suppliers of the processors are in violation of the inventory reporting requirements. Selection of processors by OTS will require approximately 2 weeks. Further follow-up by OE Headquarters prior to inspection by the Regions will require approximately 2 weeks.

ii) Informatics One month after publication of the initial inventory, a complex computer system will be available to OE for selection of inspection candidates. OE can request candidates based on any of the parameters reported for the inventory with a turn around time of 2 days.

b) Non-inventory data bases

Date available to OE outside of the inventory are limited and not extremely reliable. (See Appendix A for description of data sources.) While there are a number of listings of importers, there is no comprehensive listing of specific chemical substances by importer. Information on manufacturers is also poor

and makes no distinction between manufacturers and processors. As a result, establishment of a complete, reasonably accurate industry profile for comparison with the inventory reporting data is not possible. The limited data which are available could be used as a starting point in selecting manufacturers and importers for inclusion in an inspection schedule only for select violations as indicated in (II. B. 3.b.2)).

OE can expect a turn around time of 2 days to obtain a list of inspection candidates from any non-inventory data base on computer tape and available within EPA. If a non-inventory computer tape must be compared with the inventory, it may take as long as two weeks to obtain results. If non-inventory data is available only in bound form, the time required to obtain a candidate list will be 2 days for inventory printout and at least 2 weeks by OE personnel or a contractor to make the manual comparison.

2) Investigation/inspection

OE will have to investigate any substantive reports of violation before instituting any enforcement action. Resources required will range from those required for writing a letter to the alleged violator requesting clarification of the circumstances to those required for an on-site inspection.

The following elements were considered to determine resource requirements for establishment inspections:

- o preparation time
- o travel time
- o books and records inspection
- o inspection report preparation

Requirements per inspection will vary with differences in travel time, the complexity of the potential violation being investigated, and the experience of inspectors in conducting this type of inspection. Given these variables, PTSED feels that an average inspection will require 5 days.

3) Case Preparation

Case preparation will vary depending on whether a case is settled or goes to a hearing. PTSED estimates that case preparation through settlement will require 15 days while case preparation through a hearing will require 15 days for write-up and 15 days for litigation (a total of 30 days.)

It is estimated that violations will be discovered in 10% of the inspections conducted. Of the resulting cases, it is estimated that 85% will be settled while 15% will go to a hearing.

d. Application of available resources to strategy resource requirements

Based on the figures contained in the preceding section (III.A.1.b.) and the resources available in FY79 and FY80, the following calculation can be made to summarize the scope of the inventory reporting enforcement program in FY79 and FY80.

30 workdays	=	Headquarters inspection schedule development FY 79
10 Workdays	=	Headquarters inspection schedule development FY 80
5 workdays	=	one inspection
220 workdays	=	one work year
4 workyears	=	resources available in FY79
3 workyears	=	resources available in FY80
X	=	total number of inspections
.10 X	=	number of case preparations
(.10X)(.85)(15)	=	number of case preparations for settlement
(.10X)(.15)(30)	=	number of case preparations for hearing

1) 4 work years x 220 work days/ work year = 880 workdays

2) 30 + 5X + 1.27X + .45X = 880 workdays
X = 126 inspections in FY79

1) 3 work years 220 workdays/workyear = 660 workdays

2) 10 + 5X + 1.27X + .45X = 660 workdays
X = 98 inspections in FY80

The inspections will be assigned to the Regions by Headquarters based on the pattern revealed in the selection of subjects for investigation. Regions will also be responsible for any case preparation resulting from the inspections. Regions should, however, adhere to the Concurrence Procedures (See March 27, 1979 memo to Regions) prior to proceeding with any case. These procedures are particularly important to insure a consistent approach in cases involving an R & D substance since the definition for such a substance may be subject to varying interpretations. In cases where classification of a substance as R & D is genuinely open to dispute, Headquarters will take over the case.

2. Need for Delegation of Authority and Confidentiality Clearance

All Regions have authority to conduct inspections under TSCA. Currently, however, Regions do not have adequate enforcement personnel cleared to access and copy confidential information in the course of an inspection or to access confidential data reported to EPA which may be necessary for adequate case preparation. If sufficient Regional personnel do not receive confidentiality clearances, the inspection and case preparation responsibilites must shift to Headquarters.

B. Outreach

Headquarters will be responsible for implementing Outreach as described in II. B. 3. a.

C. Compliance Monitoring Program

Once OE has selected subjects for compliance monitoring, an on-site inspection will be used as the most effective tool for discovering violations. Before the inspection program can proceed, the following issues must be addressed:

1. Confidentiality

Because it is quite likely that inspectors conducting a §8(b) inspection will need to gain access to information claimed confidential, all inspectors must have a security clearance from the Office of Toxic Substances.

Inspectors must be thoroughly familiar with procedures in the TSCA Confidential Business Information Security Manual. Confidential data reviewed and collected as part of an inspection must be treated with the same strict security measures as confidential data submitted to the Agency under TSCA reporting requirements.

2. Training

All TSCA inspectors should be familiar with basic principles of chemistry. No advanced training in chemistry, however, is necessary for conducting inspections related to inventory reporting requirements.

Inspectors must be thoroughly familiar with the Inventory Reporting Regulations, the Inventory Enforcement Strategy, and the procedures for conducting TSCA inspections as outlined in the PCB Inspector's Manual and Appendix C of this Strategy. There will be no need for sample collection.

3. Inspection Sites

Since it is likely that complete records will be kept at corporate headquarters or a company's major business office, the initial inspection should be conducted there. If necessary, additional inspections may be required at specific production sites.

4. Inspection for R & D Substances

Certain violations such as failure to maintain records or reporting false production data may readily be detected in a books and records inspection. The determination that a substance has been reported in violation of the R & D exclusion will be more difficult. A substance may be initially presumed by EPA to be an R & D chemical because it is produced in annual quantities of less than 1000 lbs. and there is no other public information available to indicate that it has been produced for a commercial purpose. While a books and records inspection may not clearly rebut or affirm this presumption, the following considerations should be kept in mind:

Pre-Revised Inventory Publication

- o A manufacturer must be able to produce clear evidence that a substance is used for commercial purpose. Sale of a substance is not enough alone to justify its classification as a reportable substance in commercial use. A manufacturer must be able to produce, documentation such as letters from customers certifying that the chemical in question is being used for purposes other than research and development.

- o A company must use consistent criteria for distinguishing R & D from test market and other commercial substances. EPA should honor these criteria as long as the company is consistent in their application. A company may not, for example, use one set of criteria to support inclusion of a substance in the inventory and another set to justify exemption of a substance from premanufacture notification requirements under §5(h)(3) of TSCA.

Post Revised Inventory Publication

After publication of the revised inventory, an additional test may be used in conjunction with tests listed above to determine whether a substance should be considered an R & D substance. A substance produced in small quantities, even if sold, will be considered an R & D substance if used under the direction of a technically qualified individual. A person who because of his training, education or experience 1) is able to appreciate the health & safety aspects of the substances used under his supervision;

2) is responsible for enforcing methods of scientific experimentation, analysis, or chemical research to minimize such risks and 3) is responsible for safety assessments and clearances related to the procurement, storage, use and disposal of the chemical substance as required by the scope of the R & D activity is considered a technically qualified individual. A great degree of control by the manufacturer and a great degree of technical qualification on the part of those handling or supervising the use of a substance will distinguish a substance held to be for R & D from one considered to be for a commercial purpose other than R & D.

5. Post Inspection Procedures

After each inspection, the inspector shall write an Inspection Report based upon information on the Violation Worksheet (Appendix C) 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, the Violation Worksheet, a copy of his applicable Field Notes and other relevant supporting documents to the case preparation officer. The inspector shall keep the original Field Notes in his files and shall keep on file copies of all other material sent to the case preparation officer.

D. Enforcement Proceedings

Regional enforcement officials shall examine each Inspection Report and any other relevant material submitted by the inspector and make the following determinations:

1. Is there a probable violation?

2. If so, what type of enforcement action, if any, should be brought?

3. Against whom should the enforcement action be brought?

4. If the enforcement action is one for administrative civil penalty assessment, how much should the proposed civil penalty be?

Guidelines for making each of these determinations are provided below:

1. Determination that a Violation Exists

Each failure by a person to comply with a specific inventory reporting requirement for a single chemical substance shall constitute a separate violation. To determine whether a probable

violation exists, the case preparation officer shall consult the Violation Citation Charges (Appendix D) and Evidence in Support of Charges (Appendix E) and compare them with all the evidence provided in the Inspector's Report. The case preparation officer may determine that there is insufficient evidence to support a violation charge. If additional evidence can be obtained without unreasonably intensive efforts and the violation if substantiated is not insignificant, the case preparation officer should ensure that steps are taken to remedy any evidentiary deficiencies.

If the case preparation officer determines that the available evidence will support a violation charge, he/she will transmit the material to the Regional enforcement attorney who will determine what enforcement action should be brought against the alleged violator.

2. Selection of Proper Enforcement Action

The Agency may bring a number of enforcement actions against an alleged violator. The Agency may:

a) issue a notice of non-compliance
b) assess an administrative civil penalty
c) institute a civil court action
d) institute a criminal court action

To determine what general level of enforcement action would be appropriate for the violation standing alone, the enforcement attorney shall consult the Violation Charges/Action Levels (Appendix D) and Evidence in Support of Charges (Appendix E). Thereafter, the enforcement attorney shall determine what specific enforcement action should be selected by considering the following criteria.

Notice of Non-compliance

A notice of non-compliance may be issued where:

1) the violation does not impede the Agency's ability to enforce the premanufacture notification requirement,

2) the violation affects the accuracy of the chemical profile established by the inventory but is not criticial to EPA's ability to detect other violations.

3) the violation is the first violation of the inventory reporting regulations, and

4) the violation does not appear to have been willful.

A notice of non-compliance should be issued only if the enforcement attorney determines in his/her discretion that the violation passes these tests and that the 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.

Administrative Civil Penalty

Most violations will be handled by administrative civil penalty assessed according to the procedure outlined in III. D. 4 below.

Civil Court Action

A civil court action for injunctive relief may be brought against the alleged violator in lieu of or in addition to assessment of an administrative civil penalty, if the alleged violator ignores the civil penalty.

Criminal Court Action

Criminal action will be recommended only if the alleged violator has willfully or knowingly reported an excluded substance with the knowledge that the substance, because of its toxic properties, would probably be controlled under the premanufacture notification system.

3. Liability

The Inventory Reporting Regulations define "persons" to include individuals as well as corporations, partnerships or associations. In taking enforcement action to redress violations of these regulations, therefore, EPA generally has the option of proceeding against the business entity alleged to be in violation and/or against the responsible official who signs the reporting certification or who would be responsible for doing so.

Generally, EPA will hold only the corporation liable for the actions of its officers and employees. The Agency, however, reserves its right to impose individual liability under appropriate circumstances. If EPA brings an action against a partnership or an unincorporated association, the partners/members will, of course, be jointly and severally liable. (Depending on whether the "entity" or "aggregate" theory of partnership prevails in a given state, EPA will have to name the partnership or the partners to ensure the validity of its complaint.)

In an action against a totally or partially owned subsidiary, EPA may join any parent company which plays a substantial role in the business affairs of the subsidiary.

4. Civil Penalty Assessment Procedure

a. Threshold decision and complaint

Once the enforcement attorney has determined that a civil penalty is warranted, he/she must prepare a complaint setting forth the appropriate charges as listed in Appendix D and propose to assess a civil penalty which is the sum of the independently assessable charges contained in the complaint.

b. Independently Assessable Charge

A separate civil penalty shall be assessed only for each violation of the inventory reporting regulations which results from an independent act (or failure to act) of the respondent and which is substantially distinguishable from any other charge in the complaint. A given charge is independent and substantially distinguishable from any other charge for the purpose of assessing separate penalties if each provision requires an element of proof not required by the other. Thus not every charge which may appear in the complaint will be separately assessed. For example, a manufacturer may falsely report a large production volume to hide the fact that he is reporting an R & D substance for the inventory. He would be charged with two violations: reporting false information and reporting an excludable R & D substance. However, since the second charge grows out of the first, the manufacturer would be assessed a civil penalty only for reporting an excludable substance.

c. Civil Penalty Assessment System

A civil penalty system for use by EPA in implementing TSCA is currently being developed under contract. The civil penalty assessment system is composed of two elements: A Gravity Base Penalty (GBP) which provides a method of assigning penalties to violations based on their seriousness; and Adjustment Procedures which provide a method of adjusting the Gravity Base Penalty to account for mitigating and/or exacerbating factors related to the violator.

Under this system violations of TSCA have been grouped into two major categories: control violations--those involving mishandling of a regulated chemical substance and data gathering violations--those involving failure to adhere to a monitoring, recording or reporting regulation. Data gathering violations have further been divided into those associated with a regulation controlling a chemical substance and those not associated with a control regulation. The latter are aimed at developing information needed to assess the threat of a new or existing chemical substance.

Violations of the Inventory Reporting Regulations fall into the category of non-associated data gathering violations. The overall TSCA penalty system has been developed around violations of regulations of a chemical substance and must be adapted somewhat to accommodate violations of non-associated data gathering regulations. The basic structure and guidelines, however, do provide the required approach.

i) Gravity Base Penalty

The major modification of the overall TSCA civil penalty assessment system to suit inventory reporting violations occurs in the assignment of the GBP. Generally EPA will use a Gravity Base Penalty Matrix (Appendix F) to determine the GBP amount for a violation of TSCA. OE has modified this GBP matrix in two respects to accommodate the inventory reporting regulations.

Penalty amounts in the GBP matrix have been assigned based on the seriousness of the violation. Two parameters are used to established the severity of a violation: extent of damage and potential that damage will occur. For inventory reporting violations the extent of the violation defined by the section of TSCA affected and the potential damage by the potential that the violation will seriously affect implementation/ enforcement of the TSCA section.

In addition the GBP matrix has been modified to eliminate as inapplicable the "Significant" level from the "Extent of Damage" indicator and the "Mid-range" level from the "Potential Damage" indicator. The following is a description of the measures of "extent" and "potential" for violations of inventory reporting regulations.

/EXTENT/

Major - A major violation is one that affects the premanufacture notification requirements.

Minor - A minor violation is one that could affect sections of TSCA other than §5.

/POTENTIAL/

High Range - The violation directly affects EPA's ability to enforce or implement a TSCA requirement.

Low Range - The violation results in a lack of data which is important but not critical to TSCA enforcement or implementation procedures.

Based on consideration of the above-mentioned factors the following GBP's are suggested for each of of the potential inventory reporting violations. (See Appendix D for potential action levels in addition to a complaint.)

o Reporting Excluded Substances:

Extent of Damage

Major - The report affects the Agency's premanufacture notification requirements.

Potential for Damage

High - If an excluded substance is reported for the inventory, EPA will not be able to implement or enforce the §5 requirements with respect to the substance.

GBP = $25,000

o Reporting False Information:

Extent of Damage

Major - The false information affects the premanufacture notification requirements.

Minor - The false information affects sections of TSCA other than §5.

Potential for Damage

High - The false information results in the inclusion of an excluded substance and thereby affects EPA's ability to enforce or implement §5.

Low - The false information results in lack of data used to select chemicals for further study.

GBP

Major/High - The GBP will be assessed under the violation for reporting an excluded substance. No separate GBP will be assessed for false reporting.

Minor/Low - $250

o Failure to Report

Extent of Damage

Major - The failure to report affects implementation of §5 because the substance has been reported by no one.

Minor - The failure to report potentially affects only implementation of other sections of TSCA because the substance was reported by someone else.

Potential for Damage

High - It may result in needless pre-manufacture notification by other manufacturers.

Low - It results in a lack of data for use in selection of chemicals for further study.

GBP

Major/High - $25,000

Minor/Low - $250

o Failure to Maintain Records

Extent of Damage

Major - The failure to maintain records for production years and use for a commercial purpose could affect implementation of section 5.

Minor - The failure to maintain records could affect implementation of TSCA sections other than section 5.

Potential Damage

High - The lack of production and commercial use records cannot be compensated by other information to substantiate reporting of a non-excluded substance.

Low - In most cases lack of records can be compensated with other information and will result only in a lack of substantiation for data which is important but not critical to EPA selection of substances for further control.

GBP

Major/High - The GBP will be assessed under the violation for reporting an excluded substance. No separate GBP will be assessed for failure to maintain records.

Minor/Low - $250

o Failure to Include All Information

Extent of Damage

Major - The failure affects premanufacture notification.

Minor - The failure affects sections of TSCA other than §5.

Potential Damage

High - The failure results in inclusion of an excluded substance.

Low - The failure results in a lack of data affecting selection of substances for further control.

GBP

Major/High - The GBP will be assessed under the violation for reporting an excluded substance. No separate GBP will be assessed for failure to include all information.

Minor/Low - $250

o Failure to Report in Time

Failure to report on time will be considered under two time frames - before initial inventory publication and after initial inventory publication.

Before Initial Inventory Publication

No GBP

Untimely reporting theoretically affects the integrity of the inventory as a basis for premanufacture notification. In fact, however, as long as reports were received in time to be included in the initial inventory, the Agency will be able to implement §5 properly.

After Initial Inventory Publication

After initial inventory publication, the violation automatically changes to Failure to Report and should be handled under those guidelines.

o Clerical Errors

EPA will take no enforcement action against mere clerical errors.

ii) Adjustments Factors

All the rules and procedures presented in the overall TSCA Penalty Policy for adjustments should be applied to the GBP for inventory reporting violations.

d. Computation of the Civil Penalty

Day of Violation Defined Since the inventory reporting regulations establish specific deadlines for compliance, the duration of any violation discovered could be computed from the deadline of the date of compliance. Such an approach, however, would result in unduly harsh penalties. Therefore, for purposes of computing the civil penalty for an inventory reporting violation, the day of violation will include only the day of discovery.

e. Worksheet

The Civil Penalty Assessment Worksheet (Appendix H) shall be used to compute the proposed civil penalty and to record any subsequent adjustment to the proposed amount. The Worksheet serves as a guide to the Agency in arriving at a final civil penalty, and as a memorandum of the Agency's deliberations concerning the violations cited. The Worksheet need not be sent to the respondent as part of the complaint but should be made available to him upon request. Detailed instructions for computing the proposed penalty and completing the Worksheet appear in Appendix G.

E. Program Integration

1. TSCA Programs

a. Impact of Violation

Only two violations will have a major direct impact on other TSCA implementation and enforcement programs. Reporting of an excluded substance or a failure to report at all will impact implementation and enforcement of the §5 premanufacture notification requirements.

b. Communication Mechanism

1) The Regions will notify OE Headquarters of potential enforcement actions for either of the above-mentioned violations through the Concurrence Procedures.

2) If OE Headquarters concurs in the action, it will notify OTS of the pendency of the action and will confer with OTS to determine whether the circumstances of the alleged violation warrant:

a) premanufacture notification including a halt to production for 90 days and a civil penalty for violating the inventory reporting requirements, or

b) premanufacture notification with no halt in production and a civil penalty, or

c) premanufacture notification with or without a halt to production and a notice of non-compliance

d) a civil penalty.

3) OE will notify OTS of the outcome of the enforcement proceeding.

4) A reported substance which was excluded from the inventory but which is being manufactured or imported at the time the violation is discovered is subject to the premanufacture notification requirements as is an eligible substance for which no report was submitted to EPA. When premanufacture notification is required, OE Headquarters will check with OTS to ensure that §5 procedures have been initiated by the violator.

5) A person who reported an excluded substance but is not manufacturing/importing it at the time the violation is discovered will face a civil penalty and removal of the substance from the inventory. OE/OTS will announce removal of the substance through a Federal Register notice.

2. Other EPA Programs

Information reported under the inventory reporting regulations may aid other EPA enforcement programs in their compliance monitoring activities. With the exception of the discovery of an unreported substance, which might be of interest to the Water Permits Program, information discovered through inventory compliance monitoring activities will be of little value to other EPA enforcement programs.

APPENDIX A-1
DATA SOURCES: Summary

Data Source	Manufacturer Name & Address	Distinction Processor Manufacturer	Importer Name & Address	Listing by SIC Code	Listing by CAS #	Listing by Chemical	Listing by Chemical Group	Listing Chemical Group	Production Volume/ Capacity	Total Sales	Sales/ Chemical	Previous EPA Violation
Dun and Bradstreet	yes	no	no	yes	no	no	no	no	no	gross sales	no	no
Industry Assistance	yes	no	yes	no	no	no	no	no	no	no	no	no
ITC	yes	no	no	no	no	incomplete	yes	yes	by chemical or chemical group	no	by chemical or chemical group (not by manufacturer)	no
ORD	yes	no	no	no	yes	400 organics	no	no	incomplete	incomplete	incomplete	no
OSHA	yes	no	no	yes	no	no	no	no	no	no	no	no
PTS/EIS	yes	no	no	yes	no	no	no	no	no	yes	no	no
SRI	yes	no	no	no	yes	10,000	no	no	no	no	no	no
NEIC Violation List	yes	no	no	yes	no	no	no	no	no	no	no	yes
Customs Bureau TSUS	no	no	no	no	no	no	by Customs regions	yes broad categories	no	no	no	no
AM. Importers Assn. Directory	no	no	1200 brokers importers	no	no	no	general categories of imports only	general categories of imports only	no	no	no	no
Register of Am. Importers & Exporters	no	no	35,000	no	no	no	general categories of imports only	general categories of imports only	no	no	no	no

Data Sources
Manufacturers/Chemical Substances

Name	Subject Coverage	Coverage Date	Update Frequency	Availability	Comments
Dun & Bradstreet	. U.S. firms by SIC code . gross sales	1859-present	variable	EPA/OPE Steve Weil 755-2770	. no distinction between manufacturer/processor . no production figures . no listing by chemical substance . data not regularly updated & often inaccurate
Industry Assistance List	. manufacturers . importers . trade associations . law firms, consultants etc. 41,000 entries		continual	Office of Industry Assistance Joe Boyle 755-3852	. based on D&B, write-ins, etc. . no production, sales, or SIC data
International Trade Commission (ITC) "Synthetic Organic Chemicals - U.S. Production and Sales"	. domestic production (by original manufacturers only) and sales of synthetic organic chemicals and raw materials from which they are made . generally minimum production volume reported is 5,000 lbs. . minimum sales value is $5,000 . items listed by primary manufacturer . alphabetical listing of reporting manufacturers and their addresses . data supplied by 800 producers	1916-present	annual	Hard copy in EPA Library Computer access through Steve Heller OPM/54938	. statistics for chemical or group are given only when there are 3 or more producers and there is no possibility of violating confidentiality . all manufacturers are not listed by chemical substance

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Manufacturers/Chemical Substances

Name	Subject Coverage	Coverage Date	Update Frequency	Availability	Comments
ORD Organic Chemical Producers Data Base	. 400 organic chemicals listed by CAS # may include: . total chemical production & prices . site specific production capacity	variable	variable	Cincinnati IERL Dave Becker (8) 684-4481	. does not contain complete product slate for every plant . inorganic & small volume of specialty chemicals are not addressed . data is not uniformly available for all listings . will probably be on inventory
OSHA-Industry List	. name and address of all firms inspected . 4 digit SIC codes . ranked by injury severity		variable	OSHA Susan Nelson Office of Policy and Analysis Integration & Evaluation Room 4605 or Jack Katalinas Head, Mgmt. Info. System Rm. 3700 523-7115	. no information on production or sales . no distinction between manufacturers and processors
PTS/EIS Plants	. U.S. firms with more than 20 employees, annual sales over $500,000 . 4 digit SIC codes . sales by plant in category . county by county . market share 117,000 citations		revised quarterly	NEIC Doug Seba (8) 234-5306	. no distinction between manufacturers & processors . no breakdown by specific chemical substance . no production volume . no sales data per chemical substance

Manufacturers/Chemical Substances

Name	Subject Coverage	Coverage Date	Update Frequency	Availability	Comments
Stanford Research Institute (SRI) "Directory of Chemical Producers"	. 10,000 chemicals . manufacturers . production capacity		annual	OPE Judy Nelson (1977) Betty Johnson (415) 326-6200 X-68627 availability only in hardback	. no distinction between manufacturer & processor . no actual production volume . no sales information

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Importers/Chemical Substances

Name	Subject Coverage	Coverage Date	Update Frequency	Availability	Comments
Customs Bureau TSUS	. listing by broad chemical categories (TSUS #) . regional figures on import volume and price		annual	Available but no ready access because of confidentiality considerations	. no listing by chemical substance . no listing by manufacturer . no sales figures by manufacturer or chemical substance
American Importers Association Directory	. 1200 members-brokers importers		annual	available PTSED Ted Rowan AADA (212) 490-2723	. lists only general categories of imports
American Importers and Exporters Directory	35,000 names			1974 ed. in library PTSED has on order	. inaccurate . listing only by general categories i.e., ferilizers

Substances Not Regulated Under TSCA

Name	Subject Covered	Coverage Date	Update Frequency	Availability	Comments
OPP/EPA	. registered pesticides name . registrants		current	Elgin Fry Paul Cassy 69430	need active ingredients, not products
FDA			current	Food Ralph Strand 245-1567 Drugs Winston Cobb 427-8171	

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EPA Violation Information

Name	Subject Coverage	Coverage Date	Update Frequency	Availability	Comments
Air Compliance Data System	Violations listed by: . point source . SIC code . county	1972-present	variable	Stationary Source Enforcement Division Hq's Frank Smith 755-0103	. no distinction between manufacturers & processors
PCS	. facility locations for permit holders . SIC code . permit information		variable	Water Enforcement Bill Milligan 755-0991	. no violations listed
PEMS	. manufacturers by estm. # . by state . by violation	1974-present	variable	PTSED	
NEIC List	Listing of violators of other EPA regs. by SIC code		current	NEIC-Denver Doug Seba	working on comprehensive listing available to PTSED for selection of firms for inspection schedule

Additional Information Sources

Name	Subject Coverage	Coverage Date	Update Frequency	Availability	Comments
Census Bureau				not available to PTSED	Confidential
Interstate Commerce Commission				not available to PTSED	Confidential

Violation: Reporting Substances Excluded from the Inventory
R&D Substances

Regulatory Requirements	Inspection Procedure	Documentation
§710.4(c)(3) Any chemical substance manufactured, processed, or imported solely in small quantities for research and development as defined in §710.2(y) is excluded from the inventory.	. Ask for the company's criteria for determining whether a chemical substance is to be classified for R&D.	. Make copy of written criteria. . If written criteria are not available, obtain a statement from a responsible official outlining the criteria and attesting to their use by the company.
§710.2(y) Small quantities for research and development are defined as: 1) quantities of a substance no greater than reasonably necessary for purposes of: . scientific experimentation on; . analysis on; . chemical research on; . analysis of; . any research or analysis for the development of a product; 2) quantities used by or directly under the supervision of a technically qualified individual after publication of the revised inventory.	. Ask what specific procedures are involved in developing a test marketing program for a chemical substance.	. Make a copy of written procedures. . If no written procedures are available, obtain a statement from a responsible official outlining the procedures and attesting to their use by the company.
	. Ask for company documentation in support of non - R&D classification for this particular chemical substance	. Make a copy of any documentation . If no documentation is available, obtain a statement from a responsible official outlining specific support for the company's classification of the substance.
There is a presumption that products manufactured, imported or processed in quantities of less than 1000 lbs. are for R&D purposes. A person reporting a substance produced in such quantities has the burden of certifying that it is not for R&D.	. Ask to see production records for the chemical substance from the first year of production.	. Make a copy of production records. . Make a notation in the field book of production records which available.
	. Ask to see sales records for the chemical substance from the first year sales took place.	. Make a copy of sales records. . Make a notation in the field book of sales records which are not available.
	. Ask to see records listing buyers. Ask Co to produce correspondence from customers demonstrating that the substances has been commercially distributed or is in test marketing phase.	. Make a copy of names, addresses and phone numbers for later verification of the quantity of the chemical substance sold and the use of the chemical substance by the buyer.

R&D continued

Regulatory Requirements	Inspection Procedures	Documentation
	. Ask to see records indicating size and number of production site(s) for the chemical substance.	. Make a copy of available records. . Make a notation of observations in the field book if any on-site visit is make.
	. Ask to see records indicating the internal use to which the chemical is put if not sold.	. Make a copy of available records. . Obtain an affidavit certifying this use from a responsible company official.
	. Ask to see any advertisments regarding the use of the substance.	. Make a copy of any advertisements. . Make a notation in the field book if no advertisements are available.
	. Ask about the educational background and present professional duties of any person in charge of use or distribution of the substance. (after publication of revised inventory)	. Obtain a statement from a responsible company official as well as the person in charge of the use or distribution of the substance attesting to that person's education and professional responsibilities.

Violation: Reporting Substances Excluded from the Inventory
Substances Not Manufactured, Processed, or Imported Since January 11, 1975

Regulatory Requirements	Inspection Procedure	Documentation
§710.4		
Any chemical substance not manufactured, processed or imported for a commercial purpose since January 1, 1975 is excluded from the inventory	. Ask to see production records or (for importers) purchase records for the chemical substance from 1975-1977.	. Make a copy of available records. . Make a notation in the field book of periods for which there are no such records.
	. Ask to see sales records for the chemical substance from 1975-1977.	. Make a copy of available records. . Make a notation in the field book if there are no sales records.
	. Ask to see records listing buyers of the chemical substance from 1975-1977.	. Make a copy of names, addresses, and telephone numbers for verificiation of the year and the amount of the sale.
	. Ask to see records of use if the chemical substance is not sold.	. Make a copy of records indicating internal use. . Obtain a statement certifying internal use from a responsible company official.
	. Ask to see advertisements regarding sale or use of the substance from 1975-1977.	. Make a copy of advertisements. . Make a notation in the field book if no copies of advertisements exist.

Violation: Reporting Substances Excluded From the Inventory
Chemical Substances Regulated Under Other Acts

Regulation Requirements	Inspection Procedure	Documentation
§710.4(c)(1) Any substance not considered a "chemical substance" as provided in subsection 3(2)B of TSCA and in the definition of "chemical substances" in §710.2(h) is excluded from the inventory. §710.2(h) "Chemical substance" does not include: (1) Any pesticide when manufactured, processed or distributed in commerce as a pesticide. (2) Tobacco or any tobacco product, but not including any derivative products. (3) Any source material, special nuclear material, or by product material. (4) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.	. Ask to see records substantiating a use that does not fall into the excluded categories. . Ask to see advertisements regarding the non-excluded use of the substance. . Ask to see records listing buyers who use the substance for a non-excluded purpose and correspondence demonstrating use by buyers for non-excluded purpose. . Ask to see sales records for non-excluded uses as well as excluded uses. . Ask to see production records	. Make a copy of the records . Obtain a statement certifying the use from a responsible company official. . Make a copy of any advertisements. . Make a notation in the field book if no such advertisements are available. . Make a copy of addresses and phone numbers for later verification of the non-excluded use. . Make a copy of the records . Make a notation in the field book if information is not available. . Make a copy of any records distinguishing between amounts of the chemical substance produced for excluded and non-excluded uses. . Make a notation in the field book if the information is not available.

Violation: Reporting False Information
(Production Volume/Site Limitation)

Regulatory Requirements	Inspection Procedure	Documentation
§710.5		
Manufacturers and importers (other than small manufacturers or importers) who are required to report must report in addition to:	. Ask to see records indicating the number and size of production sites	. Make a copy of available records If records are not available, make notation of this in the field book.
. the identity of the chemical substance . monomers used at greater than 2% (by weight) in the manufacture of the polymer; and . whether the substances reported are manufactured/imported (initial inventory) or imported/processed (revised inventory),	. Ask to see production records for the chemical substance from 1975-1977.	. Make copy of records. Compare this information with data indicating the number and size of production sites to check for disparities.
. the site(s) where the substance is manufactured/imported and for manufacturers and processors whether such activity is site specific,	. Ask to see sales records for 1975-1977 . Ask to see a list of buyers.	. Make a copy of the records. . If they are not available, note this in the field book. . Make a copy of names, addresses and phone numbers for later verification of sales.
. the amount manufactured at each site or imported during 1977.	If you suspect that an R&D chemical has been reported follow the additional procedures outlined in B-1,2.	

Violation: Failure to Report At All

Regulatory Requirements	Inspection Procedure	Documentation
§710.3(a) Domestic manufacturers and importers must report for the initial inventory concerning all chemicals they manufacture or import for a commercial purpose in 1977 if: 1) 30% or more, by weight, of the products they manufacture or import consist of the types described under Standard Industrial Classification (SIC) Groups 28 or 2911, or 2) the total pounds of reportable substances equal one million pounds or more per site for manufacturers (even if not in SIC 28 or 2911) 3) the chemical substance was manufactured or imported in quantities greater than 100,000 pounds.	. Ask to see records supporting failure to report . Ask to see production records for all substances manufactured in 1977. . Ask to see records of total amount of chemical substances imported in 1977.	. Make a copy of any records . Make a notation in the field book of any recoards not available. . Make a copy of records indicating that 30% by weight of the chemical substances are in SIC code 28 and 2911. . Make a copy of records indicating total reportable chemical substances manufactured or imported is one million pounds or more.
§710.3(c) Processors and users of a chemical substance for a commercial purpose are not subject to initial inventory requirements.		. Make a copy of records indicating that any chemical substance is manufactured or imported in quantities greater than 100,000 pounds. . Make a notation in the field book if any of the above mentioned records are not available.

Violation: Failure to Maintain Records

Regulatory Requirements	Inspection Procedure	Documentation
§710.1(c) Each person who reports under these regulations shall maintain records that document information reported under these regulations and, in accordance with the Act, permit access to and the copying of such records by EPA officials.	. Ask to see records substantiating all information required to be reported for a chemical substance . identity . monomers used at greater than 2% (by weight) in the manufacture of any polymer whether manufactured, processed or imported. . production site(s) . whether site-limited . amount manufactured at each site or imported during 1977.	. Make copies of substantiating information. . Make a note in the field book of any records not maintained.

Violation: Failure to Report All Required Information

Regulatory Requirements	Inspection Procedure	Documentation
Initial Inventory §710.3(a)(1)	. Ask to see total sales figures for 1977	. Make a copy of records. If records are not available, make a notation in the field book.
Any person who manufactured chemical substances in 1977 must report: 1) All chemical substances at each site for which 30% or more by weight fall into SIC Group 28 or 2911. 2) All chemical substances at each site where one million pounds or more were manufactured. 3) Any chemical substance manufactured at a site in quantities greater than 100,000 lbs. §710.3(a)(2)	. Ask to see 1977 production records for each suspect product.	. Make a copy of the records . If they are not available, make a notation to this effect in the field book.
Any person who imported chemical substances in 1977 must report: 1) All chemical substances for which 30% or more by weight fall into SIC Group 28 or 2911. 2) All chemical substances imported as part of a total of one million pounds. 3) Any chemical substance imported in quantities greater than 100 000 lbs.		

Violation: Failure to Report All Required Information

Regulation Requirements	Inspection Procedure	Documentation
§710.5 Manufacturers and importers required to report must report: 1) the identity of the chemical substance, 2) those monomers used at greater than 2% (by weight) in the manufacture of a polymer, 3) whether the substance is manufactured or imported Manufacturers must also report: 1) the site at which the substance is manufactured and whether the chemical substance is manufactured only within a site. 2) the amount of the chemical substance manufactured at each site. Importers must report the total amount of chemical substance imported. §710.5(a)(3) Any small importer or manufacturer (total annual sales of company, parent-company, and all companies owned or controlled by the parent together are less than $5 million) is exempt from reporting production volume (for quantities less than 100,000 pounds) and site information.		

Appendix C-1

Inventory Reporting Regulations

Recommended Format

Establishment Inspection Checklist

Date_____

Name of Facility

Dun and Bradstreet #

Location

Phone Number

_____
Inspector

Persons Contacted:

Name	Title	Phone Number

Record Maintenance (1977)

Chemical Identity

Monomers used at greater than 2% (by weight) in the manufacture of a polymer.

Chemical Substance is
- Manufactured
- Processed
- Imported

Production
- 30% by weight in SIC Group 28 or 2911
- Total
- Per Chemical Substance

Sales
- Total
- Per Chemial Substance

Distribution

Use
- Internal (Site-limited)
- External

Advertisements

Production Site(s)
- Size
- Number

Criteria for R&D Substances

Criteria for test marketing substances

Qualifications and responsibilities of the person in charge of production & distribution of a chemical substance

later revised inventory publication

Appendix D-1

Citation Charges and Action Levels for Violations of the Inventory Reporting Regulations Promulgated Under Section 8(a) of the Toxic Substances Control Act

PERSON FAILED TO COMPLY WITH THE PROVISIONS OF THE INVENTORY REPORTING REQUIREMENTS PROMULGATED UNDER SECTION 8(a) OF THE TOXIC SUBSTANCES CONTROL ACT IN THAT THE PERSON:

A1. Failed to report concerning a chemical substance manufactured in the U.S. for a commercial purpose during 1977 as required because 30% or more by weight of the products manufactured are described by Standard Industrial Classification (SIC) Group 28 or 2911. (42 FR §710.3(a)(1)(i)(A))

Action Level: Complaint and/or
Premanufacture Notification Requirement

A2. Failed to report concerning a chemical substance manufactured in the U.S. for a commercial purpose during 1977 as required because the total pounds of reportable chemical substances manufactured at that site equals one million pounds or more.
(42 FR §710.3(a)(1)(i)(B))

Action Level: Complaint and/or
Premanufacture Notification Requirement

A3. Failed to report concerning a chemical substance manufactured in the U.S. for a commercial purpose during 1977 as required because manufactured at a site in quantities equal to or greater than 100,000 pounds.
(42 FR §710.3(a)(1)(ii))

Action Level: Complaint and/or
Premanufacture Notification Requirement

A4. Failed to report concerning a chemical substance imported into the U.S. for a commerical purpose because 30% or more of the products imported are described by Standard Industrial Classification (SIC) Group 28 or 2911. (42 FR §710.3(a)(2)(1)(i)(A))

Action Level: Complaint and/or
Premanufacture Notification Requirement

A5. Failed to report concerning a chemical substance imported into the U.S. for a commercial purpose during 1977 as required because the total pounds of reportable chemical substances imported equals one million pounds or more. (42 FR §710.3(a)(2)(i)(B))

Action Level: Complaint and/or
Premanufacture Notification Requirement

A6. Failed to report concerning a chemical substance imported into the U.S. for a commercial purpose during 1977 as required because imported in quantities equal to or greater than 100,000 pounds. (42 FR §710.3(a)(2)(i)(B))

Action Level: Complaint and/or
Premanufacture Notification Requirement

A7. Failed to report a chemical substance by the May 1, 1978 deadline without an extension (42 FR §710.6(a))

Action Level: Notice of Non-compliance or
Complaint and/or Premanufacture
Notification Requirement

A8. Failed to report the site at which he manufactured the chemical sub- as required for all but small manufacturers. (42 FR §710.5(d)(2))

Action Level: Notice of Non-compliance or
Complaint

A9. Failed to report the business address at which he imported the chemical substance as required for all but small importers (42 FR §710.5(d)(2))

Action Level: Notice of Non-compliance or
Complaint

A10. Failed to report the amount of the chemical substance which he manufactured at each site for which reporting was required in 1977. (42 FR §710.5(d)(4))

Action Level: Notice of Non-compliance or
Complaint

A11. Failed to report the amount of the chemical substance which he imported during 1977. (42 FR §710.5(d)4)).

Action Level: Notice of Non-compliance or
Complaint

A12. Failed to report that manufacture of the chemical substance is site limited. (42 FR §710.5(d)(3)

Action Level: Notice of Non-compliance or
Complaint

A13. Falsely reported the amount of the chemical substance manufactured at any site during 1977. (42 FR §710.5(d)(4))

Action Level: Notice of Non-compliance or
Complaint

A14. Falsely reported the amount of the chemical substance imported during 1977. (42 FR §710.5(d)(4))

Action Level: Notice of Non-compliance or
Complaint

A15. Reported a chemical substance excluded from the inventory because manufactured solely in small quantities for research and development. (42 FR §710.4(c)(3)).

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement

A16. Reported a chemical substance excluded from the inventory because imported soley in small quantities for research and development. (42 FR §710.4(c)(3))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement

A17. Reported a chemical substance excluded from the inventory because processed, solely in small quantities for research and development. (42 FR §710.4(c)(3))

Action Level: Notice of Non-compliance or
Complaint

A18. Reported a chemical substance excluded from the inventory because not manufactured, for a commercial purpose January 1, 1975. (42 FR §710.4(c)(4))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement

A19. Reported a chemical substance excluded from the revised inventory because not processed for a commercial purpose since January 1, 1975. (42 FR §710.4(c)(4))

Action Level: Notice of Non-compliance or
Complaint

A20. Reported a chemical substance excluded from the inventory because not imported for a commercial purpose since January 1, 1975. (42 FR §710.4(c)(4))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement

A21. Reported a chemical substance excluded from the inventory because regulated under the Federal Insecticide, Fungicide and Rodenticide Act. (42 FR §710.4(c)(1))

Action Level: Notice of Non-compliance

A22. Reported a chemical substance excluded from the inventory because regulated under the Federal Food, Drug and Cosmetic Act. (42 FR §710.4(c)(1))

Action Level: Notice of Non-compliance

A23. Failed to maintain records that document information reported under the regulations (42 FR §710.1(c))

Action Level: Notice of Non-compliance or Complaint

A24. After being presented with a warrant, failed to permit access to records that document information reported under the regulations. (42 FR §710.1(c))

Action Level: Complaint

A25. After being presented with a warrant, failed to allow EPA officials to copy records that document information reported under the regulations. (42 FR §710(c))

Action Level: Complaint

Sales/distribution records indicate that less was produced than was reported. There are no other records indicating on-site (non-sales) use to complement the sales figures.

A14. Purchase records show higher figures than those reported.
Purchase records show lower figures than those reported.

Sales/distribution records show higher figures than those reported.
Sales/distribution records show lower figures than those reported.

A15. Evidence may vary from company to company. Generally a violation can be supported if a company is inconsistent in formulating criteria defining an R&D substance for §8(b) and §5(h)(3).

The following factors which alone would not be sufficient to indicate a violation may create a stronger presumption when considered together.

Before publication of the revised inventory:

- The substance is manufactured in quantities of less than 1,000 pounds.
- The substance is sold but purchasers cannot corroborate commercial use.
- The substance is not sold, and there is no record of use in any process resulting in another commercial product.

After publication of the revised inventory:

- The substance, whether or not sold, is used by or under the direct supervision of a technically qualified individual who is concerned with evaluating the physical chemical, and performance characteristics of the substances.

A16. Evidence may vary from company to company. Generally a violation can be supported if a company is inconsistent in formulating criteria defining an R&D substance for §8(b) and §5(h)(3).

The following factors, which alone would not be sufficient to indicate a violation, may create a stronger presumption when considered together:

Before publication of the revised inventory:

- The substance is imported in quantities of less than 1,000 pounds

- The importer has no records to substantiate that the final user uses the substance for commercial purpose or uses it in a process resulting in another commercial product.

After publication of the revised inventory:

- The importer has no records to substantiate that the substance is not used by or under the direct supervision of a technically qualified individual who is concerned with evaluating the physical, chemical, and performance characteristics of the substance.

A17. Evidence may vary from company to company. Generally a violation can be supported if a company is inconsistent in formulating criteria defining an R&D substance for §8(b) and §5(h).

The following factors, which alone would not be sufficient to indicate a violation, may create a stronger presumption when considered together:

Before publication of revised inventory:

- The substance is processed in quantities of less than 1,000 pounds.
- The substance is not sold, and there is no record of use in any process resulting in another commercial product.

After publication of revised inventory:

- The substance, whether or not sold, is used by or under the direct supervision of a technically qualified individual who is concerned with evaluating the physical, chemical, and performance characteristics of the substance.

A18. Other data sources show the substance has not been manufactured since January 1, 1975.

Company production records show no evidence of manufacture since January 1, 1975.

Company sales/distribution records show no evidence of sales since January 1, 1975.

Reputed buyers fail to corroborate purchase.

Company records show no evidence of internal use.

A19. Other data sources show the substance has not been processed since January 1, 1975.

Company production records show no evidence of processing since January 1. 1975.

Company sales/distribution records show no evidence of sales since January 1, 1975.

Reported buyers fail to corroborate purchase.

Company records show no evidence of internal use.

A20. Other data sources show the substance was not imported since January 1, 1975.

Company production records show no evidence of importing since January 1, 1975.

Company sales/distribution records show no evidence of sales since January 1, 1975.

Reputed buyers fail to corroborate purchase.

Company records show no evidence of internal use.

A21. Substance has a use regulated under FIFRA and there is no evidence of another current use for the substance in advertisements sales/distribution or other company records.

A22. Substance has a use regulated under FFDCA and there is no evidence of another current use for the substance in advertisements sales/distribution or other company records.

A23. No records are available to substantiate claims upon routine inspection. Affidavit from inspector attests to this fact.

A24. Affidavit from inspector attests to the refusal by the person to permit access to records after being presented with a search warrant and informed that such refusal is a violation of the Act.

A25. Affidavit from inspector attests to the refusal by the person to allow him to copy records upon presentation of a search warrant.

APPENDIX F-1

GRAVITY BASE PENALTY MATRIX

		Extent of Damage	
		MAJOR	MINOR
Potential that Damage will Occur	High	25,000	5,000
	Range	20,000	3,000
	Low	5,000	500
	Range	2,000	250

Appendix G-I

Guidance for Computation of Civil Penalties Using the TSCA Civil Penalty Assessment Worksheet

Scope

The TSCA Civil Penalty Assessment Worksheet is to be used to compute the penalty which the Agency proposes to assess against any violator who is subject to the civil penalty sanctions of the Act and any subsequent modifications or adjustments of the proposed penalty. The Worksheet also serves as an office record of the case and as a memorandum of the Agency's deliberations concerning the penalties proposed and finally assessed for the violations cited.

Gravity Base Penalty

(1) List the "Charge Code Number" as indicated under column headed "Charge Code". Such charge code numbers must conform to the charge as written in the complaint.

(2) List each "primary" charge in the same order as it appears in the complaint. A charge which represents an independent act (or failure to act) and which is substantially distinguishable from any other charge shall be considered to be a "primary" charge and shall be independently assessed.

(3) List each "Lesser included charge" (Any charge which appears in the complaint but which does not arise from independent acts and which is not substantially distinguishable from another previously cited charge). No independent penalty shall be assessed for such a charge.

(4) The "penalty base figure", which corresponds to each "primary" charge entered in Item (2) shall be taken from the appropriate cell of the Gravity Base Penalty (GBP) Matrix.

(5) Review the "history of prior violations". If an adjustment is in order, consult the "Table of Adjustment Factors - History" and the accompanying guidance to determine the appropriate adjustment factor. Enter the percentage increase on the worksheet.

(6) Review information relating to culpability of the violator. If an adjustment is in order, consult the guidelines to determine the adjustment factor. Enter the adjustment factor (20% or 40%) on the worksheet.

(7) Review sales data and culpability level to determine if an adjustment to account for Ability to Pay is appropriate (Ability to Pay adjustments are only made when there is a level 2 or 3 culpability). Consult the guidelines to determine the adjustment factor and enter the percentage decrease on the worksheet.

(8) Total the percentages entered under Items (5), (6) and (7) and adjust the GBP in Item (4) by this percentage. Enter the resulting modified GBP on the worksheet.

(9) Enter the explanation for modification of the base figure for each primary charge on the reverse of the Worksheet.

(10) Enter the "proposed civil penalty" for each primary charge listed under Item (2). Where there has been no modification, the proposed penalty will be the same as the base figure under Item (4). For any primary charge for which the base figure has been increased or decreased, the "modified penalty base figure" derived under Item (8) shall be entered as the proposed penalty.

(11) Enter as the "total proposed penalty" the sum of the "pro posed penalties" entered under Item (10).

(12) If at the settlement conference, respondent makes and substantiates additional representations concerning history of violation, culpability, inability to pay or remain in business or "such other matters as justice may require" which the Agency could consider in mitigating the proposed penalty, enter a summary of the new facts and their substantiation. In the absence of facts and circumstances which present a legitimate basis for reduction, the Agency is under no compulsion to mitigate the proposed penalty.

(13) If reduction is deemed appropriate for the penalty proposed for a given charge, enter the percentage by which the proposed penalty should be further decreased.

(14) Compute the "negotiated penalty amount" for each primary charge based on the percentage reduction (indicated in Item (13)) of the penalty proposed for that charge (indicated in Item (10)), and enter the amount.

(15) Enter the "final civil penatly amount" for each primary charge. Where there has been no negotiation or reduction, the final penalty will be the same as the proposed penalty for that charge under Item (10). Where there has been a reduction from the proposed penalty, the "negotiated penalty amount" under Item (14) shall be the final penalty amount.

(16) If the respondent introduces new facts at the settlement conference which bear on the gravity of the violation and which may modify the original charges, enter the date of the conference, a summary of the new facts, and a summary of the substantiation. Then begin a new Worksheet to reflect the modified charges and a new proposed penalty.

Total Final Civil Penalty Assessed

(17) Enter the "total final civil penalty assessed" as a result of the following: (a) Default (number 4 in the heading of the Worksheet); (b) consent agreement (number 5 in the heading of the Worksheet) after a settlement conference;

(18) Enter the "total final civil penalty imposed" as a result of the Final Order of the Regional Administrator.

Appendix H

CIVIL PENALTY ASSESSMENT WORKSHEET

Name of Respondent_____
Address of Respondent_____

1. Complaint I.D. No._____
2. Date Complaint Issued_____
3. Date Answer Rec'd_____
4. Date Default Order Sent_____
5. Date Consent Agreement Signed_____
6. Date Final Order Sent_____
7. Date Remittance Rec'd_____

		Gravity Base Penalty	Adjustments			Proposed Penalty		Adjusted Penalty		Final Pena
(1) Charge Code Number	(2) Primary Charge(s)	(4) GBP ($ Amount in matrix cell)	(5) History Percentage Increase	(6) Culpability Percentage Decrease	(7) Inability to Pay Percentage Decrease	(8) Modified GBP ($ reflecting increase or decrease if applied)	(10) Proposed Penalty	(13) Percentage (%) Decrease (total for history, culpability, inability to pay, other matters as justice may require	(14) Negotiated Penalty Amount ($ reflecting % decrease if applied)	(15) Final Civil Penalty Amount

(3)
Lesser Included Charge(s)_____

11) Total Proposed Penalty $_____

17) Total Final Civil Penalty Assessed $____

18) Total Final Civil Penalty Imported $____

Prepared by_____

Concurrence by_____

WORKSHEET (Reverse Side)
Deriving the Modified Penalty Base Figure

(9) Modification of the Penalty Base Figure (under line(8)

Date of Modification

Reasons for Modification

Adjusting the Proposed Civil Penalty

Date of Conference

(12) Additional Representations

History

Substantiation

Culpability

Substantiation

Inability to Pay/ Continue in Business

Financial Data Offered by Respondent (Source and Summary)

Other matters as justice may require

Substantiation

(16) New Gravity Determination

New Facts

Substantiation

Prepared by

Date

APPENDIX I

FEDERAL REGISTER PUBLICATIONS

March 9, 1977	Original Proposal of Inventory Reporting Regulations (42 FR 12120)
April 12, 1977	Supplemental notice of proposed rulemaking, including additional information pertaining to proposed regulations , and instructions for use of the Candidate List of Chemical Substances (42 FR 19298)
April 28, 1977	Notice of availability of the Candidate List of Chemical Substances for use in reporting Chemicals for inclusion in the inventory. (42 FR 21639)
July 8, 1977	Notice to amend procedures for securing a copy of the Candidate List on computer-readable tape (42 FR 35183)
August 2, 1977	Re-proposal of Inventory Reporting Regulations (42 FR 39182)
October 3, 1977	Supplemental notice (42 FR 53804)
December 23, 1977	Final Inventory Reporting Regulations (42 FR 64572)
March 6, 1978	Supplemental Clarification and Notice of Meetings (43 FR 9254)
April 17, 1978	Supplemental Clarification and Availability (43 FR 16178)
October 24, 1978	Policy for Revised Inventory Reporting and Draft Report Form (43 FR 49688)

APPENDIX J-1

Statutory Authority for the Inventory Reporting Regulations and Enforcement Program

—Section 8(a)(1)(A) authorizes the Administrator to require, by rule, the maintenance of records and submission of reports regarding production by-products, population exposure, etc of a chemical substance.

—Section 8(b) directs the Administrator to "...compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States... Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to [the inventory[

...The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product."

—Section 11(a) authorizes any duly designated representative of the Administrator to "...inspect 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...Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice to the owner, operator, or agent in charge of the premises...to be inspected. 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. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

—Section 11(b) authorizes inspections extending "...to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

—Inspections are prohibited, under Section 11(b)(2), which extend to: "(A) financial data, (B) sales data (other than shipment data), (C) pricing data, (D) personnel data, or (E) research data (other than data required by this Act or under a rule promulgated thereunder), unless the nature and extent of such data are described with reasonable specificity in the written notice required by [Section 11(a)].

--Section 11(c) authorizes the Administrator to require by subpoena "...the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary" for carrying out this Act.

--Section 15(1) makes it "...unlawful for any person to fail or refuse to comply with...any requirement under Section 5 ...or any rule promulgated or order issued under Section 5."

--Section 15(2) makes it "...unlawful for any person to use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of Section 5... a rule or order under Section 5... or an order issued in action brought under Section 5...."

--Section 15(3) makes it "...unlawful for any person to fail or refuse to (A) establish and maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder."

--Section 15(4) makes it "...unlawful for any person to fail or refuse to permit entry or inspection as required by Section 11."

--Section 16(a)(1) provides for the assessment of civil penalties not to exceed $25,000 for each violation of Section 15.

--Section 16(b) provides for criminal penalties of fines of not more than $25,000 for each day of violation, or imprisonment for not more than one year, or both, for knowing or willful violations of Section 15.

--Section 17(a) gives jurisdiction to the district courts of the United States to provide specific enforcement regarding the provisions of Section 15, or to compell the taking of any action required by or under this Act.

--Section 17(b) provides for seizure and condemnation of any substance, mixture, or article manufactured, processed, or distributed in commerce in violation of this Act or any rule promulgated or order issued under this Act.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 23 1980

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Inventory Penalty Policy

TO: Enforcement Division Directors
Air & Hazardous Materials Division Directors
Surveillance & Analysis Division Directors
Pesticide Branch Chiefs

Attached is the specific penalty policy which applies the principles of the TSCA Penalty Policy to the Inventory reporting requirements. This policy should be used by regional personnel in recommending appropriate enforcement actions for Inventory reporting violations.

Richard D. Wilson
Deputy Assistant Administrator
for General Enforcement

Attachment

Inventory Penalty Policy

I. Introduction

This section of the TSCA Penalty Policy describes the application of the policy to violations of the Inventory reporting regulations. It addresses specifically:

1) The determination that a violation exists.

2) The circumstances under which assessment of a civil penalty is appropriate.

3) The independently assessable charge.

4) The concept of multi-day violations.

5) Application of the Gravity Based Penalty.

6) The use of adjustment factors.

7) Relationship to §5 penalties.

II. Violation Determination

Each failure by a person to comply with a specific Inventory reporting requirement for a single chemical substance shall constitute separate violation. Inventory violations are listed in Appendix A, "Citation Charges and Action Levels for Violations of the Inventory Reporting Regulations".

III. Appropriate Enforcement Action

For violations of the Inventory reporting regulations EPA will, in most cases, issue a notice of non-compliance or assess a civil penalty. Criminal sanctions will generally be inappropriate for Inventory reporting violations. They should be considered only for extremely egregious violations which reflect a conscious attempt at undermining of the Inventory reporting regulations.

A notice of non-compliance will be the most appropriate action if the following circumstances exist:

1) It cannot be held that the alleged violator "knew or should have known" about the Inventory reporting regulations. Circumstances to be considered in determining the reasonableness of a violation using this standard include: firm size, subscription to the Federal Register and trade publications, membership in trade associations, inclusion on Office of Industry Assistance mailing lists and prior correspondence with EPA regarding the Inventory requirements, or
2) The alleged violator acted in "good faith" in attempting to comply with the regulations. Generally, "good faith" should be found if a firm made reasonable efforts to familiarize itself with the Inventory reporting requirements, made a systematic effort to identify its eligible substances, and reported concerning them immediately upon identification, and
3) The violation could not have been expected to have a major impact on the Agency's ability to implement or enforce the premanufacture notification requirement, or
4) The violation could not have been expected to have a major impact on the accuracy of the chemical profile established under the Inventory reporting requirements.

A notice of non-compliance would, for example, be appropriate in the following circumstances:

1) A firm reported most of its substances by the reporting deadl but reported a few "overlooked" substances after the deadline. [One way of determining "good faith" is by comparing the number of late substances with an OTS printout of all substanc

reported on time.]

2) A firm learned of the reporting requirements late. Although it began compliance efforts immediately, it was not able to submit its substances on time.

[Note: The "good faith" criterion does not apply to firms who should reasonably have been aware of the Inventory reporting requirement.]

A civil penalty will be the most appropriate action in cases where circumstances indicate that a firm "knew or should have known" of the procedural or substantive requirements of the regulations or has not made a "good faith" effort to comply. Whether a firm "knew or should have known" is determined by balancing the complexity of the requirement and the firm's sophistication, size, resources, etc.

For example, a firm which subscribes to the Federal Register or belongs to a trade association and yet fails to report a substantial number of its substances on time should be assessed a civil penalty for late reporting. A civil penalty would be appropriate in this case because the firm could reasonably be expected to have familiarized itself with TSCA requirements which are printed in the Federal Register and made available through appropriate trade associations.

In some cases, a person may be charged with several violations, some of which merit a civil penalty while others merit only a notice of non-compliance. In such cases, no separate notice of non-compliance need be issued. Violations meriting a notice should be listed in the complaint as separate counts without penalties.

IV. Independently Assessable Charge

If a civil penalty is the appropriate type of enforcement action for identified violations, the enforcement attorney/case preparation officer must still determine whether a civil penalty should be assessed for each identified violation. A separate civil penalty shall be assessed only for each violation of the Inventory reporting regulations which results from an independent act (or failure to act) of the respondent and which is substantially distinguishable from any other charge in the complaint. A given charge is independent and substantially distinguishable from any charge for the purpose of assessing separate penalties if each charge requires an element of proof not required by the other. Thus, not every charge which may appear in the complaint will be separately assessed. For example, a manufacturer may fail to report at all concerning a chemical substance for which reporting is required. He could be charged separately for failing to report each item of information required by the regulations. However, since the charge for failure to report at all contains the same elements required to prove a failure to report individual items of information, a civil penalty should be assessed only for the failure to report at all.

V. Multi-day Violations

TSCA §16 authorizes the assessment of civil penalties not only for each violation but for each day the violation continues. Since the Inventory reporting regulations establish specific deadlines for compliance, the duration of any violation discovered could be computed from the appropriate deadline for compliance. Such an approach, however, would result in excessive penalties. Therefore, for purposes of

computing the civil penalty for an Inventory reporting violation, there will be only one day of violation, the day on which the violation is discovered by EPA. No Inventory violation will be considered a continuing violation.

VI. Calculation of the Gravity Based Penalty

The Inventory reporting regulations are classified as "hazard assessment" data gathering regulations under the TSCA Penalty Policy. The appropriate Gravity Based Penalty (GBP) for violations of these regulations is determined by the extent of potential damage caused by each violation as well as the circumstances surrounding the violation. [Note: The "damage" which determines the appropriate GBP for "hazard assessment" violations is different from the "damage" which determines the GBP for "chemical control" and "control associated data gathering" violations. The damage in the former case is to the ability of the Agency to carry out its regulatory functions, while in the latter two cases, the damage is to health or the environment. As a result, the GBP for "hazard assessment" violations is based on consideration of qualitative factors rather than of quantitative factors such as pounds of the chemical involved as is the case with the GBP for "chemical control" and "control-associated data gathering" violations.]

The GBP matrix for the Inventory reporting regulations has been modified to eliminate penalties in Level B (significant) on the "extent" axis as well as penalties in a number of levels on the "circumstances" axis. These modifications have been made because Inventory violations are expected to be either quite serious or relatively insignificant. There are no violations which would merit assessment of penalties at the omitted levels. Therefore, only the penalties listed on the modified matrix should be applied to Inventory violations. The modified GBP matrix follows.

EXTENT OF POTENTIAL DAMAGE

CUMSTANCES		MAJOR Level A	SIGNIFICANT Level B	MINOR Level C
HIGH RANGE	1	25,000		
	2			
MID RANGE	3	15,000		
	4			1,000
LOW RANGE	5	5,000		500
	6			200

A. Extent

The "extent" of damage caused by an Inventory reporting violation is measured by the potential impact of the violation on the Agency's ability to implement and enforce TSCA. The GBP matrix for the Inventory reporting regulations provides two levels for measuring extent:

Level A (Major) - Potential impairment of the Agency's ability to properly implement and enforce §5 PMN requirements for a given substance.

Level C (Minor)- Potential impairment of the Agency's ability to rely on the Inventory data base as a guide in the hazard assessment process for chemicals in commerce or for general enforcement of TSCA,

Potential impairment of the Agency's ability to complete timely processing of Inventory reporting forms.

B. Circumstances

The vertical axis describes the "circumstances" affecting the impact of the violation on the Agency's ability to implement or enforce TSCA.

The three ranges on the "circumstances" axis are described as follows:

High Range - Level 1 The violation could result in the improper introduction of a chemical substance into commerce without the required premanufacture review, or

Level 1	The violation causes the unnecessary submission of a PMN by a third party, and the Agency has unnecessaril spent the resources required for a complete premanufacture review.
Mid Range - Level 3	The violation causes the unnecessary submission of a PMN by a third party, and the Agency has unnecessaril spent resources in beginning premanufacture review.
Level 4	The violation results in impairment of the Agency's Inventory data base with respect to all items of information required to be reported concerning a chemical substance.
Low Range Level 5	The violation has unnecessarily caused the Agency to receive premanufacture notification forms for a given chemical.
Level 5	The violation could have resulted in subversion of the PMN requirement if the substance had been included on the Inventory.
Level 5	The violation results in impairment of the Agency's Inventory data base with respect to less than the total number of information items required to be reported concerning a chemical substance.
Level 6	The violation could have resulted in impairment of the Agency's Inventory data base with respect to some information items required to be reported concerning a chemical substance if the information had been included in the data base.
Level 6	The violation has caused the Agency to expend unanticipated resources related to the processing of Inventory forms.

C. Application of the GBP System to Inventory Reporting Violations

All Inventory reporting violations not associated with a "good fait effort to comply or committed by persons who "knew or should have known" about the Inventory reporting regulations can be assessed penalties under this application of the penalty policy as follows:

o Reporting an Excluded Substance

$25,000	Major High Level 1	Violation impairs EPA's ability to properly implement §5 in that it could result in avoidance of timely premanufacture notification because the substance was included on the Inventory.

$5,000	Major Low Level 5	The substance reported is ineligible for inclusion on the Inventory. Although the substance was not included on the Inventory, the Agency had to expend substantial resources to prevent subversion of the §5 PMN requirement.

Citation Charge Codes A13-21 (See Appendix A)

o Reporting False Information

$500	Minor Low Level 5	Substantial inaccuracies in a single report form are expected to impair the EPA hazard assessment and compliance monitoring processes.
$200	Minor Low Level 6	Substantial inaccuracies in a single report form could have impaired the EPA hazard assessment and compliance monitoring processes had the information been included in the data base. (late report). [Note: A violation will be found and will be assessed for each inaccurately reported item.

Citation Charge Codes A8-12

o Failure to Maintain Records

$25,000	Major High Level 1	The lack of production and commercial use records cannot be compensated by other information to substantiate reporting of a non-excluded substance.

Citation Charge Code A22

o Failure to Report

$25,000	Major High Level 1	The violation impairs EPA's ability to proper implement §5 in that it may result in needless PMN by a third party.
$1,000	Minor Mid Level 4	If the substance was reported by someone else, the violation affects the Agency's ability to use the Inventory data as a basis for hazard assessment and compliance monitoring.

Citation Charge Codes A1-6

o Failure to Report on Time

	Major	
$25,000	High Level 1	Persons whose late reporting has resulted in the commencement of PMN activity will be assessed a penalty under the Major extent category. The penalty level assessed will depend on the stage of the PMN review process at the time the late report is received.
15,000	Mid Level 3	
5,000	Low Level 5	

Persons whose late submissions have not interfered directly with the PMN process but will result in unanticipated expenditure of Agency resources in updating the Inventory will be assessed a Minor/Low penalty of $200/chemical.

Citation Charge Codes A7

VII. Adjustment Factors

The adjustment factors discussed in the TSCA Penalty Policy pages 9-17 can be applied to Inventory violations without further modification.

VIII. Relationship to Penalties under §5 TSCA

It should be noted that certain Inventory reporting violations may result in violation of the §5 premanufacture notification requirements as well. For example, a person who fails to report for the Inventory as required and does not submit a PMN may be assessed a one-time civil penalty for the Inventory violation and a daily civil penalty for manufacturing contrary to §5 requirements.

Appendix A

Sample Citation Charges and Action Levels for Violations of the Inventory Reporting Regulations Promulgated Under Section 8(a) of the Toxic Substances Control Act

PERSON FAILED TO COMPLY WITH THE PROVISIONS OF THE INVENTORY REPORTING REQUIREMENTS PROMULGATED UNDER SECTION 8(a) OF THE TOXIC SUBSTANCES CONTROL ACT IN THAT THE PERSON:

A1. Failed to report concerning a chemical substance manufactured in the U.S. for a commercial purpose during 1977 as required because 30% or more by weight of the products manufactured are described by Standard Industrial Classification (SIC) Group 28 or 2911. (40 CFR §710.3(a)(1)(i)(A))

Action Level: Complaint and/or
Premanufacture Notification Requirement*

A2. Failed to report concerning a chemical substance manufactured in the U.S. for a commercial purpose during 1977 as required because the total pounds of reportable chemical substances manufactured at that site equals one million pounds or more. (40 CFR §710.3(a)(1)(i)(B)

Action Level: Complaint and/or
Premanufacture Notification Requirement*

A3. Failed to report concerning a chemical substance manufactured in the U.S. for a commercial purpose during 1977 as required because manufactured at a site in quantities equal to or greater than 100,000 pounds. (40 CFR §710.3(a)(1)(ii))

Action Level: Complaint and/or
Premanufacture Notification Requirement*

A4. Failed to report concerning a chemical substance imported into the U.S. for a commercial purpose because 30% or more of the products imported are described by Standard Industrial Classification (SIC) Group 28 or 2911. (40 CFR §710.3(a)(2)(i)(A))

Action Level: Complaint and/or
Premanufacture Notification Requirement*

A5. Failed to report concerning a chemical substance imported into the U.S. for a commercial purpose during 1977 as required because the total pounds of reportable chemical substances imported equals one million pounds or more. (40 CFR §710.3(a)(2)(i)(B))

Action Level: Complaint and/or
Premanufacture Notification Requirement*

*A complaint alone will be appropriate in cases where another person has reported concerning the chemical substance. PMN should be required in addition to issuing a complaint in cases where the substance has not already been reported for the Inventory.

A6. Failed to report concerning a chemical substance imported into the U.S. for a commercial purpose during 1977 as required because imported in quantities equal to or greater than 100,000 pounds. (40 CFR §710.3 (a)(2)(i)(B))

Action Level: Complaint and/or
Premanufacture Notification Requirement*

A7. Failed to report a chemical substance by the July 1, 1979 deadline. (40 CFR §710.6(b))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement*

A8. Falsely reported the site at which he manufactured the chemical substance as required for all but small manufacturers. (40 CFR §710.5(d)(2))

Action Level: Notice of Non-compliance or
Complaint

A9. Falsely reported the business address at which he imported the chemical substance as required for all but small importers. (40 CFR §710.5(d)(2))

Action Level: Notice of Non-compliance or
Complaint

A10. Falsely reported the amount of the chemical substance which he manufactured at each site for which reporting was required in 1977. (40 CFR §710.5(d)(4))

Action Level: Notice of Non-compliance or
Complaint

A11. Falsely reported the amount of the chemical substance which he imported during 1977. (40 CFR §710.5(d)(4))

Action Level: Notice of Non-compliance or
Complaint

A12. Falsely reported that manufacture of the chemical substance is site limited. (40 CFR §710.5(d)(3))

Action Level: Notice of Non-compliance or
Complaint

* See Appendix A-1

A13. Reported a chemical substance excluded from the Inventory because regulated under the Federal Insecticide, Fungicide and Rodenticide Act. (40 CFR §710.4(c)(1))

Action Level: Notice of Non-compliance
Complaint and/or
Premanufacture Notification Requirement**

A14. Reported a chemical substance excluded from the inventory because regulated under the Federal Food, Drug and Cosmetic Act. (40 CFR §710.4(c)(1))

Action Level: Notice of Non-compliance
Complaint and/or
Premanufacture Notification Requirement**

A15. Reported a chemical substance excluded from the inventory because manufactured solely in small quantities for research and development. (40 CFR §710.4(c)(3))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement**

A16. Reported a chemical substance excluded from the inventory because imported solely in small quantities for the research and development. (40 CFR §710.4(c)(3))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement**

A17. Reported a chemical substance excluded from the inventory because processed solely in small quantities for research and development. (40 CFR §710.4(c)3))

Action Level: Notice of Non-compliance or
Complaint

A18. Reported a chemical substance excluded from the inventory because not manufactured processed or imported for a commercial purpose after January 1, 1975. (40 CFR §710.4(c)(4))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement**

**A complaint alone will be appropriate in cases where the excluded substance has not been introduced into commerce since its improper reporting. A PMN should be required in addition to a civil penalty in cases where the excluded substance has been introduced into commerce since its improper reporting.

A19. Reported a chemical substance excluded from the Inventory because it is an impurity. (40 CFR §710.4(d)(1))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement**

A20. Reported a chemical substance excluded from the Inventory because it is a byproduct with no commercial purpose. (40 CFR §710.4(d)(2))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement**

A21. Reported a chemical substance excluded from the Inventory because it is a non-isolated intermediate. (40 CFR §710.4(d)(8))

Action Level: Notice of Non-compliance or
Complaint and/or
Premanufacture Notification Requirement**

A22. Failed to maintain records that document information reported under the regulations. (40 CFR §710.1(c))

Action Level: Notice of Non-compliance or
Complaint

**See A-3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

July 22, 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Strategy for the Preliminary Assessment Information Reporting Rule (Level A Rule)

TO: Air and Hazardous Materials Division Directors
Environmental Services Division Directors
Toxic Substances Branch Chiefs

The final version of the Level A Rule was published in the Federal Register on June 22, 1982 (47 Federal Register 26992). Attached is the Compliance Strategy for this rule. A proposed strategy was circulated in July, 1980, for comment. This document reflects comments on the proposed strategy and changes to the proposed rule.

If you have any questions please contact Pamela Harris (FTS 755-9404) of my staff.

A. E. Conroy II

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division

Attachment

COMPLIANCE STRATEGY

FOR

PRELIMINARY ASSESSMENT INFORMATION REPORTING RULE

(LEVEL A)

Pesticides and Toxic Substances Enforcement Division

COMPLIANCE STRATEGY FOR THE PRELIMINARY ASSESSMENTS INFORMATION REPORTING RULE (Level A Rule)

Compliance Strategy the Preliminary Assessment Information Reporting Rule Under TSCA §8(a) - (Level A Reporting Rule)

Overview

The Environmental Protection Agency (EPA) published the Preliminary Assessment Information Reporting Rule on June 22, 1982, under the authority of Section 8(a) of the Toxic Substances Control Act (47 Federal Register 26992). Manufacturers including importers must submit a report for each listed chemical manufacturered at each site. The information collected under this rule will include current information on production, uses and potential exposures for about 250 chemicals listed in the final rule. These chemicals come from the ITC lists and the list of chemicals for which information was submitted under section 8(e). A proposed amendment adds about 50 chemicals to the list and makes reporting automatic for chemicals listed by the Interagency Testing Committee (ITC) as possibly hazardous chemicals. The Agency will use the data gathered under this rule to decide whether to initiate rulemaking on these chemicals, to set priorities for testing chemicals and to assess risks associated with chemicals. Possible future rules under TSCA regulating these chemicals include §6 Regulatory Rules, §4 Test Rules or §8 Reporting Rules.

The Preliminary Assessment Information Reporting Rule anticipates two rounds of reporting. The first round applies to manufacturers of the chemicals listed in §712.30 of the rule. Processors will report in the second round of reporting, the procedures for which have been reproposed in 47 Fed. Reg. 27009, dated June 22,1982. Processors will be asked to report only if the Agency does not obtain sufficient information about the chemicals from the manufacturers.

The Pesticides and Toxic Substances Enforcement Division (PTSED) will concentrate its major compliance monitoring efforts on the detection of the following violations: (1) failure to report, (2) incomplete or inconsistent reports, and (3) the reporting of false information. These violations undermine the risk assessment process and potentially prevent regulation of a dangerous chemical. The enforcement activities will also assist OTS in assessing overall validity of the information submitted.

Requirements of the Regulation

Who Must Report

Manufacturers who have to report are those who produce or import any of the listed chemical substances or who apply any method of extraction, refinement or purification to a mined substance to make it marketable as a listed chemical substance. (An undefined or variable concentration mixture not intended for marketing as a listed chemical is not subject to this rule.)

Importers should report chemical substances imported in bulk in any grade of purity, in aqueous solution or containing additives (such as stabilizers or other chemicals) to maintain the integrity or physical form of the substance. This does not include formulated mixtures of two or more chemicals that are not additives.

Listed Chemicals

The final rule applies to the approximately 250 chemical substances and three categories listed by Chemical Abstract Service (CAS) number in 40 CFR §712.30. (The three categories of chemicals need to be considered only by persons who reported confidential chemical identities for the Inventory.)

Those subject to this rule should report an isomer under the specific isomer CAS number if they were producing an isomer alone. They should report a chemical under the more general CAS number if they are producing a mixture of isomers. This is the same policy used for inventory reporting.

Exemptions

A small business exemption applies if a site satisfies both of the following two criteria:

- It manufactures less than 45,400 kilograms (100,000 pounds) of the chemical and
- The parent company sales are less than $30,000,000.

A small quantity exemption applies if a site manufactures less than 500 kilograms (1,100 pounds) of the chemical.

Other exemptions are for importers of mixtures and articles, manufacturers of research and developme t chemicals (1) and manufacturers who solely produce the chemical as an impurity or a byproduct or a nonisolated intermediate. There are no exemptions for test marketing (2).

---

(1) Research and development chemicals: This term includes use of the chemical for scientific experimentation, analysis (for example, use as reagents or indicators for quality control), and research, including research or analysis for product development. This exemption applies only if there are no commercial uses of the chemical. If there are commercial uses, then both the commercial and the research and development uses must be reported.

(2) Test marketing: This term means distribution in commerce of a limited amount of a chemical substance or mixture or article containing such substance or mixture to a defined number of potential customers during a predetermined testing period to explore market capability prior to broader distribution in commerce.

What to Report

The information required by this rule must be reported on the Preliminary Assessment Information Reporting form. (A copy of the form begins on page 27005 of the attached Federal Register Notice.)

Persons subject to this rule must submit an individual form for each site manufacturing or importing a chemical substance listed in the rule.

The submitter reports information about the reporting year, the name and CAS number of the chemical, the reporting establishment, its location and technical contact on page one of the form. On page two the submitter answers questions about production, processing, use and exposure of the chemical. The Agency will use this information as part of its regulatory priority setting process.

Submitters should report "readily ascertainable" information. This is the most accurate information easily available to the submitter.

The data reporting section of the form (Section IV on page 2) has two parts: Part A: Plant Site Activities and Part B: Chemical Substance Processing. Production, processing and use at each single domestic manufacturing site must be reported on Part A. Part A information also includes the number of workers, and quantities of the chemical that are or are not recovered. Part B of the form applies to the processing of the chemical by others. Part B will account for the quantity of chemical that is distributed from the manufacturing site. The answers to the questions on this part of the form will allow the Agency to determine the extent of exposure to workers, the environment and the general population from the chemical.

Part A

- Items 1 and 2 - Total quantities of chemical imported and domestically produced.
- Item 3 - Quantities of chemical lost
  - Item 3(a) indicates quantities of chemical lost during manufacture. (3(a)- 3(b) + 3(c) + 3(d)).
  - Item 3(b) indicates quantities lost to the environment
  - Item 3(c) indicates quantities in wastes treated to destroy the chemical
  - Item 3(d) indicates quantities in wastes not treated to destroy the chemical

° Items 4, 5, 6, and 7 - Quantities of chemical, worker hours and number of workers associated with enclosed, controlled release and open process categories.

- Item 4 covers manufacture of the chemical.
- Item 5 covers on site use as a reactant.
- Item 6 covers on site nonreactant.
- Item 7 covers on site preparation of products.

° Item 8 - Quantity of chemical the manufacturer makes into products to be used by industry or in consumer products, includes:

- The chemical itself and mixtures containing the chemical.
- Articles with some release of the chemical possible.
- Articles with no release.

Part B

° Item 9 - Quantity of chemical the customer makes into products to be used by industry or consumers.

° Item 10 - Trade names under which the manufacturer markets the chemical to his customers. (To be answered only if customers' uses are unknown for more than 20 percent of the total quantity manufactured and imported.)

° Item 11 - Manufacturer's estimate of the quantity of chemical that is processed in enclosed, controlled or open processes by their customers.

Reporting Period

A company should report a chemical's production during the last complete corporate fiscal year as of the date the chemical is listed in §712.30. (The company reports the period covered by its report on page 1 in the upper right corner.) If the company did not manufacture a chemical during that year, it does not report for that chemical.

When to Report

Companies should report to EPA within four months of the effective date of the rule, July 22, 1982. Companies may obtain extensions or deadlines for resubmission from OTS for good cause. (The Assessment Division will provide procedures for granting extensions).

Where to Report

Reports should be returned to EPA at the following address:

Document Control Officer
Office of Pesticides and Toxic Substances
Environmental Protection Agency
P. O. Box 2080
Rockville, Maryland 20852

Compliance Assistance

Information about the rule has been published in various trade journals, such as those published by the Chemical Manufacturers Association, Chemical and Engineering News and others, so that the chemical industries subject to the rule will be well informed about its content. The Industry Assistance Office (IAO) will send copies of the Federal Register notice and the form to all known manufacturers of the substances (from information submitted for the inventory). Members of CMA will not receive packages in the initial mailing. Under an agreement between CMA and IAO, CMA members will call IAO and specify the number of forms needed and the contact to whom IAO should mail the forms. IAO will then mail the forms to these people. (This procedure has been adopted because the mailing list is set up to mail forms to plant sites whereas most CMA members will want the forms mailed to corporate headquarters.) IAO will keep a list of all companies to which it mailed forms. Persons who do not receive forms as a result of the initial mailings may obtain them by calling the IAO (800-454-9065) which is the source of all forms. Persons who need assistance in filling out the forms, may also call IAO which will direct their question to someone in the Agency who can assist them. This person will return the call. In addition, persons who submit forms that reflect misunderstandings of the instruction will receive a chance to correct them. OTS will return the original, incorrect form to the submitter with a letter explaining the form's deficencies and a deadline for resubmission. Submitters who desire further advice on resubmissions may call IAO.

Regulated Industries

Manufacturers of the 250 chemicals named will be required to report the information requested on the appropriate forms. It is anticipated that 330 companies will report on activities at 450 plants for a total of 1300 reports. Processors may be asked to report at a later date.

IAO will supply PTSED with a list of companies which may be subject to the rule based on the Inventory and the updated IOA mailing list of the reporting forms.

Compliance Background

Objectives
The objective of the compliance strategy is to ensure that all required information is reported in a timely and accurate fashion.

Types of Violation
There are four types of violations under TSCA §15(3)(B):

- o Falsification of reports;
- o Failure to report;
- o Incomplete or inconsistent reporting;
- o Late reports.

Falsification of Reports: Falsification of any of the items required by the rule would lead the EPA to draw incorrect conclusions about the threat to health and the environment posed by the continued manufacture or import of the chemical.

Submission of a falsified form does not satisfy the requirements of this rule under TSCA §8(a), and is a violation of TSCA §15(3)(B) of TSCA. In addition, knowing falsification of information submitted to the government is a criminal offense.

Failure to Report: Failure to submit a completed report as required by the rule would greatly impair the Agency's ability to make decisions concerning a chemical's effects on health and environment. Failure to submit the reports required by this rule is a violation of TSCA §15(3)(B).

Failure to Report Completely or Consistently: Incomplete or inconsistent reports also impair the Agency's ability to make informed regulatory decisions. Incomplete or inaccurate forms do not satisfy the requirements of this rule. In many cases, OTS will give the submitter a chance to correct an incomplete or inconsistent form. Reports submitted within the time granted by OTS for resubmission of corrected or completed forms will not be treated as violations. Continued resubmission (after two correction cycles) of incomplete or inconsistent forms will be treated as a violation.

Failure to Report on Time: Late reports impair the Agency's ability to compile data on individual chemicals. The data requested is necessary to determine if further action is necessary under TSCA and if so, what form it should take. Late reports unnecessarily delay the regulatory process. Reports which arrive later than 30 days after the deadline for submittal, resubmittal or extension will be referred to PTSED for enforcement response. (OTS will process reports which are less than 30 days late in the normal manner.)

Compliance Monitoring

Compliance monitoring for this rule will be performed in three phases. These phases are Reports Processing and Verification, Neutral Administrative Inspections, and Response to Tips and Complaints. At all times, during all three phases all information reported or collected from companies will be treated as Confidential Business Information (CBI) following TSCA CBI procedures unless otherwise specifically cleared through proper channels. Each phase depends to some extent upon cooperation between PTSED and OTS. Since OTS is familiar with the regulated community, it will play a significant role in violation detection.

Phase I: Reports Processing and Verification

Phase I of the compliance monitoring scheme is intended to detect incomplete or inconsistent reports and late reports. These violations will be detected in the course of routine processing of reports by the Informatics General Corporation, the contractor for OTS. Review of forms will indicate incomplete reports. Reports which contain certain types of inconsistent information will also be detected as part of the routine processing. Late reports are those received significantly later (30 days) than the required deadline.

Many inconsistent and incomplete forms will be the result of misunderstanding of the reporting requirements and procedures. OTS will return an incomplete or inconsistent form to the site which submitted it for correction. (See "Compliance Assistance" for an explanation of the procedure for this activity.) If the completed or corrected form is sent to OTS within the designated time, no enforcement action will be necessary. If no satisfactory response is forthcoming, OTS will refer incomplete or inconsistent reporting, as well as late reporting and apparent nonreporting violations to PTSED for appropriate enforcement response. Documentation of OTS contacts with the company in violation will accompany the referral. OTS will also certify, as appropriate, that the Agency did not receive the reports within 30 days of the allowed reporting deadline or that the reports do not satisfy the requirements of the rule.

Since these violations are usually self-evident, and will generally be confirmed in the course of OTS correspondence with the company, no inspections will be necessary for this phase of the program. Violation detection activities by OTS in this phase are a consequence of the routine processing of the forms by Informatics. Details of the OTS processing procedures are available from the Information Control Branch (ICB) of OTS.

Phase II: Neutral Administrative Inspection Scheme (NAIS)

Phase II will detect falsification of information from sites which filed completed forms and some failures to report. This will be accomplished by performing verification inspections.

Verification inspections will be targeted from among all the sites which submitted forms. As the EPA receives the reporting forms, the data along with the document control number for each form will be put into the computer. The computer data base will then contain production and geographical information on all reporting sites. A computer program will select the sites to be inspected using two criteria:

- Size - one fourth of the sites selected for inspection will be in the top fourth of those submitting forms by production volume, one fourth will be in the second fourth and so forth.

- Geographical distribution - the percent of sites chosen in any state should equal the percent of the total forms received which came from that state.

Within these two parameters selection will be random. The computer program will consider an initial universe that consists of all sites which reported.

A few, about 5-10%, of the verification inspections will investigate companies which did not report but are listed on the Inventory as manufacturers of a listed chemical. These inspections will be targeted by the Compliance Monitoring Branch (CMB) from Headquaters. The CMB will obtain from IAO a list of sites which received forms or are on the Inventory as manufacturers of Level A chemicals. Together with OTS, CMB will determine which sites on the list did not return forms. Companies which are clearly no longer in business or have already been identified as violators of the rule will be deleted from the list of non-reporters. These inspections will be targeted so that the percent of the inspections performed in each Region is equal to the percent of companies on the list which are in that Region. Otherwise the selection will be random.

Inspection reports will be forwarded to PTSED's Compliance Monitoring Branch (CMB). These reports will be compared with information received by OTS. OTS and PTSED personnel will decide if the information obtained during the inspection is consistent with the information reported to the Agency. If it is not, then PTSED will refer the case to the Region for appropriate action.

Significant, unexplained differences between data reported and the data in the file represent a violation. The Agency will take enforcement action.

Phase III: Response to Tips and Complaints

Some violations may be reported to EPA by complaints from competitors, former employes or other sources. Referrals from the various divisions of OTS are another source of information about possible violations. These complaints will be forwarded to PTSED for investigation. The nature of the investigation will depend on the nature of the alleged violation. The first step of an investigation is to determine if the manufacturer is subject to the rule and if a report has been

received by OTS. The case will then be referred back to the Regions for an on site inspection, if appropriate. The Agency will investigate all complaints and initiate an enforcement response, if indicated.

Inspection Scheme

There are two reasons for an inspection of a company.

1. Suspicion of violation based on a complaint or tip or referral from OTS.

2. Verification of data submitted by companies. (Neutral Administrative Inspection Scheme - See Phase II).

Both types of inspections will be targeted from Headquarters (CMB) on a quarterly basis. The Agency will investigate all allegations of violations. Allegations which are received in the regions should be forwarded to headquarters. At least 50% of resources available for Level A inspections will be used to perform NAIS inspections.

CMB will begin targeting inspections 90 days after the compliance deadline. This 90 days allows time for the processing of a large number of reports so that the selection of sites will be more truly random within the parameters. This time will also allow for the resolution of some reporting problems.

Each quarter CMB will know how many inspections each Region will have to perform to investigate allegations of violations.

CMB will target inspections of companies which did not return forms. This number will not exceed 10% of the inspections performed during that quarter. (This number may be increased if the Agency discovers that a large number of violations are occurring in this group.)

CMB will then ask the reports processing group to target the remaining inspections using the selection program described in the discussion of Phase II. At least 5 alternates should also be selected (CMB may vary this number based on experience). If a company selected by the program has already been inspected or targeted, CMB will replace it with one of the alternates.

This procedure will target manufacturing sites. CMB should call the technical contact reported on the form and determine whether the pertinent records are available at the plant site or at corporate headquarters. The location of the records will be the location of the inspection. By consulting the Inventory and the computer where information from all the forms is stored, CMB can develop a list of all Level A chemicals potentially manufactured by the targeted site or company. CMB will select a maximum of ten chemicals for the inspector to investigate. If the records on these chemicals agree with the data reported, no further inspections will be performed. If there are discrepancies between the records and the forms, then the Inspector will return to the company and investigate all the pertinent records on all the chemicals.

While the rule has no recordkeeping requirements, relevant records are likely to be kept for tax or business purposes, or to comply with other Federal regulations. Section 11 of TSCA provides that EPA has access to these records.

All companies inspected for compliance with Level A will also be inspected for compliance with all other appropriate TSCA rules and regulations. Also companies subject to Level A reporting requirements will be inspected for compliance with this rule if EPA inspectors visit the company for any other TSCA inspection.

ADMINISTRATIVE CONSIDERATIONS

Program Management

PTSED and OTS have developed report processing procedures that will detect suspected violations of failure to report, failure to report completely and consistently, and late reporting. PTSED and OTS will also target inspections under the NAIS described in this document. The Regions will conduct the inspections.

Coordination with OTS is important. The results of inspections will incidentally give OTS an estimate of the overall reliability of the data reported under this rule.

Assistance from OTS is necessary to violation detection. A key piece of evidence to false reporting is the report that OTS received. Personnel from OTS will also help enforcement personnel determine the significance of discrepancies between data reported and data found in the files. Since the rule only requires that "readily available information" be used to complete the form, there are plausible explanations for some minor inconsistencies between data already on file with EPA and data discovered in the course of an inspection. Consultation with OTS will be necessary in most cases, so that only significant inconsistencies are the subject of enforcement actions.

Any tips that indicate a possible violation will be investigated first at Headquarters. If further investigation is indicated, the case will be referred to the Region. A result of all inspections will be sent to the Compliance Monitoring Branch (CMB). CMB will collaborate with OTS to determine if a violation has occurred. Any violations detected by Headquarters or the Regions will be referred to the appropriate Region for enforcement response, with concurrence from Headquarters.

Allocation of Responsibility

PTSED

- Policy and Stategy Guidance
- Liaison between Regions and OTS
- Violation determination (with OTS)

OTS

- Processing of reports (detection and certification of reporting violations)
- Targeting NAIS inspections using computer program
- Assisting PTSED in determining when a violation has occurred

Regions

- Perform inspections
- Relay inspection reports to PTSED for determination of violation
- Develop cases and litigation with Headquarters concurrence.

Program Integration

Information received under this Rule may be useful to working groups which are developing regulations under TSCA for specific chemicals. Release of data to these groups will be in conformance with TSCA procedures for handling Confidential Business Information.

Appendix: Definitions of Terms

Byproduct: Any chemical substance or mixture produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

Chemicals from natural sources: Chemical substances which are extracted from an ore, from oil, or from any other natural source.

Impurity: A chemical substance unintentionally present with another chemical substance or mixture.

Intermediate: Any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions.

Non-isolated intermediates: Any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process but not including tanks or other vessels in which the substance is stored after its manufacture.

Reactant: A substance which enters into and is altered by a chemical reaction.

Process categories:

Enclosed Process - The process is designed and operated so that there is not intentional release of the chemical. In this process category, only fugitive or inadvertent releases occur and special measures are taken to prevent worker exposure and environmental contamination. "Special measures" refer to procedures and equipment that are monitored and used to prevent worker exposure, and scrubbers and other recovery equipment employed to prevent environmental release. Equipment with emergency pressure relief venting would be allowed in this category; routine venting would not. With regard to handling the manufactured chemical, persons who handle closed packages containing the material would be counted under "enclosed process. Persons who package or transfer the unpackaged chemical would be counted in one of the following categories.

Controlled Release Process - The process is operated in a controlled manner to minimize release of the chemical into the workplace. Release should generally be within prescribed limits. These limits may be dictated by government regulations or by company guidelines. If the chemical is vented outside the plant, the process is a "controlled release" process. Do not count general space ventilation fans.

Open Process - The chemical is routinely in direct contact with the atmosphere (workplace or outside the plant) and no measures are taken to prevent release. For example, reaction vessels are open vats, the chemical is transported or stored in open containers, or the chemical is freely vented into the workplace atmosphere.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

AUG 30 1982

MEMORANDUM

TO: Air & Waste Management Division Directors
Environmental Services Division Directors
Toxic Substances Branch Chiefs

SUBJECT: Asbestos Reporting Rule Compliance Strategy

On July 30, 1982, the Environmental Protection Agency published the Asbestos Reporting Rule. Attached is a copy of the the Compliance Strategy for this rule.

A draft of the strategy was circulated to the Regions during July for comment. The final version of the strategy incorporates those comments where appropriate.

If you have any questions, please call Pamela Harris at FTS 382-5649.

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division

cc:
Asbestos Coordinators

ASBESTOS REPORTING RULE
COMPLIANCE STRATEGY

Pesticides and Toxic Substances Enforcement Division

Asbestos Reporting Rule
Compliance Strategy

OVERVIEW

The purpose of the Asbestos Reporting rule is to obtain current information about major aspects of asbestos manufacture and processing to support the Agency's asbestos investigations into the risks from asbestos (47 Federal Register 33198, July 30, 1982). This rule is being developed in conjunction with analyses by the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), and the Mine Safety and Health Administration (MSHA). The CPSC is studying asbestos in consumer products, while OSHA and MSHA are reviewing the current occupational exposure standard.

The Rule requires that persons subject to the Rule complete and submit certain forms to EPA.

The objectives of the compliance strategy are to ensure that

- o All persons who should report do report;
- o Information is reported accurately;
- o All reports are received by the Agency in a timely fashion.

Possible violations of the rule are failure to submit forms, failure to properly complete forms, late reporting, and falsification of information.

Compliance monitoring activities will consist of reviewing notices received, cross checking industry lists to determine that all persons who are subject to the rule do report, investigating reports of noncompliance, and inspecting the records of some manufacturers importers and processors.

REQUIREMENTS OF THE RULE

The reporting requirements of the rule are outlined below:

A. Who must report (§763.65)

1. Persons who were miners, millers or primary processors of asbestos or importers of bulk asbestos in 1981 (§763.56(a)) (EPA form 7710-36) must report.

2. Secondary processors of asbestos or importers of asbestos mixtures (§763.65(b)) (EPA form 7710-37 parts I and II) must report.

3. Persons who are importers of asbestos mixtures or articles containing asbestos in 1981 (§763.65(c)) (EPA form 7710-37, parts I and III) must report.

4. Some persons described in parts 2 and 3 above, will be selected in a sample survey to fill out EPA form 7710-36, (§763.65(d)).

B. What to Report

1. Submitters report all information required by the appropriate sections of the EPA forms. (See the "Instruction Booklet -- Reporting Commercial and Industrial Uses of Asbestos" printed with the rule in the Federal Register for a discussion of the reporting requirements and definitions.) EPA form 7710-36 and EPA form 7710-37 can be obtained by telephoning the Industry Assistance Office (IAO) 800-424-9065.

2. Miners, primary processors and secondary processors must report information "known or readily ascertainable" by the respondent, including all information in a person's possession or control, plus all information that a reasonable person might be expected to possess, control, or know, or could obtain without unreasonable burden or cost.

3. Information already reported to CPSC may be referenced on the form and need not be submitted unless the respondent has informed the CPSC of his objection to sharing data with EPA in which case submission to EPA is mandatory). (Information for 1981 which was not required by CPSC but is required by EPA must be submitted on EPA forms.)

C. Exemptions (§763.65(f))

1. Secondary processors of asbestos who process asbestos to repair articles, construct buildings or other similar activities or to apply, assemble, install, erect, consume or repackage the mixture without modification are exempt.

2. Persons who are small manufacturers, processors or importers, as defined by §763.63(m) (i.e., who employed no more than 10 full-time employees at any one time in 1981) are exempt.

D. Schedule for Reporting

1. Miners, millers, primary processors and importers of bulk asbestos (§763.65(a)) EPA form 7710-36 must be submitted by November 30, 1982.

2. Secondary Processors and importers of asbestos mixtures (§763.65(b) and (c)) must report by October 30, 1982.

3. Those secondary processors who are selected for additional reporting shall submit the required data within 90 days of the receipt of EPA notification to do so.

E. Where to Report

Respondents will mail completed forms to

U. S. Environmental Protection Agency
Post Office Box 2070
Rockville, MD 20852

F. Confidential Business Information

Respondents may claim information confidential by checking the appropriate spaces on the form and signing the certification statement.

REGULATED INDUSTRIES

The rule applies to persons who are miners or primary processors of asbestos, importers of bulk asbestos, asbestos mixtures or articles containing asbestos, and certain secondary processors of asbestos. PTSED has obtained a partial list of 3,131 persons to whom the rule may apply. The GCA Corporation of Bedford, Massachusetts prepared this list under a contract from EPA. The list contains the names of some companies which do not process asbestos. It also does not differentiate between primary and secondary processors. In spite of its flaws, it is an useful guide. Sources for the list are:

1. Dun and Bradstreet tape for four SIC categories.
   - 2891 Adhesive and Sealants (968 establishments)
   - 2952 Asphalt Felts and Coatings (350 establishments)
   - 3292 Asbestos Products (325 establishments)
   - 3293 Gaskets, Packing, and Sealing Devices (553 establishments)
2. Asbestos Information Association list.
3. National Emission Standards for Hazardous Air Pollutants (NESHAP) listing from EPA Compliance Data System.
4. NIOSH printout of asbestos-containing products.
5. Bureau of Mines mailing list.

6. Asbestos/Cement Pipe Producers Association.

7. Friction Materials Standards Institute members.

8. U.S. Customs List for 1980 for importers of asbestos.

9. State Industrial Directories.

The list is organized by Region. The appropriate section of the list for each Region will be sent to the Regional Asbestos Coordinator (RAC). The RAC may obtain the national list from PTSED, if he needs it. PTSED will ask the RAC to help update the list by recommending possible deletions and additions. The RAC may wish to contact state agencies which regulate the asbestos industry to obtain information to update the list. The list will also be updated by adding the names and address of persons who request the reporting form.

COMPLIANCE ISSUES

The objective of this compliance strategy is to ensure that all persons subject to this rule file their reports in a timely and accurate fashion, and that no persons subject to this rule fail to report.

Types of Violation

There are four types of violations:

1. Falsification of reports.

2. Failure to report.

3. Incomplete reporting.

4. Late reports.

Falsification of Reports: Falsification of any of the items required by the rule would lead EPA to draw incorrect conclusions about the threat to health and the environment posed by the continued manufacture or import of asbestos.

Submission of a falsified form does not satisfy the requirements of this rule under TSCA §8(a), and is forbidden by TSCA §15(3)(B). Knowing falsification of information submitted to the government is also a violation of 18 U.S.C. Section 1001 and is, or may be, a criminal offense.

Failure to Report: Failure to submit a report, as required by the rule, would greatly impair the Agency's ability to make decisions concerning asbestos' effects on health and the environment. Failure to report is a violation of TSCA Section 15(3)(B).

Incomplete Reports: Incomplete reports only partially impair the Agency's ability to regulate asbestos. If OTS can readily obtain the missing information from the submitter, then no violation will have occurred. OTS has decided to offer reporters two correction cycles to complete their report. The "8(a) Asbestos Flow Process" (1) details the OTS policy with respect to correction cycles. However, if the submitter continues to withhold critical information, a violation of TSCA Section 15(3)(B) will have occurred.

Late Reports: Late reports impair the Agency's ability to compile data on segments of the asbestos industry and will delay planned analysis. Reports received later than 30 days past the deadline for reporting or more than 30 days past any extension granted by OTS will be referred to PTSED for enforcement response. (Extensions may be granted by OTS for good cause. Reports submitted within the extended time period will not be treated as violative.)

INDUSTRY NOTIFICATION

The proposed Asbestos Reporting Rule was published in the Federal Register (46 F.R. 8200, January 26, 1981). Written comments were solicited prior to May 27, 1981. Following that date there was a 20 day period during which EPA personnel were available to meet in Washington, D.C., with interested persons. Comments were received, and responses to the comments are addressed in the final rule. In addition, articles about the rule have appeared in major trade journals.

The list of companies described in the Regulated Industries section were used as a mailing list to distribute copies of the rule and the required form. The Industry Assistance Office (800-424-9065) will be available to answer any questions about the rule or the form.

COMPLIANCE MONITORING

Compliance Monitoring Priorities

There are four methods available to the Agency to detect violations. In order of practical application they are:

1. Reviewing forms received by the Agency for timeliness, accuracy, and completeness.

2. Cross-checking the list of asbestos miners, millers, importers and processors against reporters of forms received to detect failures to report.

3. Verifying reports by reviewing company records.

4. Investigating reports of noncompliance.

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(1) "8(a) Asbestos Flow Process" is a document which outlines the report processing procedures that Informatics General Corporation, the OTS contractor, will use. These procedures will detect late reports, incomplete reports, and some reporting violations. The document is available from the Information Control Branch.

Reviewing Forms: The information required by this rule is to be submitted on the appropriate prepared forms. All required information should appear on the form. Using the procedures in the "8(a) Asbestos Reporting Flow Process", OTS and its contractor, Informatics General Corporation will process the forms. Unreported information is easily detected and will be investigated. Late reports will also be referred to PTSED. Information which appears to be unsatisfactory will also be investigated. For instance, the submitters may report unknown in several places on the form. However, repeated use of "unknown" as a response is probably unwarranted. The report processors will flag the report for investigation if "unknown" is used in place of expected data.

If a submitter has not reported satisfactory and complete information after OTS has allowed the submitter two opportunities to do so, the matter will be referred to PTSED.

When OTS refers late or incomplete reports to PTSED, OTS will describe the type of violation and certify that the report received is in violation. When suspected violations are referred, OTS will give the reasons for its conclusion that the report is or may be in violation and recommend specific investigations which the Regions may perform. (For instance, OTS may report that worker numbers are inconsistent and recommend investigation of personnel records.)

Cross-checking List of miners, millers,processors and importers. The Agency has compiled a list of persons whon may be subject to the rule. The Agency mailed a reporting package to each person on the list developed by GCA and updated as described in the Regulated Industries Section. The Agency requested recipients of the package to inform the Agency if they are not subject to the rule.

The Agency will treat non-respondents to the updated list in the following manner. (Non-respondents are persons who received a reporting package but neither submitted the form nor informed the Agency that they were not subject to the rule.)

August 30, 1982	Effective date of the rule
October 30, 1982	Secondary processors and importers of asbesos mixtures report
November 30, 1982	Miners, millers, primary processors and importers of bulk asbestos report
December 14, 1982	OTS (Chemical Control Division (CCD)) sends letter to non-respondents requesting either submittal of form or notification to EPA that they are subject to the Rule.
January 21, 1983	PTSED will send a list of persons who have still not responded to each Region. The Regions will try to determine if the persons who did not respond are subject to the rule.

If it can be determined that a non-respondent was subject to the rule, the Regions will pursue appropriate enforcement response. The Regions will inform PTSED of the results of its investigations. PTSED will inform OTS (Information Control Branch) of the results of the Regional investigations.

Reviewing Company Records: Some companies which have apparently complied with the rule will be randomly selected for inspection to verify the information on their forms. The companies which the Agency inspects will be chosen by computer using statistically valid criteria. Other companies which are on the list but did not submit a form will be randomly selected for inspection to verify that they are not subject to the rule. (See Verification Inspection Scheme.)

Investigating Reports of Noncompliance: The Consumer Product Safety Commission, state or federal agencies, current or former company employees, or competitors may have information which implies that a company is violating the requirements of the rule. Information which comes to the attention of EPA Headquarters will be transmitted to the appropriate Region for investigation. In some instances, the case may be resolved by telephone or written communication with the company. In others, inspection or subpoena of the firm's records may be necessary. The RAC should inform PTSED of all alleged violations which come to his attention.

OTS will refer submitters of forms with unresolved problems to PTSED. For example, companies which excessively report that information is unknown and continue to refuse to submit the requested information after two opportunities will be inspected. Companies that report "unknown" for more than 50% of the fields where that response is permitted may be targeted for inspection. If the inspector, using routine inspection procedures, is able to discover the information, then the company has not reported "readily available information", and is in violation of TSCA.

Neutral Administrative Inspection Scheme

There are two reasons for an inspection of a company.

1. Suspicion of violation based on a complaint, tip or referral from OTS.

2. Verification of data submitted by companies. (See Verification Inspection Scheme.)

Both types of inspections will be targeted by the Compliance Monitoring Branch (CMB), PTSED on a quarterly basis. The Agency will investigate all allegations of violations. Allegations which are received in the regions should be forwarded to headquarters.

CMB will begin targeting inspections 45 days after the appropriate compliance deadline. This 45 days allows time for the processing of a large number of reports so that the selection of sites will be more truly random within the parameters. This time will also allow the resolution of some reporting problems. Specifically the targeting will conform to the following schedule:

December 14, 1982 Begin targeting inspections of Secondary Processors

January 14, 1983 Begin targeting inspections of Primary Processors

Targeting inspections of nonsubmitters will begin 45 days after December 14, 1982, the date OTS sends letters to nonrespondents. Thus, targeting of these inspections will begin on January 31,1983.

Each quarter, CMB will know how many inspections each Region will have to perform to investigate allegations of violations. CMB will then target inspections of companies which did not return forms. This number will not exceed 10% of the inspections performed during that quarter. (PTSED may increase this percentage if the Agency discovers that a large number of persons subject to the rule have not reported.) This is to verify that persons who did not report are not in violation.

CMB will then ask the reports processing group in OTS to target the remaining inspections using the selection program described in the discussion of the Verification Inspection Scheme. At least 5 additional sites should also be selected (CMB may vary this number based on experience). If a company selected by the program has already been inspected or targeted, CMB will replace it with one of the additional sites.

This procedure will target both processing sites and corporate headquarters. If necessary, CMB should call the company's technical contact reported on the form and determine whether the pertinent records are available at the plant site or at corporate headquarters. The inspection will be conducted at the location of the records.

While the rule has no recordkeeping requirements, relevant records are likely to be kept for tax or business purposes, or to comply with other Federal regulations. Section 11 of TSCA provides that EPA has access to these records.

Verification Inspection Scheme

Verification inspections will be targeted from among all the sites which submitted forms. As the EPA receives the reporting forms, the data along with the document control number for each form will be put into the computer. The computer data base will then contain production and geographical information on all reporting sites. A computer program will target inspections from an initial universe which consists of all sites which reported using a statically valid selection criteria. These criteria include geographical distribution of the reporters, production volume, worker population, and type of industry (miners, millers, secondary processors, etc.).

A few, about 10%, of the verification inspections will investigate companies which did not report but are listed as manufacturers or processors of asbestos. These inspections will be targeted by the Compliance Monitoring Branch (CMB) from Headquarters. The CMB will obtain from IAO a list of sites which received forms or are listed elsewhere as manufacturers or processors of asbestos. Together with OTS, CMB will determine which sites on the list did not return forms. Companies which are clearly no longer in business or have already been identified as violators of the rule will be deleted from the list of non-reporters. These inspections will be targeted so that the percent of the inspections performed in each Region is equal to the percent of companies on the list of non-reporters which are in that Region. Otherwise the selection will be random.

Inspections

Inspection Guidance will be sent to the Region near the October 30, 1982, compliance date. The inspectors will compare the data on the form with the data in the company's files. Significant, unexplained differences between data reported and the data in the files represent violations. Enforcement action should be taken against violators according to the Enforcement Response Policy, with concurrence from Headquarters.

ADMINISTRATIVE CONSIDERATIONS

Program Management

OTS and PTSED have developed report processing procedures that will detect suspected violations of failure to report, failure to report completely and late reporting. PTSED will also target inspections under the NAIS described in this document. The Regions will conduct the inspections.

Coordination with OTS is important, The results of inspections will provide OTS with an estimate of the overall reliability of the data reported under this rule.

Assistance from OTS is necessary for violation detection. For instance, a key piece of evidence to false reporting is the report that OTS received. Personnel from OTS will also help enforcement personnel determine the significance of discrepancies between data reported and data found in the files. Consultation with OTS will be necessary in most cases, so that only significant inconsistencies are the subject of enforcement actions.

Any tips that indicate a possible violation are to be investigated first at Headquarters by an OTS review of the form submitted by the alleged violator. If further investigation is indicated, the case will be referred to the Region. Any violations detected by Headquarters or the Regions will be referred to the appropriate Region for enforcement response, with concurrence from Headquarters.

Allocation of Responsibility

PTSED

- o Write Policy and Strategy Guidance
- o Act as liaison between Regions and OTS
- o Concur with enforcement responses to violations

OTS

- o Process reports (detection and certification of reporting violations detected by the reporting process)
- o Target verification inspections using computer program

Regions

- o Perform inspections
- o Determine violations
- o Develop cases and litigation with Headquarters concurrence

Program Integration

Information received under this Rule may be useful to working groups which are developing other regulations under TSCA for asbestos. Release of data to these groups will be in conformance with TSCA procedures for handling Confidential Business Information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 12 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Air and Waste Management Division Directors
Environmental Services Division Directors

SUBJECT: Compliance Strategy TSCA Section 8(d)

Attached is the Compliance Strategy for the recently promulgated Toxic Substances Control Act (TSCA) Section 8(d) Health and Safety Data Reporting Rule for the submission of lists and copies of health and safety studies undertaken by manufacturers and processors on specifically listed chemicals.

This rule requires manufacturers, processors, those who propose to do so, or those who have manufactured or processed a listed substance in the past (within ten years of the date it was listed) to submit copies and lists of health and safety studies known to or undertaken by them.

Enforcement of this rule will be largely responsive rather than affirmative and will normally be initiated by Headquarters, with Regional assistance.

If you have any questions concerning this Strategy please contact Pamela Harris of my staff at FTS-382-5567.

A. E. Conroy II, Director
Compliance Monitoring Staff
Office of Pesticides and Toxic Substances

Attachment

21 NOV 1983

COMPLIANCE STRATEGY FOR TSCA SECTION 8(d)

COMPLIANCE MONITORING STAFF
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
THE U.S. ENVIRONMENTAL PROTECTION AGENCY

COMPLIANCE STRATEGY FOR TSCA SECTION 8(d)

CONTENTS

COMPLIANCE STRATEGY TSCA Section 8(d)

Overview

Section 8(d) of the Toxic Substances Control Act (TSCA) provides that EPA shall require by rule that manufacturers, processors and persons proposing to manufacture or process specified chemical substances or mixtures submit lists and copies of health and safety studies which have been conducted on these selected chemicals. The Agency published a final rule at 47 FR 38780, September 2, 1982, to implement the §8(d) requirement for a specified list of chemicals. The chemicals have been recommended by the Interagency Testing Committee (ITC) and independently selected by EPA for evaluation. The acquisition of studies on the specified chemicals is intended to aid EPA in evaluating their health and environmental effects. The reported information will also be used to determine whether the chemicals should be included in testing rules issued under §4 of TSCA. The Agency intends to use the same rulemaking authority to collect information on additional chemicals in the future.

This document contains the Agency's strategy for monitornig compliance with the §8(d) rule. It discusses the regulatory requirements, compliance monitoring priorities, and allocation of responsibility between Headquarters and the Regions.

Regulated Industry

The §8(d) reporting requirement is expected to affect approximately 650 manufacturers and processors of the chemicals listed in §716.17 of the rule as well as those persons who propose to manufacture or process a chemical listed. This number will fluctuate with additions and deletions to the list.

Requirements of the Rule

Section 8(d) of TSCA (15 U.S.C. 2607(d) authorizes the Administrator to promulgate rules which require the submission of lists and copies of health and safety studies on chemical substances or mixtures.

Who must report

Those subject to this reporting requirement include persons who currently manufacture or process any listed chemical substance or mixture for commercial purposes, those who propose to do so, and those who are not currently involved with a listed chemical but who manufactured or processed it or proposed to do so any time during the ten year period prior to the time it became listed. It should be noted that while the reporting requirement extends only to those persons who are engaged in these activities for "commercial

purposes," EPA interprets this term broadly. "Commercial purposes" refers to activities conducted by an entity which have as their purpose, in whole or in part, the obtaining of a commercial advantage. This definition is intended to exclude only those activities which are of a strictly charitable or purely academic nature. The term is not meant to exclude those manufacturers and processors who create a chemical substance as a co-product or by-product in their manufacturing process.

What chemicals/mixtures are subject to the rule

The rule (40 CFR §716) applies to all chemical substances selected by the ITC as well as other chemicals separately selected by EPA. The ITC, established under §4(e) of TSCA (15. U.S.C. 2603(e)), has recommended the chemical substances and mixtures subject to this rule for priority consideration by EPA in the issuance of testing rules under §4(a) of TSCA. Under §4(e), the ITC is directed to revise the list every six months as it deems necessary.

What must be reported

Under the rule, manufacturers and processors are required to submit copies of all completed health and safety studies within their possession, as well as a list describing any ongoing studies and studies known to the respondent. Persons who are not involved with a chemical when it is listed but manufactured or processed it or proposed to do so any time during the ten years prior to the time it is listed, are required to submit copies of studies for that chemical, but are not required to list studies.

Any person in possession of a study may be required to submit it. The rule, however, limits the initial submission of studies to manufacturers or processors of chemicals or those persons who propose to manufacture or process a listed chemical. The rule further limits the file search to studies in currently active files. For purposes of this rule, persons do not have to search files retired prior to December 31, 1979. Other persons in possession of studies would submit them only upon request by EPA after the studies had been listed by the initial group of submitters.

Copies of studies

Persons subject to the rule must submit all non-exempt health and safety studies in their possession within 60 days after the effective date of the placement of a chemical on the list. For chemicals appearing in the FR Notice of September 2, 1982 the reporting date is December 3, 1982. Included in this requirement are all those studies which were conducted or initiated by or for any manufacturer or processor and are in that person's possession. Similarly all those studies which were conducted or initiated by a person who is not subject to the requirements of this section must be submitted if the study is in the possesssion of a manufacturer or processor subject to the rule

Lists of studies

The rule requires respondents to submit a descriptive list of all ongoing health and safety studies conducted by or for them within 60 days of the placement of a chemical on the list. For chemicals appearing in the FR Notice of September 2, 1982 the reporting date is December 3, 1982. The purpose of the study, the type of data collected, and the anticipated date of completion for each study must be included. The EPA may ask persons who list studies to submit all or part of any report including preliminary reports or underlying data. In such cases, the Agency will notify the respondent by certified mail. After the initial 60-day reporting period, persons are only required to list chronic tests; long- and short-term tests of mutagenicity, carcinogenicity or teratogenicity, and the biological and environmental fate tests listed in §716.10(h) through (j).

Excluded Reporting

To avoid duplication, the rule provides for the exclusion of information which has been previously reported. The following information is specifically exempt from the reporting requirements of §716.6 and §716.7:

- studies or data which have been published in scientific literature
- studies which have been submitted to EPA or studies submitted to any other Federal agency without claims of confidentiality
- studies conducted or initiated by or for another person who is subject to the requirements of the rule
- studies of chemical substances which are not on the TSCA Chemical Substance Inventory
- studies of substances or mixtures in which a substance or designated mixture listed in §716.17 appears only as an impurity. When reporting is to be required on a substance or designated mixture that appears as an impurity, that reporting will be separately proposed in the Federal Register.
- copies or lists of the following types of studies when the subject of the study is a mixture containing one or more chemical substances or designated mixtures listed in §716.17.

  - Acute oral toxicity studies
  - Acute dermal toxicity studies
  - Acute inhalation toxicity studies
  - Primary eye irritation studies
  - Primary dermal irritation studies
  - Dermal sensitization studies
  - Physical and chemical properties except those listed in §716.10

- copies or lists of analyzed aggregations of monitoring data which was acquired up to 5 years preceding the placement of the chemical substance or designated mixture on the list in §716.17 or when such monitoring data was not analyzed to determine the exposure or concentration level of the listed chemical substance or designated mixture.

- analyzed aggregations of monitoring data on mixtures known to contain one or more substances or designated mixtures listed in §716.17, when the monitoring data are not analyzed to determine the exposure or concentration levels of the substance or designated mixture listed in §716.17.

Additionally, §716.6 states that the underlying data need not be submitted unless requested. The rule specifies certain procedures to be followed when submitting information.

How to Report

Submission of Copies of Studies

Each study submitted under §716.6 must be accompanied by a cover letter containing the following information:

- name, address, job title, and phone number of the submitting official

- the name and address of the company on whose behalf the study was made

- the identity of any impurity or additive known to have been present in the substance as studied unless its presence is specifically noted in the study.

Submissions under this section must be indexed by chemical name, including the Chemical Abstracts Services (CAS) Registry Number, if known.

Submission of Lists of Studies

Lists submitted under §716.7 must include:

- Ongoing health and safety studies conducted by or for the manufacturer including the purpose of the study, type of data collected, and progress and anticipated date of completion.

- Study title, and the name and address of any person whom the respondent knows is in possession of any unpublished studies which are not in the respondent's possession.

The lists submitted under §716.7 must be grouped by chemical, including CAS number, if known, and must be accompanied by a cover letter. The cover letter must contain the name, job title, address and telephone number of the submitting official and the name and address of the manufacturer or processor with which the official is associated and on whose behalf submission is made.

Reporting Timetable

All submissions under §§716.6 and 716.7 of the rule must be postmarked on or before 60 days after the effective date of the listing of each chemical in §716.17 or within 60 days of proposing to manufacture or process a substance or designated mixture if first done after the effective date of the substance's or designated mixture's listing in §716.17. However, a request for an extension may be granted in the event the file search is expected to be lengthy. Because the duty to report is a continuing one, all those persons who are required to submit lists of studies under §716.7 must inform EPA of any study initiated during the three year time frame commencing on the date on which the chemical substance or mixture was added to the list in §716.17. Copies of final reports of studies listed as ongoing under §716.7(a)(i) or studies initiated within the three year reporting period must be submitted to EPA within thirty days of the date they are obtained by persons required to report.

The rule also contains a sunset provision which provides that within three years after a chemical substance or mixture is added to the list in §716.17, the reporting requirement on that substance will terminate. If EPA determines that reporting on a specific chemical should be continued, a notice to that effect will be published for comment.

Confidentiality Claims

Anyone submitting §8(d) information may claim all or part of the material as confidential. Claims must be made at the time of submission and two copies of the material must be submitted; one a complete copy and one copy with confidential material deleted. Claims of confidentiality must be in accordance with §716.16 of the rule.

Enforcement Objectives

The major objective of this strategy for monitoring compliance TSCA requirements to submit health and safety studies, is (1) to use limited resources most effectively to detect violators and (2) to provide further incentive for compliance with this rule.

Voluntary Compliance

The rule precludes the effective use of an affirmative compliance program as an enforcement tool because generally it is only after EPA is informed of the existence of studies that measures can be taken to insure disclosure. Therefore, for effective enforcement of the rule, it is essential that industry be well informed of its requirements. Not only should enforcement efforts be directed towards informing industry of its obligation to report all non-exempt studies within its possession, but also of the requirement to submit lists of any studies of which it is aware. The current outreach program developed by OTS includes:

1. Notification to industry that the rule was been promulgated and that compliance must occur within 60 days. A summary of the rule's requirements was included in the notice.

2. Notification to industry if and when additional chemicals are added to the list in §716.17 of the rules.

Types of Violations

Five potential violations of the §8(d) requirements in order of priority are:

- Falsification of data
- Failure to submit copies
- Failure to submit lists
- Failure to report on time
- Failure to follow prescribed reporting procedures

Violation Detection

Falsification of Data

Data falsification seriously threatens the Agency's efforts to evaluate a substance's environmental and health effects. Violations of this sort are detected by analyzing data submitted to OTS. While the likelihood of detecting data falsification is smaller than detecting other types of violations, any case of suspected data falsification will be given highest priority.

Failure to Submit Copies of Studies

The submission of copies of studies conducted on chemicals which appear on the list is essential to EPA in §4(a) rulemaking. The submission of health and safety studies will aid EPA in its determination of whether sufficient data exists upon which to base an evaluation of the substance's environmental and health effects. If sufficient data exists, there will be no need for the promulgation of a rule requiring further testing under §4(a). Therefore, industry, through timely submission of existing studies, could partially or in some instances totally obviate the need for further testing.

Failure to Submit Lists of Studies

The rule sets forth essential reporting requirements as described below. The degree of violation associated with each requirement reflects the detriment to §4(a) rulemaking created by the failure to report.

- The submission of lists to EPA of all health and safety studies which are currently in progress will assist EPA in formulating a complete and accurate analysis of the need for further testing on a particular substance. Failure to submit such information may lead to a duplication of testing as well as an increased administrative burden in uncovering these studies upon their completion.

- Respondents must submit the names of persons who they know possess unpublished health and safety studies. Such lists are essential to the discovery and location of these documents. Additionally, these lists may serve as a means of identifying those persons who have failed to submit copies of the listed studies to the Agency as required by the rule. The lists may also be used to solicit copies of these studies from those persons who are not required to submit unless so requested by EPA.

Failure to Report on Time

The timely submission of health and safety studies is essential to efficient rulemaking under TSCA. Industry may fail to submit adverse health and safety studies in a timely fashion in an effort to delay eventual regulation of a chemical substance. The failure to inform EPA as to the existence of relevant studies within 60 days after the effective date of the listing of a chemical could result in the initiation of unnecessary rulemaking procedures.

Failure to Follow Prescribed Reporting Procedures

Generally, the EPA will not impose a civil penalty for minor failures to follow the prescribed reporting procedures. If, however, such a failure impairs the Agency's ability to adequately evaluate the sufficiency of health and safety data which is available on a particular chemical, it will be considered a failure to report or a failure to report on time, as appropriate.

Application of Detection Methods

The purpose of TSCA §8 is to help the Agency gather information about chemicals that may pose hazards to either human health or the environment. The §8(d) rule requires manufacturers and processors of specified chemical substances to provide the Agency with copies of health and safety studies in their possession and lists of studies conducted for them. The objective of §8(d) is to allow the Administrator to make informed decisions regarding the need for §4 TSCA testing.

Although compliance with the §8(d) rule is important to the Agency, EPA does not intend to conduct an extensive affirmative compliance monitoring program. The Compliance Monitoring Staff (CMS) feels that industry will voluntarily comply with the §8(d) requirements for two reasons. First, §8(d) does not require anyone to initiate health or safety studies. Persons subject to the regulation must only submit copies or lists of existing studies. Thus, the cost to industry of complying with §8(d) is low.

Second, an economic incentive exists for industry to comply with §8(d). Most of the chemicals subject to §8(d) have been selected by the Interagency Testing Committee (ITC) or referred by EPA for priority testing under TSCA §4(a). Section 4 grants authority to the Agency to require industry to conduct and pay for health and safety studies. In essence, §8(d) allows industry to avoid §4 testing if it can supply existing health and safety studies for ITC chemicals. Therefore, the Agency expects compliance from industry to avoid costly duplicative §4 testing.

The CMS will, of course, conduct inspections to detect violations of §8(d) if allegations are received from third parties. In addition to inspections conducted in response to allegations received, §4 Good Laboratory Practices (GLP) inspections could be used to review specifically targetted §8(d) studies or studies which may contain §8(d) data.

For effective, responsive enforcement, EPA must obtain information as to the existence of health and safety studies held by industry. Potential sources which OTS and CMS can use to discover §8(d) violations include the following:

- reports from employees of manufacturers, processors and distributors of chemical substances involved in the generation of such reports,
- reports from contractors/consultants who conducted health and safety studies for manufacturers, processors and distributors,

- competitors who are subject to the requirement of §8(d),
- §4 GLP inspections, and
- compliance investigations

Reports from employees

Employees of a firm subject to the reporting requirement may become aware that health and safety studies are being withheld from government scrutiny. Generally, this would involve those employees who either participated in or conducted the study itself. Industrial hygienists should be apprised of the requirements of the rule to improve communications in this area.

Reports from employees may come into Headquarters or the Regions. EPA will conduct follow up inspections since such reports alone will not be sufficient to substantiate a violation without further investigation.

Reports from contractors

Health and safety studies often are performed by persons who are contractors rather than employees of firms subject to the §8(d) requirement. Although these contractors are not subject to the §8(d) requirement, they may notify EPA if they become aware that the results of their studies have not been reported to the Agency. Similarly, purely academic and charitable institutions who are not subject to the reporting requirement of the rule may provide EPA with lists of studies which they have performed for industry. EPA will notify labs appearing on the §4 list of testing labs of the requirements of §8(d).

Reports from competitors

Under the rule, each person who manufactures or processes the selected chemical substances or designated mixtures listed in §716.17 must report all health and safety studies known to him or reasonably ascertainable by him. While this rule specifically excludes the submission of copies or lists of studies conducted or initiated by another person subject to the rule, it is reasonable to assume that there will be some overlap in the listing of studies by persons subject to the rule. Through this reporting overlap, EPA may learn of the existence of studies which have not been disclosed to the Agency. The OTS can either request or have CMS subpoena a copy of the health and safety study from those persons identified.

§4 GLP Inspections

Data reviewed in the course of a §4 GLP inspection may be data which is required to be submitted under §8(d). Inspectors should compare the list of studies the lab is currently performing with the chemical list in §716.17 to determine whether the lab is testing a chemical on the list. If an inspector encounters any data which would be required to be submitted under §8(d), the inspector should list the study title, chemical involved, who the study was conducted for, and the name of the person within the company who coordinated the study. This information should be transmitted to CMS Headquarters who will turn it over to OTS.

Compliance Investigations

The most effective use of investigation as an enforcement tool under §8(d) is as a responsive measure to the reports enumerated above. Reports should in all cases trigger further investigation rather than form the sole basis of enforcement action. These responsive inspections are preferable to neutral administrative inspections because responsive inspections focus resources on studies which are most needed by the Agency. The precise nature of each investigation may vary with the alleged violation.

Priorities

The major function of §8(d) is to insure that the Agency obtains all the existing health and safety studies on the listed chemicals. This is essential to insure that EPA is apprised of all data prior to its assessment of the need for further testing. To maximize enforcement efforts, those compliance monitoring activities aimed at detecting failure to report violations should be given first priority under this rule. The CMS should conduct compliance monitoring activities in the following order of priority to insure maximum discovery of violations:

- Response to Evidence of Failure to Submit or Falsification of Copies of Studies
- Response to Evidence of Failure to Submit Lists of Studies

Other violations will be pursued as the need arises, primarily as the result of referrals from OTS.

Administrative Considerations

Allocation of Responsibilities

Office of Toxic Substances

The Office of Toxic Substances (OTS) will:

- Be responsible for determinations of the lateness of a report or of the failure to submit a report and for transmitting their determination to CMS.

- Be responsible for analyzing data received for possible falsification.
- Be responsible for determinations of whether prescribed reporting procedures had been followed.
- Assist in the preparation of a subpoena when necessary.
- Provide CMS with current lists of chemical substances or mixtures subject to §8(d) reporting.

Compliance Monitoring Staff

The CMS will:

- Act as liaison with OTS, OLEC and Regions.
- Schedule any necessary inspections upon consultation with the Regions.
- Assist in preparation of a subpoena when necessary.
- Provide Regional Offices with current lists of chemical substances or mixtures subject to §8(d) reporting.

Office of Legal and Enforcement Counsel

The Office of Legal and Enforcement Counsel (OLEC) will:

- In conjunction with CMS and Regional Counsel, determine whether the evidence in a case is sufficient to issue a complaint.
- Assist in the preparation of a subpoena when necessary.

Regional Offices

Regional Offices will:

- Transmit any allegations received to CMS for action.
- Participate in field inspections, when necessary.
- In conjunction with Headquarters, prepare and serve any subpoena.
- Issue complaints and carry out any resulting administrative litigation or settlement.

Responsibility for responsive compliance monitoring activities under the §8(d) rule will be shared by Headquarters and the Regions. Section 8(d) investigations will be initiated by a team with representation from Headquarters OTS, CMS and OLEC and the appropriate Region(s). The team will recommend inspections if necessary, which will be performed by Regional inspectors.

In instances where the OTS refers a potential §8(d) case to CMS for action, CMS will in cooperation with the Region and OTS, investigate the allegation. The CMS will then consult with OLEC and Regional counsel to determine whether the evidence is sufficient to issue a complaint.

Any report of a violation received by a Region should be transmitted along with any available documentation to the CMS before further action is taken. The CMS will contact OTS for analysis of any documentation and to arrange for OTS participation in any further investigation. CMS will schedule any necessary inspections. The CMS will consult the OLEC and Regional Counsel to determine whether the evidence is sufficient to issue a complaint. If a subpoena is necessary to obtain data, Regional Counsel will prepare it in conjunction with the OTS, OLEC and CMS. The OTS will be responsible for analyzing the data received in response to the subpoena.

In all cases the Regions will issue complaints and be responsible for resulting administrative litigation or settlement.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 31 1980

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Guidance for Pilot TSCA Cooperative Enforcement Agreements

TO: Enforcement Division Directors
Air & Hazardous Materials Division Directors
Surveillance & Analysis Division Directors

As I indicated to you in my memorandum of October 7, 1980, the Office of Enforcement (OE) intends to institute a pilot program of Federal/State cooperative enforcement agreements under the Toxic Substances Control Act (TSCA). The attached document contains final guidance governing implementation of the pilot program.

In FY81, the Agency will award $1,000,000 among up to five States submitting proposals for cooperative programs designed to monitor compliance with PCB regulations. The Agency will initially invite Connecticut, Maryland, Ohio, Michigan and California to submit proposals. The Regions should work with these States to develop the proposals. States propose to use Federal funds to extend the range of activities conducted with existing State environmental protection resources, since the Agency cannot guarantee funding beyond FY82.

We anticipate that the Regions, with assistance from appropriate Headquarters personnel, will have pilot TSCA agreements negotiated with the States by April 1, 1981.

If you have any questions, please contact John Martin of my staff at 755-1075.

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division

Attachment

cc: Toxics Contacts

I. Introduction

The Office of Enforcement (OE), under authority of Section 10 and 28 of the Toxic Substances Control Act (TSCA), will implement a pilot program of financial assistance to States during FY 1981 in the form of Cooperative Enforcement Agreements. The general objectives of this program are to:

Prevent or eliminate unreasonable risks to health or the environment from certain chemical substances;

Encourage coordinated Federal/State regulatory actions with regard to toxic substances control;

Expand compliance monitoring resources for TSCA enforcement;

Sponsor cooperative surveillance and analytical procedures; and

Avoid duplication of effort.

In FY81, the program will be aimed at achieving these objectives as they relate specifically to monitoring compliance with the PCB regulations promulgated under Section 6 of TSCA [43 FR 7150, Feb. 17, 1978; 44 FR 31514, May 31, 1979]. This memorandum sets forth policies and procedures to be followed by States and Regions participating in the TSCA pilot cooperative agreement program for PCB compliance monitoring. The Office of Enforcement, through the Pesticides and Toxic Substances Enforcement Division (PTSED), will have approximately $1,000,000 for this pilot program in FY81. Several States will be selected to receive the initial pilot cooperative agreements.

The FY81 pilot program is aimed at monitoring compliance with TSCA PCB regulations because the Federal enforcement program for PCB control is the broadest chemical control regulatory program which has been implemented under TSCA. This program will be administered jointly by participating Regional offices and by Headquarters. If this program is successful, EPA will consider expanding it as other chemical control regulations are promulgated under TSCA. Specifically, EPA hopes that the States, with EPA assistance, can play an important role in the development of enforcement strategies and in compliance monitoring for the Asbestos in Schools Program once that regulation is finalized.

II. Basic Application Criteria

Before EPA will consider a proposed State program, the State must demonstrate that it meets the following criteria:

A. Need for a Toxic Substances Control Program in the State

Each State must demonstrate that the funds for which the application is made will be used in a new or expanded enforcement program designed to alleviate substantially a demonstrated PCB problem. This demonstration should consist of two parts:

1. The toxic substances problem should be defined by the extent of the manufacture, processing, and use of PCBs in the State and the extent of exposure of humans and the environment to PCBs.

2. The degree to which the proposed program will alleviate the problem should be illustrated by a summary comparison of the expected accomplishments of the proposed program with the past accomplishments or limitations of any existing program.

B. Ability to Implement the Program

Each application must demonstrate that there are no impediments to the State's ability to carry out its proposed program. The applicant should address the following areas as well as any others which might pose problems:

1. Authority to Conduct the Proposed Program

A State must have enacted legislation which empowers it:

a. To enter into a cooperative agreement with EPA, and

b. To conduct the specific compliance monitoring activities it proposes under a cooperative agreement.

Such legislation may provide for State authority to control toxic substances and specifically PCBs. It may, however, also be phrased in more general terms dealing, for example, with the preservation of public health, safety, and welfare, or the cessation of a public nuisance. EPA is interested in exploring the possibilities of administering this program under different types of legislative authority and will actively seek to involve States which rely upon these different types of authority for jurisdiction over toxic substances.

States should consider the preemption guidelines of TSCA Section 18 in determining what cooperative agreement activities may be carried out under State authority. Specifically, Section 18 preempts State authority as to chemicals regulated under TSCA Section 6 with several exceptions. Preemption occurs unless (1) the State requirement is identical to the Federal requirement, (2) the State regulation is adopted under the Clean Air Act or a Federal law other than TSCA, or (3) the State regulation prohibits the use of the Federally regulated chemical within the State. In addition State regulations governing disposal of a substance also regulated under TSCA Section 6 are not preempted to the extent that they are identical to or more stringent than the Federal disposal regulations.

2. Authority to Accept Federal Funds

A State which cannot implement a program under this cooperative agreement without prior authorization by its legislature to spend Federal funds must include a statement indicating the date on which such authorization will be obtained. Commitment of EPA funds will be contingent on such authorization by the State legislature.

3. Access to Confidential Business Information

A State should also describe the extent of its authority to gain access to confidential business information, the specific types of data considered confidential, and the extent to which the State may disclose such confidential business information to EPA to enforce TSCA.

All applications should include an opinion of the State Attorney General regarding the adequacy of the relevant provisions in State law and regulations that provide these authorizations.

C. Designated Lead Agency

The EPA recognizes that a State may have a number of agencies with separate authority for regulating toxic substances including PCBs. Where this is the case, EPA will enter into a cooperative agreement only with the State lead agency designated for this purpose by the Governor. If the cooperative program for monitoring compliance with PCB regulations is successful, EPA intends to expand the program to include compliance monitoring for other TSCA regulations. These may include the Asbestos in Schools regulations and other regulations under Section 6 of TSCA. Thus, future cooperative agreements for compliance monitoring under TSCA are likely to include activities

related to a number of different chemical control regulations. Therefore, a State should consider the long term advisability of designating a lead agency which has broad authority rather than one which would have jurisdiction only over PCBs. A letter from the Governor's office must be submitted with each application explaining why the designated agency is the most appropriate State agency to head this program. The letter should also provide the lead agency with authority to contract or enter into interagency agreements with other State agencies, as necessary, for the performance of any enforcement activities proposed in the application.

III. Required Proposal Elements

The completed application shall contain a proposal for planning and evaluation of the program, an action plan detailing activities to be conducted by the State. and the proposed budget over the period of the agreement. In addition, the application must set forth procedures governing quality assurance programs applicable to inspections and sampling; the handling of confidential business information; case preparation and referral to EPA; and the submission of reports to EPA.

STEI

A. Planning and Evaluation

Each application shall describe the State's proposal for managing its PCB program. This management plan should specifically address 1) how the State established its program objectives and priorities and 2) how the State intends to evaluate the effectiveness of its program.

1. State Program Objectives and Priorities

Prior to establishing its PCB enforcement program objectives and priorities, each State must establish a profile of PCB use and exposure in the State. In establishing the profile each State must consider:

- The number of each type of PCB user,
- The extent of PCB storage, disposal, and manufacture within the State,
- The history of PCB spills and contamination within the State, and
- The history of PCB violations within the State.

After establishing the profile of PCB use and exposure in the State, each lead agency should discuss how it established and applied specific criteria and ranked areas for priority emphasis in its coopperative PCB enforcement program. The level of priority will provide a basis for allocating resources in the State's management plan.

In ranking its own priorities, each State should consider EPA priorities and the respective capabilities of the State and the EPA Regional Office to address most effectively the various PCB problems in the State.

The national PCB enforcement priorities and activities listed below indicate where EPA places its emphasis in a PCB enforcement program. The resources to be spent on activities under each priority are listed as a percentage after each heading.

a) Inspections of the following PCB User Industries-65%

Metals
Chemicals
Paper and Lumber
Mining
Transformer repair services
Automobiles
Textile
Stone, Clay and Glass
Railroad
Utilities

1) Inspection of PCB records for completeness, discrepancies

2) Physical examination of inventories, to:

- Verify records,
- Determine the location of equipment,
- Verify the marking of equipment and PCB transport vehicles,
- Check for evidence and take samples of suspected leaks and spills,
- Determine compliance with storage requirements,
- Determine compliance with PCB container requirements

b) Inspection of PCB Disposal Facilities-15%

1) Inspection of records for completeness and discrepancies,

2) Physical examination of inventories on hand.

c) Spill Investigations-10%

1) Conduct investigations when PCB spills are reported,

2) Take samples of PCB contamination attributed to spills.

d) Inspection of PCB Storage Facilities (those which are not owned or operated by the regulated industries)-5%

1) Inspection of records for completeness and discrepancies,

2) Physical examination of inventories to determine compliance with storage and recordkeeping regulations.

e) Inspection of Manufacturing Facilities-5% -- Determining compliance with PCB manufacturing restrictions by checking records.

In addition to these activities, EPA is also interested in the development of programs to ensure proper handling of PCB equipment used in commercial buildings. This may be best addressed through an educational program alerting the management of these types of buildings to the problems associated with PCB usage, storage, and disposal.

The EPA recognizes that the emphasis of a PCB enforcement program may differ from State to State due to differences in the number of storage facilities, disposal facilities, industries which use PCB equipment, and the respective compliance monitoring authorities and capabilities of EPA and the State. As a result, the amount of time a State wishes to spend in such activities may not coincide with the national priorities as listed. The national enforcement priorities should merely serve as a guide for those States where all the activities listed occur. The EPA and the State will negotiate the order to arrive at a PCB enforcement program which best serves the needs of both the State and EPA. While States are encouraged to engage in as many activities of the national program as possible, it is not necessary for a State to undertake all activities to receive assistance.

2. Program Evaluation

A well managed PCB cooperative enforcement program requires periodic evaluation to ensure that limited resources are used effectively. The goal of the evaluation process is to identify needed program adjustments that will foster the achievement of program objectives. Such adjustments could include shifting priorities, changing the level of compliance monitoring activities or improving the training of enforcement staff.

The State should develop a mechanism to evaluate its proposed PCB program. The description of the evaluation mechanism should address the following:

- o Functional Responsibility. It is essential that the State clearly identify the person(s) responsible for performing program evaluation.

- o Timing. The State should specify when program evaluations will occur. Generally evaluations should be made five and eleven months into the program. They should take place prior to the State-EPA mid-year and end-of-year reviews in order to permit discussion of any steps EPA should take to improve the program as well as any improvements the State should make.

- o Evaluation Methods. Each State should identify specific evaluation tools and describe how it will use these tools to evaluate various program elements. Among the evaluation activities which could be included are:

  - Development and analysis of report or tracking forms to determine trends in PCB violations for use in evaluating program priorities.

  - Review of inspection and case files to determine the adequacy of compliance monitoring activities.

B. Action Plan

Once the State has developed its list of priority areas under the agreement it should discuss its plan for carrying out a balanced program to address each of these areas during the period of the agreement. Where the nature of the output permits, the Action Plan should contain a nunerical summary of the outputs to be performed under the grant agreement for each quarter. For example, the State will summarize the number and type of PCB facility inspections to be performed for each quarter. Where the nature of the outputs does not permit numerical expression, a clear narrative statement of the outputs should be included. (Appendix III contains a suggested format for reporting the projected outputs).

C. Proposed Budget

Each appplication must contain the State's proposed budget for the program. Expenditures must be supported by itemized statements or fact sheets showing the cost for equipment, personnel, training, supplies, contractual services, etc. EPA, when funding activities under the agreement, will give priority to ongoing operating expenses that are directly

related to the enforcement of PCB laws, i.e., inspections, investigations, sample analysis, travel, start-up costs for inspectional and analytical equipment. Non-essential equipment purchases will be given low priority. The requirements of OMB Circular A-102 attachment O apply to all procurement actions.

The State's share of the "total project cost" shall be 25% and may be paid in direct or allowable indirect contributions, or by in-kind contributions. Expenses incurred by the State for activities not specifically stated as grant commitments, but related to PCB compliance monitoring activities, may be credited toward the State's contribution with Regional office approval. These activities can either replace scheduled commitments or be used in creating a new output category specific to a particular State. An example of such an expense may be a portion of a State program funded solely by the State and not included in the cooperative agreement.

D. Conditions of the Cooperative Agreement

PCB enforcement cooperative agreement awards will be subject to the General Grant Regulations (40 CFR Part 30). The applicant shall also agree to the following conditions:

1. Quality Assurance

a. During all inspections, investigations, and sample collections performed under the authority of TSCA, inspectors shall adopt standard forms and procedures as outlined in the EPA TSCA Inspection Manual. To assure sample integrity, EPA chain-of-custody procedures shall be adopted during sampling, handling, shipping, storage and analysis of PCBs collected under Federal law.

b. During all inspections, investigations, and sample collections performed under the authority of State law, State procedures and forms should be used. During sampling, handling, shipping, storage and analysis of PCBs collected under State law, proper chain-of-custody procedures must be adopted to assure sample integrity. An accurate written record must be maintained to trace the possession of each sample from the moment of collection through its introduction into evidence.

c. Samples collected shall be analyzed by the State laboratory or as specified in the application for assistance, using EPA approved testing methods. All violative samples should be verified by a check analysis performed by a second chemist.

d. The State shall participate in the EPA Check Sample Program. Under this program EPA shall submit a PCB sample of known concentration to State laboratories for analysis. EPA shall review the results obtained and notify the State regarding EPA's assessment and provide assistance to the State laboratory if there were any problems with the analysis.

e. Where the State refers a case to EPA for enforcement action, the State may be required to participate in the Sample Analysis Verification procedure. This involves a verification analysis of the sample obtained and analyzed by the State which will serve as a basis for the enforcement action. The State may also, at times, desire such a check before initiating an action.

f. The EPA shall provide knowledgeable personnel for the training of inspectors, analytical chemists and case preparation officers in accordance with EPA practices and procedures. The State shall avail itself of chemist training courses as offered by EPA regarding procedures, instrumentation and methodology. States are also encouraged to participate in professional association meetings such as AOAC and other professional training courses.

g. A State must meet certain procedural criteria for any quality assurance (QA) program.* A State must:

i) Submit a QA Program Plan for participating State labs;
ii) Submit a QA Project Plan;
iii) Provide for a QA System Audit;
iv) Submit QA reports as determined by the Regions and Headquarters; and
v) Express the cost of the QA Program in a laboratory as a percentage of the total analytical costs.

*Minimum QA requirements are explained more fully in Guidelines and Specifications for Implementing Quality Assurance Requirments for EPA Contracts and Interagency Agreements Involving Environmental Measurements, May 19, 1980. Copies of this document and additional PCB-specific QA materials may be obtained from PTSED personnel.

2. Confidential Business Information

The conditions governing access by States to confidential business information shall be governed entirely by each State's own legislative authority in this area.

A State which does not have its own authority to access data identified as confidential business data under TSCA shall not request access to such information while conducting inspections under an Enforcement Agreement.

3. Case Preparation and Enforcement

The State shall review the quality and sufficiency of all evidence gathered in the course of any of the inspectional, laboratory and investigatory activities performed under the cooperative agreement. If the evidence reveals a possible violation of only the State's PCB laws, the State shall pursue an appropriate remedy provided by State law. Where such evidence reveals a possible violation of both State and Federal law, the State may bring appropriate enforcement action under State law or may refer the case to EPA for prosecution under the Federal statute. If a State does not take action on a case within 30 days of completing its investigation the case shall be referred to EPA for action. If the State refers the case to EPA, the State shall in conjunction with the EPA Regional office prepare and make available testimony and other evidence pursuant to procedures adopted by EPA. The State shall also provide witnesses for public hearings and appearances court upon request of the EPA Regional office. Where evidence reveals a possible violation of Federal law only, the State shall immediately forward the information to the EPA Regional office and prepare testimony and provide witnesses as necessary.

4. State Reports

a. The State shall prepare and submit to the Regional office quarterly reports of accomplishments under the outputs specified in the cooperative agreement within 15 days after the quarter ends. Failure to submit timely reports may be grounds for the retention of grant funds by the Regional office or suspension or termination of the agreement. (The State may use the format suggested in Appendix III to report actual outputs).

b. The State shall send a copy of the results of any sample analysis made under the authority of TSCA to the person from whom the sample was collected. The State shall be relieved of this responsibility only if the Regional office assumes it as part of the cooperative agreement.

c. Copies of all inspecional and analytical reports shall be submitted to the Regional office as soon after completion as possible.

IV. Implementation of the FY1981 Grant Program

A. Summary of EPA Role

The EPA intends to determine the feasibility of developing a cooperative program with the States for monitoring compliance with selected provisions of TSCA. As a first step, EPA will explore a cooperative program for monitoring compliance with the PCB regulations. In this effort, Headquarters has primary responsibility for:

1. Developing national priorities and strategy for the PCB enforcement program;

2. Preparing guidance for implementing and managing the program;

3. Establishing criteria for the award of funds; and

4. Making funds available to the Regions for disbursement to the States.

Headquarters and the Regions have responsibility for:

1. Working closely with the States to develop a complementary Federal/State program which considers State as well as EPA priorities and resources;

2. Providing review and funding approval of applications;

3. Developing training and laboratory support for State personnel; and

4. Conducting program evaluations.

Each participating Region should establish a TSCA PCB Enforcement Agreement Review Panel for the purpose of reviewing and evaluating all PCB enforcement cooperative agreement applications received by the Regional office. The Panel should consist of members from the following offices:

1. Regional PCB Compliance Monitoring Program Office;

2. Regional Enforcement Division;

3. Regional Grants Office;

4. PTSED, Grants Analysis and Information Section, and

5. PTSED, Policy Section

B. Preproposal Negotiation

The Regions should work closely with the States in preparing the application which should clearly specify the responsibilities of the State and of EPA. Regional offices will also consult with PTSED during this negotiation stage.

C. Application Submission

The formal application for assistance will consist of an Application for Federal Assistance EPA Form No. 5700-33 and the PCB enforcement program plan ("Part IV Narrative Statement", Sample Format in Appendix I). The "Part IV Narrative Statement" should include a discussion of the State's eligibility, its management plan, specific outputs, budget, and conditions of the cooperative agreement.

EPA will normally fund only one PCB enforcement agreement per State. It is required, therefore, that States having several agencies with different PCB authorities submit a single proposal. The proposal must designate one agency with authority to contract or enter into interagency agreements with other agencies for the performance of all necessary enforcement activities. Applications must be submitted by March 1, 1981.

Office of Management and Budget (OMB) circular A-95 (revised) (41 FR 2052, January 13, 1976) provides for State and area wide clearinghouse evaluation and coordination of Federally assisted programs and projects. All States applying for TSCA PCB enforcement assistance shall comply with all applicable requirements of OMB circular A-95 pursuant to the EPA General Grant Regulations (40 CFR Part 30).

D. Application Review

Funding for cooperative agreements will be allocated on the basis of the appropriateness of the State's program plan when compared to the criteria set forth above.

Each application will be subject to two reviews: (1) a technical and program evaluation by the TSCA PCB Enforcement Agreement Review Panel to determine the merit of the proposed outputs in view of the goals and objectives of the PCB enforcement cooperative program and (2) an administrative evaluation by the Regional Grants Administration Office to determine whether the application meets the requirements of the EPA General Grant Regulations (40 CFR Part 30).

At each stage of the evaluation, the State may be required to provide further information or to amend the application to satisfy the concerns of the Review Panel.

The Panel will evaluate the program set forth in each grant application to determine (1) the consistency and compatibility of the appplicant's objectives and expected results with EPA's priorities and policies in implementing a PCB enforcement program, (2) the feasibility of achieving such objectives and the expected results in view of the State's existing problems, program authority, resources and procedures, (3) the need for and reasonableness of the cost for budgeted items, including equipment, and (4) the reasonableness of the outputs in relation to the resources expended.

Based on this evaluation, the Regional office should provide written comments to the State on its application within 30 days of EPA receipt of the application.

To aid the Regions and States in negotiating and evaluating outputs under the cooperative agreement, a list of time factors is provided in Appendix II.

E. Grant Award Process

PCB compliance monitoring enforcement agreements will be awarded by the Regional office after concurrence by Headquarters. As both the Regional offices and Headquarters gain more experience with these program agreements, the amount of Headquarters involvement will decrease. Since the Regional Grants Administration Office is responsible for maintaining the administrative integrity of grants awarded, it will examine the grant application to assure that the applicable requirements of the General Grant Regulations are fulfilled. Cooperative agreements will be awarded by May 1, 1981. Although agreements are normally funded on a fiscal year basis, because this is a pilot program, the normal funding period will be waived, and agreements should be awarded for a period of one year.

F. Accountability Under the Cooperative Agreement

Accounting for funds awarded under the agreement (including receipts, State matching contributions and expenditures) must be maintained in accordance with all applicable EPA grant regulations and with generally accepted accounting principles. Headquarters suggests that the Regional Grants Administration Office review State accounting practices and procedures prior to award of funding to assure the State's ability to maintain appropriate records.

Funds will be paid in advance for allowable project costs in the manner provided in 40 CFR 30.615-1.

State expenditures under the agreement must follow cost categories (i.e., budget line item or by program element) established in the original agreement.

The State must maintain support vouchers and records of expenditures to show application of funds to activities for which the agreement was intended. Such records will be subject to inspection and audit by the Regional EPA Audit office, other offices of EPA or by other authorized agencies.

G. Training

Training under this program will be conducted by the EPA Regional office with support from EPA Headquarters. Training will consist of instruction in inspectional and sample collection techniques, sample analysis, case preparation, and handling of confidential business information claims. Training will take place prior to the funding period when possible and will consist of both classroom and on-the-job training. If new personnel are being hired to carry out this program, training should take place within 60 days after the signing of the cooperative agreement. Training materials will include the TSCA Inspection Manual and sample analysis protocols. Headquarters will make these materials available to the Regions by March and will meet with the Regions to discuss the specifics of training program development.

H. Program Evaluation

Program evaluation is an essential ingredient of the management and administration of the grant program. Regional personnel should meet with appropriate State officials on a quarterly basis to review and evaluate the grant program from both a State and regional point of view. If quarterly visits are not possible due to travel restrictions or other constraints, at least two visits per year must be made. Headquarters will participate in the mid-year and end-of-year review. Mid-year and end-of-year reviews must be conducted within 30 days of the end of the quarter.

During the mid-year and end-of-year evaluation meeting the review team should:

1. Compare the actual accomplishments with the proposed outputs in the grant agreement;

2. Review sample collection documents, inspection reports, investigation reports and reports of analysis for accuracy and quality;

3. Review accounting procedures for accuracy and completeness; and

4. Discuss any problems or unusual developments affecting grant performance.

If the review indicates deficiencies in any of the above areas, the review team should be prepared to offer suggestions and guidance such as additional inspector or chemist training, renegotiation of grant outputs, etc.

The end-of-year review should also include an assessment of the planning and management of the program at the State and Federal levels. This assessment should take into account the data collected, trends suggested by the data, rates of compliance as noted from inspectional reports, the effectiveness of the program in its present state, appropriateness of priorities based on compliance monitoring results, quality of the program, and any changes which could be made in the program to increase its effectiveness. Such a critical assessment is especially crucial in a pilot program of this type.

The Regional office shall prepare a written report of each evaluation and send a copy to the State within 30 days of the evaluation. The report should include a discussion of the basis for, and possible solutions to, any deficiencies found in the program. The State shall be allowed 15 working days from the date of receipt of the report to concur with or respond to the evaluation report. A copy of the Regional evaluation report and the State's response will be sent to Headquarters by the Region.

I. State Reporting

The PCB enforcement agreement plan must provide for the State to prepare and submit to the Regional office all information required. Failure to submit timely reports may be grounds for the retention of funds by the Regional Office or suspension or termination of the agreement.

J. Regional Reporting

The Regions must forward copies of all quarterly, mid-year and annual reports to PTSED for review. PTSED should also be kept informed of any problem areas or serious deficiencies that develop within a State program.

K. Modification, Suspension or Termination of the Agreement

The provisions and funding of the agreement must be modified by EPA and the State if it is found that actual accomplishments differ significantly from the planned accomplishments. These changes may include, but are not limited to, changes in the outputs, changes in the date of performance of specific outputs, or changes in the budget for the period of the agreement. Changes in the agreement are effective only upon the execution of a written amendment. If performance by the State does not improve after modification of the agreement, steps may be taken by EPA to suspend or terminate the agreement.

APPENDIX I

"Part IV Narrative Statement" - Sample Format

I. State Profile

A. Basic Criteria

The State must provide a narrative statement addressing the following areas as discussed in the guidance:

1. Need for a Program
2. Ability to Implement the Program

   a. Authority to Conduct the Proposed Program,
   b. Authority to Accept Federal Funds,
   c. Access to Confidential Business Information.

3. Designated Lead Agency

B. Personnel Summary

	Workyears currently comitted to PCB compliance monitoring and enforcement	Projected workyears under federally funded PCB complianc monitoring and enforcement program
Director/Administrator		
Supervisory (Inspt/Chem.)		
Inspectional		
Chemist		
Lab Techs		
Clerical		
Legal		

II. Proposed Statement of Work

The Statement of Work should explain the overall objectives of the proposal, a general plan for achieving these objectives, and how the grant funds are to be utilized. The following areas must be addressed in the proposal:

A. Planning and Evaluation
B. Action Plan
C. Proposed Budget

III. Conditions of the Cooperative Agreement

This section should indicate that PCB enforcment agreement awards are subject to the General Grant Regulations in 40 CFR Part 30. In addition this section shall contain the State's agreement to conditions governing the following areas as discussed in the guidance:

A. Quality Assurance
B. Handling of Confidential Business Information
C. Case Preparation and Enforcement
D. State Reporting

APPENDIX II

TIME FACTORS

Activity	Workhours to complete
Typical inspection including collection of 3-6 samples.	8
Preparation and shipment of samples (per inspection)	4
Preparation of preliminary Inspection Report	16
Preparation of Final Field and Analysis Reports	12

Sample Analysis

TIME REQUIRED TO PERFORM AN ANALYSIS FOR PCBs ON ONE SAMPLE OF EACH TYPE OF SUBSTANCE.

Transformer Oils	10 hrs
Silicon Oils	12 hrs
Hydraulic Fluids	15 hrs
Soil/Sludge/Sediment	32 hrs
Water	30 hrs
Fish	42 hrs
Vegetation	33 hrs

FOR ADDITIONAL SAMPLES OF THE SAME TYPE, BEING ANALYZED AT THE SAME TIME, MULTIPLY THE TIME REQUIRED TO ANALYZE ONE SAMPLE

NUMBER OF SAMPLES	MULTIPLICATION FACTOR
2	1.06
3	1.12
4	1.18
5	1.24
6	1.5
7	1.75
8	2.36
9	2.42
10	2.48

PTSED has compiled the above time factors to assist the Regions and States in negotiating and evaluating PCB cooperative enforcement agreements. These time factors are based on the Agency's experience in PCB inspection and analytical work done by both Regional staff and contractors. These factors will be subject to review and adjustment as the State program is implemented and better information becomes available.

The above figures include all inspectional or analytical time spent to complete an activity, including supervisory time, travel time, preparation time, office work, etc. The Regions must remember that the times given are large enough to include the prorated time for administrative type activities of inspectors and chemists. When using these figures to evaluate a grant application, reasonable administrative, case preparation, legal and clerical support time can be charged in addition to inspectional and analytical time.

These time and cost factors should be used as a guide in negotiating and evaluating grant applications. The number of inspections, samples, analyses, etc., multiplied by the time factors should equal the approximate number of work hours required under the grant. To ensure equal treatment of all States, it should be assumed that a normal work year consists of 1800 work hours after allowing for leave and holidays.

Deviations from these time factors can be expected due to differences in travel time, local procedures, etc. However, work hours grossly in excess of these computed levels must not be permitted. Significant differences between the amount requested and the amount computed must be justified, e.g., need for extensive travel time, or the applicant should be directed to either reduce the requested funding level or increase the output commitments. If an applicant's commitments are in excess of the computations the Regional office must assure itself that the quality of work is not suffering at the expense of quantity of outputs.

APPENDIX III

Projected (Actual) Outputs Under TSCA Enforcement Grant

Activity	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter		Total	
	Insp.	Samp	Insp.	Samp	Insp.	Samp	Insp.	Samp	Insp.	Samp
1. PCB User Industry Inspections										
Automobiles										
Chemicals										
Metals										
Mining										
Paper and Lumber										
Railroads										
Stone, Clay and Glass										
Textiles										
Transformer repair Services										
Utilities										
2. PCB Disposal Facilities Inspections										
3. PCB Storage Investigations										
4. PCB Storage Facilities Inspections										
5. PCB Manufacturing Facilities Inspections										

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 19 1981

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Supplemental Guidance Procedures for State Inspectors Acting Under the Authority of TSCA Section 11

TO: Enforcement Division Directors
Air & Hazardous Materials Division Directors
Pesticides Branch Chiefs
Region I, III, V & IX

I. Introduction

The Pesticides and Toxic Substances Enforcement Division (PTSED) is administering a Pilot Cooperative Enforcement Program under the Toxic Substances Control Act (TSCA). Last December, PTSED sent guidance to the Regions for use in soliciting grant proposals from States which expressed interest in participating in this pilot program. The draft applications indicate that most States will conduct program compliance monitoring under Federal rather than State authority. Therefore, this Office has determined that supplemental guidance is necessary regarding the inspection procedures to be followed by State inspectors. The purpose of this guidance is to detail inspection procedures for State inspectors acting under the authority of Section 11 of TSCA.

II. Background

The express language of Section 11, states that inspection activities under TSCA are not limited to EPA personnel. Any "duly designated representative" of the Administrator may inspect premises where chemical substances are manufactured, processed, stored, or held, (Section 11(a)). Pursuant to Section 11(a), the Administrator may designate State inspectors as representatives for the purpose of conducting PCB compliance activities.[1]

1. Section 10(a) and Section 28 authorize the proposed cooperative enforcement program.

The Office of Enforcement (OE) has decided that State inspectors, while acting as representatives of the Administrator, shall not have access to TSCA Confidential Business Information (CBI). This decision is based, in part, on Section 14 of TSCA which limits access to CBI. Even though Section 14 allows representatives of the Administrator to obtain CBI, the Agency is concerned that State inspectors might not be subject to criminal penalties for wrongful disclosure under Section 14(d). Accordingly, State inspectors are not authorized to obtain TSCA CBI under the current Pilot Cooperative Enforcement Program. This limitation applies only to the current program, and the Agency reserves the right to determine that State inspectors may obtain CBI in other future programs.

III. Confidential Business Information

Discussion

Whenever the Agency makes an oral or written request for information from a business under TSCA, the business has the right to claim the information as CBI (40 CFR §2.203(a)). The phrase "CBI" includes the concept of trade secrets. Under this concept, a business has the right to limit use or disclosure of trade secrets so that the business may obtain or retain business advantages arising from its rights in the information (40 CFR §2.201(e)). CBI status immediately attaches to the information once it is claimed and certified that the information meets the requirements for CBI as shown in the CBI Notice.[2] The Agency implements special procedures to safeguard against disclosure of CBI to unauthorized persons.

In the present PCB Cooperative Enforcement Program, State inspectors acting under the authority of Section 11 are not authorized access to CBI. The success of the program should not be adversely affected because of this limitation, however. Few CBI claims are anticipated during PCB inspections since the information collected will not usually yield commercial advantages to competitors. Experience with contract inspectors indicates few claims are made. Consequently, the Agency does not anticipate that the lack of CBI authority will interfere with the majority of State inspections.

Additionally, State inspections in this Pilot Cooperative Enforcement Program may have dual inspection authority granted by both TSCA Section 11 and also under relevant State legislation. In such cases, a State inspector may choose to conduct the inspection under State law. When conducting an inspection under State law, the inspector is not barred by

2. The General Counsel is the designated agent to institute an intra-Agency challenge to a CBI claim (40 CFR §2.207(a)).

TSCA from collecting CBI and may collect any information State law authorizes him to obtain. The inspection procedures detailed in the following parts of this memo do not apply to State inspectors acting under State PCB law.

Inspection Procedures

The TSCA Inspection Manual, (Volume 1, January 1980, hereinafter, the "Manual"), explains the procedures that Agency inspectors follow during enforcement inspections. These procedures are, with certain modifications outlined below, binding upon State inspectors conducting inspections under Section 11. (Headquarters will provide the Regions with a sufficient number of Manuals to distribute to the State inspectors.)

Prior to the inspection, the State should telephone the facility which is targeted for inspection. State personnel should set a specific time and date for an inspection. During the conversation, the facility representative should be asked to designate and ensure the presence of a responsible company official who can supply the inspector with requested information, and to guide him during the inspection and make CBI claims.

A) Entry

Under Section 11, the inspector is required to present the owner, operator, or agent in charge of the facility with:

- Proper credentials identifying the holder as a duly authorized representative of the EPA Administrator; and
- A written notice of inspection.

Additional entry requirements which must be followed are found in Chapter 3 of the Manual. Since State inspectors acting under Section 11 are not authorized access to CBI, they must follow additional special steps. The additional steps vary depending upon the availability of a facility official who has authority to make CBI claims. The Manual should be disregarded to the extent that its procedures for CBI differ from what appears below.

B) Opening Conference

The Inspector must present a TSCA Inspection Confidentiality Notice (in Manual Chapter 6, hereinafter, Notice) to the facility owner or agent in charge during the opening conference. This Notice informs facility officials of their right to claim as CBI any information (documents, physical samples, or other material)

collected by the inspector which meet the criteria shown on the Notice, (detailed below). The inspector must ascertain whether the facility official to whom the Notice was given has the authority to make CBI claims for the company. The facility official's signature must be obtained at the appropriate place on the Notice certifying that he does or does not have such authority.

1. Official Is Available

If the official has authority to make CBI claims, the next step for the inspector is to outline inspection plans with the facility official to allow the official to assert any CBI claims. The inspector must indicate what records or samples need to be seen to document compliance with the PCB rule. The official should be informed that to claim any information as CBI requires him to certify the following for each piece claimed:

a. Your company has taken measures to protect the confidentiality of the information and it intends to continue to take such measures.

b. The information is not, and has not been, reasonably obtainable without your company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).

c. The information is not publicly available elsewhere.

d. Disclosure of the information would cause substantial harm to your company's competitive position.

The above listed criteria for CBI appear on the Notice presented to the facility official. If the facility official chooses not to make a CBI claim, the inspection may proceed.

Alternatively, the facility official may make a CBI claim. This is done by completing the Declaration of Confidential Business Information form (hereinafter DCBI). As earlier noted, each item claimed as CBI must meet all four of the criteria on the Notice. The inspector must not argue with plant officials who decide to make CBI claims. The role of the inspector is only to educate the facility official about the CBI requirements. The inspector must regard the decision of the facility official as final.

After a CBI claim is made, the inspector must determine if the inspection objectives can still be met. This decision is guided by the scope of the CBI claim. For example, a facility

official might claim as CBI data which reflects the company's total volume of PCB disposal. Under this circumstance, the inspector should request that the official send this documentary evidence to the EPA regional office following usual CBI procedures:

a. Each page of each document should be stamped "Confidential Business Information."

b. A dated cover memo should accompany the submission indicating that the information is part of a State conducted inspection under TSCA and date of inspection.

c. The documents should be placed inside an envelope also marked as "Confidential Business Information." This envelope should be placed inside a plain envelope and mailed immediately to the Document Control Officer in the appropriate Regional Office.

The inspection may, of course, continue as to other documents for which a CBI claim is not asserted. Likewise, the inspector may collect samples which document compliance with the PCB rule. Inspectors should consult Chapter 3 of the Manual to assure that all collected records and samples are properly identified. The admissibility in an enforcement action of this evidence depends upon these procedures being followed.

At the closing conference, the inspector must issue a receipt for all collected samples and documents. Any documentary evidence which the facility sends to the Region should also be acknowledged on the receipt. The purpose of this receipt is to protect the Agency by showing that facility officials knew what documents and samples were taken. The closing conference also provides an opportunity for answering questions which may develop during the course of the inspection.

2. Official is Unavailable

After presenting his credentials, the inspector may find that the facility official to whom the Notice was given does not have the authority to make CBI claims for the company. Although the facility owner and the agent in charge are assumed to have the authority to make CBI claims, it is also possible that these officials will want to consult their attorneys (or superiors in the case of agents in charge) regarding this issue. The following alternatives exist for dealing with these problems.

If no authorized officials are immediately available, the State inspector must temporarily terminate the inspection. Before leaving the facility, the inspector should confirm the identity of officials who are responsible for CBI claims. The State should then contact, by letter, the responsible

official to determine if a CBI claim is going to be made. If the responsible official does not make a CBI claim, the inspection can be re-scheduled and conducted by the State.

Alternately, if the company official asserts a CBI claim in his response to the letter, the State inspectors may re-schedule the inspection only if the inspection can be conducted so that there is no contact with CBI. If this limitation would thwart the purpose of the inspection, the case should be referred to the Region. The Agency expects that very few companies will make CBI claims in the context of these PCB inspections. However, it is necessary that these procedures be followed to ensure that companies have a meaningful opportunity to assert CBI claims.

IV. Summary

A) Where the State inspector conducts the inspection under State authority:

1) State procedures control;

2) There are no CBI limits beyond those of State law; and

3) Enforcement action is pursued under State law.

B) Where the State inspector conducts the inspection under Federal authority (Section 11, TSCA):

1) Federal procedures must be followed (as detailed in this memo);

2) CBI limitations apply;

3) Enforcement is pursued under Federal law by the Region.

If you have any questions regarding these procedures, please contact John Martin of my staff at 202-755-0935.

A. E. Conroy II

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division

TSCA COMPLIANCE PROGRAM POLICY No. 6-PCB-1

Responsibility for Compliance with PCB Rule

TSCA Section: 6(e)

Issue:

If PCB-containing equipment is owned by one party but is used by another party, or is located on the property of someone other than the owner, who is responsible for assuring that such equipment complies with the laws regarding PCBs?

Policy:

In general, the Agency intends to hold the owners of PCB containing equipment responsible for compliance with the PCB Rule [40 CFR Part 761]. However, in all cases involving PCB use by a person who does not own the equipment, or PCB equipment located on property owned by a third party, the Agency will consider the facts of each case to determine whether the user or landowner should be held responsible for compliance, either in addition to, or instead of, the owner of the PCBs.

With one exception, the owner of PCB-containing equipment is responsible for compliance with the Interim Measures Program (46 FR 16090, March 10, 1981). The exception is that a user who is not the owner of a PCB-containing transformer which poses an exposure risk to food or feed products has the obligation in comply with the Interim Measures Program until the user has informed the owner that the transformer poses an exposure risk to food or feed products.

Discussion:

Since the decision of the Court in Environmental Defense Fund v. Environmental Protection Agency (EDF v. EPA), 636 F. 2d 1267 (D.C. Cir. 1980), which invalidated the portion of the Agency's regulations that characterized transformers, capacitors, and electromagnets as totally enclosed, electrical equipment containing PCBs can be used legally only by persons observing the Interim Measures Program. That program, which primarily consists of inspection and maintenance requirements for transformers, appeared in the Federal Register on March 10, 1981 (46 Fr 16090). The Court order which established the Interim Measures Program stated that the owner of a PCB-containing transformers has the obligation to comply with the Program, with one exception. A user

who is not the owner of a PCB containing transformer which poses an exposure risk to food or feed products has the obligation to comply with the Interim Measures Program until the user has informed the owner that the transformer poses an exposure risk to food or feed products. Thus, the responsibilities for complying with this program are clear.

The Interim Measures Program is not the only regulatory requirement that must be met for PCB containing equipment. The PCB Rule, 40 CFR Part 761, contains marking and recordkeeping requirements for in-use equipment. Any uncontrolled discharge of PCBs from the equipment may constitute improper disposal. Additionally, leaking equipment is not totally enclosed and thus cannot be used legally.

The PCB Rule does not contain any precise statement concerning who is responsible for these requirements when the owner is not the same person as the user. As a matter of compliance program policy, the Agency intends to hold the owners of PCB-containing equipment responsible for compliance with the PCB Rule. However, in all cases involving PCBs used by a person not the owner, or located on property owned by a person other than the owner of the PCBs, the Agency will consider the facts of each case to determine whether the user or landowner should be held responsible for compliance, either in addition to, or instead of, the owner of the PCB-containing equipment. In determining responsibility for compliance, the Agency will consider, without limitation, the following factors:

- o Written agreements between the parties. Contracts that provide that the user will service the equipment, or that the user agrees to comply with all laws argue in favor of the user's being responsible.

- o Prior actions by the parties. If one of the parties has traditionally serviced the equipment, or taken responsibility for compliance with regulations on the equipment, this will influence the Agency's decision on liability.

- o Access to the equipment. If one party has restricted or no access to the equipment, this argues strongly against that party's responsibility for compliance.

- o Reasonable actions in emergencies. Even where the other factors indicate that the owner is responsible for regulatory compliance, the Agency expects users of PCB containing equipment to act reasonably in the event of a rupture or other environmental emergency. Thus, the failure by a user to notify the owner promptly of any rupture might subject the user to liability under TSCA.

As dictated by the specific instance, the Agency will also consider any other pertinent factors in determining who should be held accountable for compliance with the law. Any person who uses PCB-containing equipment or has such equipment on his property, and is uncertain about his responsibility for compliance is strongly urged to contact the owner of the equipment to reach an agreement on this subject. Such persons should also be remained that uncontrolled discharges of PCBs may result in exposure of workers or members of the public to PCBs. Such exposure may result in liability under other Federal law (such as the Occupational Safety and Health Act) or State or local law.

This memorandum is only a statement of compliance program policy under TSCA. It is not intended to affect any rights or liabilities any person may have under any other law or by virtue of any contract. It also does not change the Agency's position that persons may not enter into contracts which absolve them of their responsibility or liability for violation of the PCB Rule. (See 44 FR 31538-9, May 31, 1979, for the Agency's position in this regard.)

Key Words:

Responsibility for Compliance
Liability
Penalties
Unlawful Acts
Noncompliance

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Date

TSCA COMPLIANCE PROGRAM POLICY No. 6-PCB-2

Distillation, Solvent Extraction, Filtration, and other Physical Separation Methods for PCBs

TSCA Section: 6(e)

ISSUE:

Does the physical separation of PCBs from liquids and solids require EPA approval?

POLICY:

The physical separation of PCBs from liquids and solids requires an approval if the use or disposal of these liquids and solids avoids, or is alternative to, the disposal requirements that would have applied to the original material before separation. An approval is required for physical separation activities that can be construed to be part of, or an initiation of a disposal activity. However, an approval is not required for physical separation activities which process PCBs during authorized servicing activities and reuse the processed materials in equipment authorized for continued use in the PCB rules. An approval is also not required for treatment of PCB contaminated water where the treatment medium is properly disposed of and the water is discharged in accordance with a NPDES permit.

DISCUSSION:

The PCB regulations (40 CFR 761.60, 44 FR 31514) require EPA approval of activities which dispose of PCBs and PCB Items. In 1979, a company approached EPA for a policy on the use of filters for physically removing PCBs from transformers. At that time, EPA interpreted "disposal" to mean only activities which alter or destroy PCB molecules, while activities which physically separate or concentrate PCBs from liquids or solids were judged not to constitute "disposal" and not, therefore, to require an approval. Examples of techniques which physically separate PCBs from liquids and solids include filtration, distillation, and solvent extraction.

In 1982, after some experience with this policy, EPA realized that the application of the above approach to physical separation methods had the potential to create a major avenue for avoiding the PCB disposal requirements. The PCB rules require specific disposal options for materials containing PCBs. Unapproved alternatives to these disposal requirements have the potential to circumvent the rules and pose unnecessary risks.

EPA reviewed its interpretation of the PCB regulations regarding physical separation and found that the original PCB rules clearly do not exempt PCB processing activities (including physical separation techniques) from the disposal requirements.

While activities which process or distribute PCBs for purposes of disposal are not subject to processing and distribution in commerce bans, such activities are subject to disposal regulations. Section 761.20(c)(2) [emphasis added] provides: "PCBs or PCB Items may be processed and distributed in commerce in compliance with the requirements of this Part for purposes of disposal in accordance with requirements of §761.60 [PCB disposal requirements]."

Accordingly, unless an activity is authorized by the disposal regulations, one must obtain specific approval for the activities from the Regional Administrator or the Assistant Administrator for Pesticides and Toxic Substances in accordance with section 761.60(e)(1982). Note, however, that it is not the intention of this policy to require approval of physical separation activities regarding the clean-up of leaks and spills of PCBs or to require approval of inadvertant separations due to natural forces (such as evaporation and gravity) that are not construed to be part of a disposal activity. It is also not the intention of this policy to require approval of physical separation activities that are part of manufacturing processes that incidentally manufacture PCBs. The physical separation of PCBs from products and waste streams in manufacturing processes will be considered during the upcoming rulemaking on the applicability of a regulatory cutoff for the manufacture of PCBs ("the uncontrolled rule").

The following example of the use of a physical separation technique is applicable. Capacitors must be disposed of by incineration or by an approved alternate method equivalent to incineration (40 CFR 761.70). It is theoretically possible to develop a capacitor disposal method the first step of which is to separate the PCBs from the solid materials (e.g., solvent extraction). The separation process, requires specific prior approval by the Regional Administrator or Assistant Administrator for Pesticides and Toxic Substances under section 761.60(e) since it is part of the disposal method but is not authorized under section 761.60. If such a method were successful in completely removing all detectable PCBs from the solids, the PCB-free solid materials could later be salvaged without subsequent treatment or EPA approval. Although the PCBs removed from the solid materials and any unprocessed materials require incineration, it is also theoretically possible to obtain approval to use a physical separation technique to remove PCBs from the liquid materials in a similar manner.

In contrast, a permit is not required to service electrical equipment for purposes of reducing PCB concentrations. Physical separation techniques can be used to service PCB-containing electrical equipment as long as the processed materials are ultimately returned to electrical equipment regulated under the PCB rule. This type of servicing is authorized under 40 CFR

761.30(a). Filtering PCBs from the dielectric fluid of transformers and returning that fluid to the transformer is an example of this type of activity. Because the processed liquids and solids are returned or reused in regulated equipment, EPA controls the ultimate disposition of all the processed materials and no disposal requirements are circumvented.

Without an EPA disposal approval, processed liquids and solids that formerly contained PCBs must be treated as if they still contain PCBs and may not be distributed in commerce without an exemption under section 6(e)(3)(B) of the Toxic Substances Control Act (TSCA). Therefore, it is possible to physically separate PCBs from liquids and solids without EPA approval as long as these liquids and solids are treated (used, stored, disposed of, etc) as if they still contain their original PCB concentration. The PCB residue which results from physical separation activities, as well as any materials not eventually reused in regulated electrical equipment, must be disposed of in a manner which complies with section 761.60. In the event the separation method results in dilution of the PCBs, the original PCB concentration determines the required disposal method.

A permit is not required to physically separate an organic phase from an aqueous phase of collected water (e.g. leachate, lagoon water, storm water). The organic phase must be disposed of according to the regulations for its concentration of PCBs. The aequeous phase may be disposed of by means of filtration to remove any residual PCBs (e.g. activated carbon) provided the filter medium is disposed of in accordance with the regulations for solids containing that concentration of PCBs, and the water, if discharged to navigable waters, is discharged in accordance with a National Pollutant Discharge Elimination System (NPDES) permit granted under the Clean Water Act. Water cannot legally be discharged from a point source without meeting the permit conditions. Through this permitting process, EPA limits the amount of PCBs in the water prior to discharge. Since EPA controls the amount of PCBs released with the water, and also controls the disposal of any PCBs physically separated from the water (40 CFR 761.60), no additional approval under TSCA is necessary or warranted. This form of physical separation may be compared to the policy of not requiring approvals for physical separation methods which result in all materials going to controlled equipment or proper disposal under the PCB regulations.

Section 761.30 authorizes servicing of electrical equipment for purposes of reducing PCB concentrations. After such servicing, this electrical equipment may be reclassified if, after at least 3 months of in-service use, the PCB concentration is reduced below the appropriate level.

See Also:
TSCA Compliance Program Policy No. 6-PCB-3

References:
Letter to SED, Inc dated April 2, 1981
Letter to Amtrak dated July 20, 1982

Key Word Headings:
Physical Separation, Disposal

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TSCA COMPLIANCE PROGRAM POLICY No. 6-PCB-3

Residual PCBs in Processed Liquids and Solids

TSCA Section: 6(e)

ISSUE:

Are PCBs at concentrations less than 50 ppm in liquids and solids that have been physically separated from higher concentration PCB materials regulated for the purpose of disposal?

POLICY:

PCBs at concentrations less than 50 ppm in liquids and solids that have been physically separated from higher concentration PCB materials are regulated as if they still contain the original PCB concentrations.

DISCUSSION:

Section 40 CFR 761.1 states that a substance containing less than 50 ppm PCBs because of any dilution shall be treated for disposal purposes as though it contains its original PCB concentration. This means that diluted PCBs would be subject to EPA disposal regulations under 40 CFR 761.60, even though other substances in concentrations less than 50 ppm are not. Accordingly, if a PCB concentration under 50 ppm resulted from an activity in which PCBs originally in concentrations above 50 ppm were physically separated from other material, any separated PCBs would be subject to EPA disposal regulations under 40 CFR 761.60. This includes those PCBs contained in a fraction with a concentration less than 50 ppm (e.g. the "light" fraction from a distillation process.)

A separator who is servicing electrical equipment may dispose of the "heavy" PCB fraction according to 40 CFR 761.60 and return the "light" fraction to the electrical equipment, in which case all materials are controlled by the PCB regulation. In the alternative (if he intends to produce a light fraction which will not be disposed of according to the PCB rule or reused in electrical equipment), the separator must obtain a disposal approval from either the Assistant Administrator for Pesticides and Toxic Substances or a Regional Administrator under 40 CFR 761.60(e). Only after the light fraction has been shown to contain no detectable PCBs, however, can the activity be approved by EPA as a disposal activity and considered an unregulated material.

It has been suggested that the disposal regulations either do not or should not apply to the light fraction unless the dilution process was intentionally done to circumvent the EPA disposal regulations. This interpretation is not correct. Section 761.1

does not permit any dilution of PCBs to affect the applicability of the PCB rules, unless the dilution is specifically provided for in the regulation. The regulation also does not provide for inquiry into the intent of the person performing the separation.

See Also:
TSCA Compliance Program Policy No. 6-PCB-2

References:
Letter to SED, Inc. dated April 2, 1981
Letter to Amtrak dated July 20, 1982

Key Word Headings:
Physical Separation, Disposal

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Date: 8-16-83

TSCA COMPLIANCE PROGRAM POLICY No. 6-PCB-6

Allocation of Enforcement Liability for Violations of the One-Year Disposal Deadline for PCB Articles or PCB Containers

TSCA Section: 6(e)

Issue:

How does EPA allocate enforcement liability among persons who violate the requirement that PCB articles and PCB containers be disposed of within one-year after being placed into storage.

Policy:

EPA will allocate enforcement liability for a failure to dispose of PCB waste within one year after it is placed into storage between the generator and the ultimate disposal facility based on the contribution by either party to the violation. A generator delivering PCB waste to a disposal facility later than 90 days before the end of the one-year disposal deadline will be held liable if the disposal facility can not dispose of the waste in time. A disposal facility receiving PCB waste later than 90 days before the end of the one-year deadline will not be held liable if the PCB waste is disposed of within 90 days.

Discussion:

Section 40 CFR 761.65(a) limits storage of PCBs designated for disposal to one year. This requirement also states that "any PCB Article or PCB Container stored for disposal before January 1, 1983, shall be removed from storage and disposed of...before January 1, 1984. Any PCB Article or PCB Container stored for disposal after January 1, 1983, shall be removed from storage and disposed of...within one year from the date it was first placed into storage."

The one-year time limit is intended to insure prompt disposal of PCBs removed from service. However, the requirement does not preclude some waste generators or intermediate waste handlers from storing the waste for long periods of time (up to 12 months) before releasing it for ultimate disposal. As a result, facilities which receive the waste for ultimate disposal may not have sufficient time to dispose of the waste within the one-year time limit.

EPA will allow facilities receiving waste a year after being put into storage by the generator an additional 90 days after receipt to dispose of the wastes without incurring enforcement liability. Because representatives of the two approved, landbased commercial incinerators have provided technical data showing that PCB waste is disposed of within 90 days after receipt by the facility, EPA

has determined that ninety days is sufficient lead-time for the disposer to receive and dispose of PCB waste. Therefore, if a generator delivers waste to a disposal facility with ninety days or more remaining in the one-year deadline, the disposer is responsible for destroying the material before the deadline. The liability shifts to the generator if the material is delivered to the disposal facility with less than ninety days remaining in the one-year allowed for disposal after storage. The disposer, however, will share in the liability if he does not dispose of the waste within ninety days from the date it is received at the disposal facility.

EPA will utilize the scale below to allocate liability between the generator and disposer.

	WHEN DELIVERED TO DISPOSER	WHEN DISPOSED	LIABILITY	
			GENERATOR	DISPOSER
I	more than 90 days before 1 yr. deadline	after 1 yr. deadline	none	entire penalty
II	90 days before 1 yr.	within 1 yr.	none	none
III	60 days before 1 yr.	1 mo. late	1/3 penalty	none
IV	30 days before 1 yr.	60 days late	2/3 penalty	none
V	last day	3 mos. late	entire penalty	none
VI	after 1 yr.	within 90 days of receipt	entire penalty	none
VII	after 1 yr.	after 90 days of receipt	entire penalty	entire penalty

See Also: TSCA Compliance Program Policy 6-PCB-7.

References:

Key Words:

PCBs, ultimate disposal facility, disposal deadline.

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Date

TSCA COMPLIANCE PROGRAM POLICY No. 6-PCB-7

Reference Date for Violations of the One-Year Storage for Disposal Deadline for PCB Waste Resulting From Physical Separation.

TSCA Section: 6(e)

Issue:

What date will EPA use as a reference date for violations of the one-year storage for disposal deadline for PCB waste resulting from physical separation?

Policy:

The one-year storage limit on PCBs resulting from physical separation begins on the date the original PCB articles or PCB containers were placed into storage for disposal. Drums or bins containing PCBs resulting from physical separation shall be required to be marked with the date corresponding to the earliest dated PCB material in the drum.

Discussion:

The PCB Storage for disposal requirements (40 CFR 761.65) prescribe that any PCB article or PCB container "shall be removed from storage and disposed of ... within one year from the date it was first placed into storage." This provision is intended to prevent long-term storage of PCB materials. To help insure prompt disposal, incoming PCB articles and containers are required to be dated when they arrive at the storage facility (40 CFR 761.65).

Some disposal firms, particularly metal recovery and salvage operations, physically separate the PCB-contaminated core from the article or container, recycle the metal portion after rinsing, and store the remaining PCB portion in drums for disposal by incineration or other treatment. The drums may contain PCB wastes that result from physically separated articles or containers that were placed into storage on different dates. There is some confusion among physical separators regarding the correct date to apply to these drums.

A similar problem arises at incineration facilities which shred PCB articles and other solid materials and place these shredded parts in drums before feeding them to the incinerator. Components of many PCB articles may be placed in the same drum.

EPA has never articulated a policy regarding the storage for disposal requirements and how they apply to PCB waste that results from physical separation. However, the Agency has developed a policy on disposal of PCBs that have been physically separated from regulated liquids and solids. This policy has direct bearing on the storage for disposal requirements.

EPA's position is that PCBs at concentrations less than 50 ppm in liquids and solids that have been physically separated from higher concentration PCB materials are regulated as if they still reflect the original PCB concentrations. Operations such as distillation and solvent extraction have the effect of diluting the PCB concentration in the original material. Section 40 CFR 761.1 states that a substance containing less than 50 ppm PCBs because of any dilution shall be treated for disposal purposes as though it contains the original PCB concentrations. This means that diluted PCBs would be subject to EPA disposal regulations (40 CFR 761.60), as well as the storage for disposal requirements (40 CFR 761.65). PCB Articles have specific disposal requirements (40 CFR 761.60) and all parts of the article are controlled by the rule.

The date used as the starting date for the one year storage for disposal deadline on a PCB article or PCB container prior to physical separation shall be the earliest date of the PCB items in a container. Such PCB items must be disposed of within one-year from the earliest dated item.

See Also: TSCA Compliance Program Policy 6-CFC-6.

References:

Key Words:

PCB, physical separation.

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TSCA COMPLIANCE PROGRAM POLICY No. 6-CFC-1

Product Labeling for Both Essential and Non-Essential CFC Aerosol Propellant Uses

TSCA Section: 6(a)

Issue:

Will EPA initiate enforcement action against processors of CFCs as an aerosol propellant for use in products whose labeling bears directions for both essential and non-essential uses?

Policy:

CFC aerosol propellant products whose labeling bears directions for both essential and non-essential uses create the rebuttable presumption that those CFCs have been processed in violation of the CFC regulations. The Agency will bring an enforcement action against the processor, unless the processor can prove that the CFCs have been processed only for an essential use.

Discussion:

The Agency promulgated regulations under authority of the Toxic Substances Control Act (40 CFR Part 762) stating that after December 15, 1978, no person may manufacture, import, process, process for export or distribute in commerce for processing any fully halogenated chlorofluoroalkane (CFC) for any aerosol propellant use except:

1. Use in an article which is a food, food additive, drug, cosmetic or device exempted under 15 U.S.C. 2602; or

2. The following essential uses listed in Part 762.58:

   a. Mercaptan stench warning devices,
   b. Release agent for molds used in the production of plastic and elastomeric materials,
   c. Flying insect pesticides for use in non-residential food handling areas except when applied by total release or metered valve aerosol devices, and for space spraying of aircraft,
   d. Diamond-grit spray,
   e. Non-consumer articles used as cleaner-solvents, lubricants, or coatings for electrical or electronic equipment,
   f. Articles necessary for safe maintenance and operation of aircraft,

g. Uses essential to the military preparedness of the United States as determined by the Administrator and the Secretary of Defense.
h. Pharmaceutical Rotary Tablet Press Punch Lubricants. (FR Notice Tuesday January 5, 1982 pp 148-49)

Since publication of the regulations, the Agency has also issued a special essential use exemption for the following:

Temporary exemption for Automatic Timed Release Insecticide Dispensing Systems Used in Storage of Tobacco. (May 19, 1982 to December 31, 1982)

The purpose of the regulations is to ensure that CFCs are not processed as aerosol propellants for any non-exempt/non-essential uses. The Agency, however, has found CFC-propelled aerosol products with labeling containing directions for both essential and non-essential uses. Although the CFC regulations do not prescribe labeling for products containing CFCs processed for non-essential/non-exempt aerosol uses, it is only reasonable to presume that a product has been processed for any use directed on its label. Such labeling may include the product container label or any other collateral literature distributed with or apart from the product.

The Agency presumes that any CFC aerosol-propelled product bearing directions for a non-essential/non-exempt use has been processed for this unlawful use. A processor can rebut this presumption by showing that

a. it processes CFCs only for an identifiable group of users and that each of these users use CFCs only for exempt uses, or

b. each of these users, by virtue of the nature of their business, could use CFCs only for exempt uses, or that

c. by sticker labeling the non-exempt/non-essential uses which appear on the label have been fully nullified.

In the absence of such showings, the Agency will bring appropriate enforcement action against processors of CFC aerosol propelled products whose labels include directions for both essential and non-essential uses.

See Also:

CFC Enforcement Response Policy.

References:

40 CFR Part 762.

Key Words:

Aerosol Propellant, CFCs, Chlorofluoroalkane, Essential-use.

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